~~S 4348 IS~~

~~II~~
~~117th CONGRESS~~
~~2d Session~~ **Purpose: In the nature of a substitute.**

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

~~IN THE SENATE OF THE UNITED STATES~~ **Referred to the Committee on _____ and ordered to be printed**

~~May 26, 2022~~ **Ordered to lie on the table and to be printed**

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY MRS. MURRAY (for herself and Mr. BURR)

~~introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions~~ **Viz:**

~~A BILL~~

~~To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.~~

~~Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,~~ **Strike all after the enacting clause and insert the following:**

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the "Food and Drug Administration Safety and Landmark Advancements Act of 2022" or the "FDASLA Act of 2022".

(b) Table of Contents.—The table of contents for this Act is as follows:

TITLE I—FEES RELATING TO DRUGS

Sec.910.Protecting infants and improving formula supply. ~~Sec.905.Enhance intra-agency coordination and public health assessment with regard to compliance activities.~~

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) Short Title.—This title may be cited as the "Prescription Drug User Fee Amendments of 2022".

(b) Finding.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) is amended—

(1) in paragraph (1), in the matter following subparagraph (B), by striking "an allergenic extract product, or" and inserting "does not include an application with respect to an allergenic extract product licensed before October 1, 2022, does not include an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, does not include an application with respect to";

(2) in paragraph (3), in the matter following subparagraph (C)—

(A) by inserting "licensed before October 1, 2022, a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022," after "an allergenic extract product"; **and**

(B) by adding at the end the following: "If a written request to place a product in the discontinued section of either of the lists described in subparagraph (C) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then, for purposes of assessing the prescription drug program fee under section 736(a)(2), the Secretary shall consider such product to have been included in the discontinued section on the later of (i) the date such request was received, or (ii) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale. For purposes of subparagraph (C), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale."; and

~~(C)~~**(3)** by adding at the end the following:

"(12) The term 'skin-test diagnostic product'—

"(A) means a product—

"(i) for prick, scratch, intradermal, or subcutaneous administration;

"(ii) expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

"(iii) not intended to be a preventive or therapeutic intervention; and

"(iv) intended to detect an immediate or delayed-type skin hypersensitivity reaction to aid in the diagnosis of—

"(I) an allergy to an antimicrobial agent;

"(II) an allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or

"(III) infection with fungal or mycobacterial pathogens; and

"(B) includes positive and negative controls required to interpret the results of a product described in subparagraph (A).".

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) Types of Fees.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "2018" and inserting "2023";

(2) in paragraph (1)—

(A) in subparagraph (A), by striking "subsection (c)(5)" each place it appears and inserting "subsection (c)(6)";

(B) in subparagraph (C), by inserting "prior to approval" after "or was withdrawn"; and

(C) by adding at the end the following:

"(H) EXCEPTION FOR SKIN-TEST DIAGNOSTIC PRODUCTS.—A human drug application for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A)."; and

(3) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking "subsection (c)(5)" and inserting "subsection (c)(6)";

(ii) by striking "Except as provided" and inserting the following:

"(i) PAYMENT OF FEES.—Except as provided"; and

(iii) by adding at the end the following:

"(ii) PREVIOUSLY DISCONTINUED DRUG PRODUCTS.—If a drug product that is identified in a human drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list identified in section 735(3), and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(B) by amending subparagraph (B) to read as follows:

"(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

"(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 505(j)(7);

"(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)), to another product on the list of products compiled under section 505(j)(7) (not including the discontinued section of such list); or

"(iii) a skin-test diagnostic product.".

(b) Fee Revenue Amounts.—Section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "2018 through 2022" and inserting "2023 through 2027";

(B) by redesignating subparagraphs (C) through (F) as subparagraphs (D) through (G), respectively;

(C) by inserting after subparagraph (B) the following:

"(C) The dollar amount equal to the strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));";

(D) in subparagraph (D), as so redesignated, by striking "(c)(2)" and inserting "(c)(3)";

(E) in subparagraph (E), as so redesignated, by striking "(c)(3)" and inserting "(c)(4)";

(F) in subparagraph (F), as so redesignated, by striking "(c)(4)" and inserting "(c)(5)"; and

(G) in subparagraph (G), as so redesignated, by striking clauses (i) through (v) and inserting the following:

"(i) $65,773,693 for fiscal year 2023.

"(ii) $25,097,671 for fiscal year 2024.

"(iii) $14,154,169 for fiscal year 2025.

"(iv) $4,864,860 for fiscal year 2026.

"(v) $1,314,620 for fiscal year 2027."; and

(2) in paragraph (3)—

(A) in subparagraph (A), by striking "2018, $878,590,000" and inserting "2023, $1,151,522,958"; and

(B) in subparagraph (B)—

(i) by striking "2019 through 2022" and inserting "2024 through 2027"; and

(ii) by striking "subsection (c)(3) or (c)(4)" and inserting "subsection (c)(4) or (c)(5)".

(c) Adjustments; Annual Fee Setting.—Section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(1) in paragraph (1)(B)(ii), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington–Arlington–Alexandria, DC–VA–MD–WV";

(2) by redesignating paragraphs (2) through (6) as paragraphs (3) through (7), respectively;

(3) by inserting after paragraph (1) the following:

"(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees—

"(A) for fiscal year 2023, by $9,000,000; and

"(B) for fiscal year 2024 and each subsequent fiscal year, by $4,000,000.";

(4) in paragraph (3), as so redesignated—

(A) in subparagraph (A)—

(i) by striking "for inflation"; and

(ii) by striking "paragraph (1)" and inserting "paragraphs (1) and (2)";

(B) by amending subparagraph (B) to read as follows:

"(B) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal

year 2021, as described in the notice titled 'Prescription Drug User Fee Rates for Fiscal Year 2021' (85 Fed. Reg. 46651; August 3, 2020). The workload categories used in forecasting shall include only the activities described in such notice and, as feasible, additional activities that are directly related to the direct review of applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in forecasting any non-core review activities, including any activities that the Secretary referenced for potential future use in such notice but did not utilize in the setting fees for fiscal year 2021.";

(C) by striking subparagraph (C);

(D) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively;

(E) in subparagraph (C), as so redesignated—

(i) by striking "year) and" and inserting "year),"; and

(ii) by **striking the period and** inserting ", and subsection (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment)."; and

(F) in subparagraph (D), as so redesignated, by striking "paragraph (5)" and inserting "paragraph (6)";

(5) in paragraph (4), as so redesignated—

(A) by amending subparagraph (A) to read as follows:

"(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least the following amounts of operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year, as follows:

"(i) For fiscal year 2023, at least 8 weeks of operating reserves.

"(ii) For fiscal year 2024, at least 9 weeks of operating reserves.

"(iii) For fiscal year 2025 and subsequent fiscal years, at least 10 weeks of operating reserves."; and

(B) in subparagraph (C), by striking "paragraph (5)" and inserting "paragraph (6)";

(6) by amending paragraph (5), as so redesignated, to read as follows:

"(5) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees—

"(A) for fiscal year 2023, by $44,386,150; and

"(B) for fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv), as applicable, multiplied by the Consumer Price Index for urban

consumers (Washington–Arlington–Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2021—

"(i) for fiscal year 2024, $60,967,993;

"(ii) for fiscal year 2025, $35,799,314;

"(iii) for fiscal year 2026, $35,799,314; and

"(iv) for fiscal year 2027, $35,799,314."; and

(7) in paragraph (6), as so redesignated, by striking "2017" and inserting "2022".

(d) Crediting and Availability of Fees.—Section 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

(e) Written Requests for Waivers, Reductions, and Refunds.—Section 736(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is amended to read as follows:

"(i) Written Requests for Waivers, Reductions, Exemptions, and Returns; Disputes Concerning Fees.—To qualify for consideration for a waiver or reduction under subsection (d), an exemption under subsection (k), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver, reduction, exemption, or return not later than 180 days after such fee is due. A request submitted under this paragraph shall include any legal authorities under which the request is made.".

(f) Orphan Drugs.—Section 736(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is amended—

(1) in paragraph (1)(B), by striking "during the previous year" and inserting ", as determined under paragraph (2)"; and

(2) in paragraph (2), by striking "that its gross annual revenues" and all that follows through the period at the end and inserting "supported by tax returns submitted to the Internal Revenue Service, or, as necessary, by other appropriate financial information, that its gross annual revenues did not exceed $50,000,000 for the last calendar year ending prior to the fiscal year for which the exemption is requested.".

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENT.

Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) is amended—

(1) by striking "2018" each place it appears and inserting "2023";

(2) by striking "Prescription Drug User Fee Amendments of 2017" each place it appears and inserting "Prescription Drug User Fee Amendments of 2022";

(3) in subsection (a)(4), by striking "2020" and inserting "2023"; and

(4) in subsection (f), by striking "2022" each place it appears and inserting "2027".

SEC. 105. SUNSET DATES.

(a) Authorization.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2027.

(b) Reporting Requirements.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2028.

(c) Previous Sunset Provision.—Effective October 1, 2022, subsections (a) and (b) of section 104 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall be assessed for all human drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 107. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDING.

(a) Short Title.—This title may be cited as the “Medical Device User Fee Amendments of 2022”.

(b) Finding.—Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

Section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i) is amended—

(1) in paragraph (9)—

(A) in the matter preceding subparagraph (A), by striking “and premarket notification submissions” and inserting “premarket notification submissions, and de

novo classification requests";

(B) in subparagraph (D), by striking "and submissions" and inserting "submissions, and de novo classification requests";

(C) in subparagraph (F), by striking "and premarket notification submissions" and inserting "premarket notification submissions, and de novo classification requests";

(D) in subparagraphs (G) and (H), by striking "or submissions" each place it appears and inserting "submissions, or requests"; and

(E) in subparagraph (K), by striking "or premarket notification submissions" and inserting "premarket notification submissions, or de novo classification requests"; and

(2) in paragraph (11), by striking "2016" and inserting "2021".

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) Types of Fees.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking "2018" and inserting "2023"; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking "2017" and inserting "2022";

(ii) in clause (iii), by striking "75 percent" and inserting "80 percent"; and

(iii) in clause (viii), by striking "3.4 percent" and inserting "4.5 percent";

(B) in subparagraph (B)(iii), by striking "or premarket notification submission" and inserting "premarket notification submission, or de novo classification request"; and

(C) in subparagraph (C), by striking "or periodic reporting concerning a class III device" and inserting "periodic reporting concerning a class III device, or de novo classification request".

(b) Fee Amounts.—Section 738(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is amended—

(1) in paragraph (1), by striking "2018 through 2022" and inserting "2023 through 2027";

(2) by amending the table in paragraph (2) to read as follows:6,L2(4,4,4,4,0,0),tp0,p10,10/12,s60,8,8,8,8,9

1"Fee Type1Fiscal Year 20231Fiscal Year 20241Fiscal Year 20251Fiscal Year 20261Fiscal Year 2027

Premarket Application$425,000$435,000$445,000$455,000l$470,0004

Establishment Registration$6,250$6,875$7,100$7,575l$8,465";

and

(3) in paragraph (3), by amending subparagraphs (A) through (E) to read as follows:

"(A) $312,606,000 for fiscal year 2023.

"(B) $335,750,000 for fiscal year 2024.

"(C) $350,746,400 for fiscal year 2025.

"(D) $366,486,300 for fiscal year 2026.

"(E) $418,343,000 for fiscal year 2027.".

(c) Annual Fee Setting; Adjustments.—Section 738(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(c)) is amended—

(1) in paragraph (1), by striking "2017" and inserting "2022";

(2) in paragraph (2)—

(A) by striking "2018" each place it appears and inserting "2023";

(B) in subparagraph (B)(ii), by striking "2016" and inserting "2022";

(C) in subparagraph (C)(i)(II), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington–Arlington–Alexandria, DC–VA–MD–WV"; and

(D) in subparagraph (D), by striking "2022" and inserting "2027";

(3) in paragraph (3), by striking "2018 through 2022" and inserting "2023 through 2027";

(4) by redesignating paragraphs (4) and (5) as paragraphs (7) and (8), respectively; and

(5) by inserting after paragraph (3) the following:

"(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustment under paragraph (3), the base establishment registration fee amounts for such fiscal year shall be increased to reflect changes in the resource needs of the Secretary due to improved review performance goals for the process for the review of device applications identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022, as the Secretary determines necessary to achieve an increase in total fee collections for such fiscal year, equal to the following amounts, as applicable:

"(i) For fiscal year 2025, the product of—

"(I) the amount determined under subparagraph (B)(i)(I); and

"(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

"(ii) For fiscal year 2026, the product of—

"(I) the sum of the amounts determined under subparagraphs (B)(i)(II), (B)(ii)(I), and (B)(iii)(I); and

"(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

"(iii) For fiscal year 2027, the product of—

"(I) the sum of the amounts determined under subparagraphs (B)(i)(III), (B)(ii)(II), and (B)(iii)(II); and

"(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

"(B) AMOUNTS.—

"(i) PRESUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the presubmission written feedback goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2025, $15,396,600 if the goal for fiscal year 2023 is met.

"(II) For fiscal year 2026—

"(aa) $15,396,600 if the goal for fiscal year 2023 is met and the goal for fiscal year 2024 is missed; or

"(bb) $36,792,200 if the goal for fiscal year 2024 is met.

"(III) For fiscal year 2027—

"(aa) $15,396,600 if the goal for fiscal year 2023 is met and the goal for each of fiscal years 2024 and 2025 is missed;

"(bb) $36,792,200 if the goal for fiscal year 2024 is met and the goal for fiscal year 2025 is missed; or

"(cc) $40,572,600 if the goal for fiscal year 2025 is met.

"(ii) DE NOVO CLASSIFICATION REQUEST AMOUNT.—For purposes of subparagraph (A), with respect to the de novo decision goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2026, $6,323,500 if the goal for fiscal year 2023 is met.

"(II) For fiscal year 2027—

"(aa) $6,323,500 if the goal for fiscal year 2023 is met and the goal for fiscal year 2024 is missed; or

"(bb) $11,765,400 if the goal for fiscal year 2024 is met.

"(iii) PREMARKET NOTIFICATION AND PREMARKET APPROVAL AMOUNT.—For purposes of subparagraph (A), with respect to the 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2026, $1,020,000 if the 4 goals for fiscal year 2023 are met.

"(II) For fiscal year 2027—

"(aa) $1,020,000 if the 4 goals for fiscal year 2023 are met and one or more of the 4 goals for fiscal year 2024 is missed; or

"(bb) $3,906,000 if the 4 goals for fiscal year 2024 are met.

"(C) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the following goals shall be determined as specified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022 and based on data available as of the applicable dates as follows:

"(i) The performance of the presubmission written feedback goal—

"(I) for fiscal year 2023, shall be based on data available as of March 31, 2024;

"(II) for fiscal year 2024, shall be based on data available as of March 31, 2025; and

"(III) for fiscal year 2025, shall be based on data available as of March 31, 2026.

"(ii) The performance of the de novo decision goal, 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal—

"(I) for fiscal year 2023, shall be based on data available as of March 31, 2025; and

"(II) for fiscal year 2024, shall be based on data available as of March 31, 2026.

"(D) DEFINITIONS.—For purposes of this paragraph, the terms 'presubmission written feedback goal', 'de novo decision goal', '510(k) decision goal', '510(k) shared outcome total time to decision goal', 'PMA decision goal', and 'PMA shared outcome total time to decision goal' have the meanings given such terms in the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

"(5) HIRING ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (3) and (4), if applicable, the base establishment registration fee amounts shall be decreased as the Secretary determines necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount under subparagraph (B), if the number of hires to support the process for the review of device applications falls below the following thresholds for the applicable fiscal years:

"(i) For fiscal year 2025, 85 percent of the hiring goal specified in subparagraph (C) for fiscal year 2023.

"(ii) For fiscal year 2026, 90 percent of the hiring goal specified in subparagraph (C) for fiscal year 2024.

"(iii) For fiscal year 2027, 90 percent of the hiring goal specified in subparagraph (C) for fiscal year 2025.

"(B) HIRING ADJUSTMENT AMOUNT.—The hiring adjustment amount for fiscal year 2025 and each subsequent fiscal year is the product of—

"(i) the number of hires by which the hiring goal specified in subparagraph (C) for the fiscal year before the prior fiscal year was missed;

"(ii) $72,877; and

"(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was missed.

"(C) HIRING GOALS.—

"(i) IN GENERAL.—For purposes of subparagraph (B), the hiring goals for each of fiscal years 2023 through 2025 are as follows:

"(I) For fiscal year 2023, 144 hires.

"(II) For fiscal year 2024, 42 hires.

"(III) For fiscal year 2025—

"(aa) 24 hires if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i); or

"(bb) 83 hires if the base establishment registration fees are increased by the amount determined under paragraph (4)(A)(i).

"(ii) NUMBER OF HIRES.—For purposes of this paragraph, the number of hires for a fiscal year shall be determined by the Secretary, as set forth in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

"(6) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjustments under paragraphs (3), (4), and (5), if applicable, if the Secretary has operating reserves of carryover user fees for the process for the review of device applications in excess of the designated amount in subparagraph (B), the Secretary shall decrease the base establishment registration fee amounts to provide for not more than such designated amount of operating reserves.

"(B) DESIGNATED AMOUNT.—Subject to subparagraph (C), for each fiscal year, the designated amount in this subparagraph is equal to the sum of—

"(i) 13 weeks of operating reserves of carryover user fees; and

"(ii) the 1 month of operating reserves described in paragraph (8).

"(C) EXCLUDED AMOUNT.—For the period of fiscal years 2023 through 2026, a total amount equal to $118,000,000 shall not be considered part of the designated amount under subparagraph (B) and shall not be subject to the decrease under subparagraph (A).".

(d) Small Businesses.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in subsection (d)(2)(B)(iii), by inserting ", if extant," after "national taxing authority"; and

(2) in subsection (e)(2)(B)(iii), by inserting ", if extant," after "national taxing authority".

(e) Conditions.—Section 738(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is amended—

(1) in paragraph (1)(A), by striking "$320,825,000" and inserting "$398,566,000"; and

(2) in paragraph (2), by inserting "de novo classification requests," after "class III device,".

(f) Authorization of Appropriations.—Section 738(h)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(3) AUTHORIZATION OF APPROPRIATIONS.—

"(A) IN GENERAL.—For each of the fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined in subparagraph (B), less the amount of reductions determined in subparagraph (C).

"(B) REVENUE AMOUNT.—For purposes of this paragraph, the revenue amount for each fiscal year is the sum of—

"(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under subsection (c)(2); and

"(ii) the performance improvement adjustment amount for the fiscal year under subsection (c)(4)(A), if applicable.

"(C) AMOUNT OF REDUCTIONS.—For purposes of this paragraph, the amount of reductions for each fiscal year is the sum of—

"(i) the hiring adjustment amount for the fiscal year under subsection (c)(5), if applicable; and

"(ii) the operating reserve adjustment amount for the fiscal year under subsection (c)(6), if applicable.".

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENT.

(a) Performance Reports.—Section 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is amended—

(1) by striking "fiscal year 2018" each place it appears and inserting "fiscal year 2023"; and

(2) by striking "Medical Device User Fee Amendments of 2017" each place it appears and inserting "Medical Device User Fee Amendments of 2022";

(3) in paragraph (1)—

(A) in subparagraph (A), by redesignating the second clause (iv) (relating to

analysis) as clause (v); and

(B) in subparagraph (A)(iv) (relating to rationale for MDUFA program changes), by striking "fiscal year 2020" and inserting "fiscal year 2023"; and

(4) in paragraph (4), by striking "2018 through 2022" and inserting "2023 through 2027."

**** 1** ~~(2)~~**(b)** Reauthorization.—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking "2022" and inserting "2027"; and

(2) in paragraph (5), by striking "2022" and inserting "2027".

SEC. 205 ~~SEC. 204~~. ACCREDITATION PROGRAMS.

(a) Accreditation Scheme for Conformity Assessment.—Section 514(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(d)) is amended—

(1) in the subsection heading, by striking "Pilot";

(2) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "pilot";

(B) in subparagraph (A)—

(i) by inserting "meeting criteria specified by the Secretary in guidance" after "testing laboratories";

(ii) by inserting "in guidance" after "by the Secretary"; and

(iii) by striking "assess the conformance of a device with" and inserting "conduct testing to support the assessment of the conformance of a device to"; and

(C) in subparagraph (B)—

(i) by striking "determinations" and inserting "results";

(ii) by inserting "to support" after "so accredited"; and

(iii) by striking "a particular such determination" and inserting "particular such results";

(3) in paragraph (2)—

(A) in the paragraph heading, by striking "DETERMINATIONS" and inserting "RESULTS";

(B) in subparagraph (A)—

(i) by striking "determinations by testing laboratories" and all that follows through "such determinations or" and inserting "results by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such results or of the";

(ii) by inserting a comma after "or testing laboratories";

(iii) by inserting "or recognition of an accreditation body" after "accreditation of such testing laboratory"; and

(iv) by striking "such device" and inserting "a device"; and

(C) in subparagraph (B)—

(i) by striking "by a testing laboratory so accredited" and inserting "under this subsection"; and

(ii) by inserting "or recognition of an accreditation body" before "under paragraph (1)(A)";

(4) in paragraph (3)(C)—

(A) in the subparagraph heading, by inserting "AND TRANSITION" after "INITIATION"; and

(B) by adding at the end the following: "After September 30, 2023, such pilot program will be considered to be completed, and the Secretary shall have the authority to continue operating a program consistent with this subsection."; and

(5) by striking paragraph (4).

(b) Accredited Persons.—Section 523(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(c)) is amended by striking "2022" and inserting "2027".

SEC. ~~205~~ **206**. SUNSET DATES.

(a) Authorization.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i; 379fj) shall cease to be effective October 1, 2027.

(b) Reporting Requirements.—Section 738A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1) shall cease to be effective January 31, 2028.

(c) Previous Sunset Provision.—Effective October 1, 2022, subsections (a) and (b) of section 210 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. ~~206~~ **207**. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. ~~207~~ **208**. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (as defined in such part as of such day) that on or after October 1, 2017, but before October 1, 2022, were received by the Food and Drug Administration with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE; FINDING.

(a) Short Title.—This title may be cited as the "Generic Drug User Fee Amendments of 2022".

(b) Finding.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) Types of Fees.—Section 744B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "2018" and inserting "2023";

(2) in paragraph (2)(C), by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027";

(3) in paragraph (3)(B), by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027";

(4) in paragraph (4)(D), by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027"; and

(5) in paragraph (5)(D), by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027".

(b) Fee Revenue Amounts.—Section 744B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the heading, by striking "2018" and inserting "2023";

(ii) by striking "2018" and inserting "2023"; and

(iii) by striking "$493,600,000" and inserting "$582,500,000"; and

(B) in subparagraph (B)—

(i) in the heading, by striking "2019 THROUGH 2022" and inserting "2024 THROUGH 2027";

(ii) by striking "For each" and inserting the following:

"(i) IN GENERAL.—For each";

(iii) by striking "2019 through 2022" and inserting "2024 through 2027";

(iv) by striking "$493,600,000" and inserting "the base revenue amount under clause (ii)"; and

(v) by adding at the end the following:

"(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year is the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(3).."; and

(2) in paragraph (2)—

(A) in subparagraph (C), by striking "one-third the amount" and inserting "24 percent";

(B) in subparagraph (D), by striking "Seven" and inserting "Six"; and

(C) in subparagraph (E)(i), by striking "Thirty-five" and inserting "Thirty-six".

(c) Adjustments.—Section 744B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A)—

(i) by striking "2019" and inserting "2024"; and

(ii) by striking "the product of the total revenues established in such notice for the prior fiscal year" and inserting "the base revenue amount for the fiscal year determined under subsection (b)(1)(B)(ii)"; and

(B) in subparagraph (C), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington-Arlington-Alexandria, DC–VA–MD–WV"; and

(2) by striking paragraph (2) and inserting the following:

"(2) CAPACITY PLANNING ADJUSTMENT.—

"(A) IN GENERAL.—Beginning with fiscal year 2024, the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

"(B) CAPACITY PLANNING METHODOLOGY.—The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

"(i) be derived from the methodology and recommendations made in the report titled 'Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations' as announced in the Federal Register on August 3, 2020 (85 Fed. Reg. 46658); and

"(ii) incorporate approaches and attributes determined appropriate by the Secretary, including those made in such report recommendations, except the workload categories used in forecasting resources shall only be those specified in

section VIII.B.2.e. of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022.

"(C) LIMITATIONS.—

"(i) IN GENERAL.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

"(ii) ADDITIONAL LIMITATION.—An adjustment under this paragraph shall not exceed 3 percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be 4 percent if—

"(I) for purposes of an adjustment for fiscal year 2024, the Secretary determines that, during the period from April 1, 2021, through March 31, 2023—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022);

"(II) for purposes of an adjustment for fiscal year 2025, the Secretary determines that, during the period from April 1, 2022, through March 31, 2024—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined);

"(III) for purposes of an adjustment for fiscal year 2026, the Secretary determines that, during the period from April 1, 2023, through March 31, 2025—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined); and

"(IV) for purposes of an adjustment for fiscal year 2027, the Secretary determines that, during the period from April 1, 2024, through March 31, 2026—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

"(bb) thirty-five percent or more of abbreviated new drug

applications submitted related to complex products (as so defined).

"(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under subsection (a), the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

"(3) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2024 and subsequent fiscal years, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B).

"(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

"(i) 8 weeks for fiscal year 2024;

"(ii) 9 weeks for fiscal year 2025; and

"(iii) 10 weeks for each of fiscal year 2026 and 2027.

"(C) DECREASE.—If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 12 weeks of such operating reserves.

"(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under subsection (a) publishing the fee revenue and fees for the fiscal year involved.".

(d) Annual Fee Setting.—Section 744B(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(d)(1)) is amended—

(1) in the heading, by striking "2018 THROUGH 2022" and inserting "2023 THROUGH 2027";

(2) by striking "more" and inserting "later"; and

(3) by striking "2018 through 2022" and inserting "2023 through 2027".

(e) Effect of Failure To Pay Fees.—The heading of paragraph (3) of section 744B(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is amended by striking "AND PRIOR APPROVAL SUPPLEMENT FEE".

(f) Crediting and Availability of Fees.—Section 744B(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(i)(3)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) is amended—

(1) in subsection (a)—

(A) by striking "2018" each place it appears and inserting "2023"; and

(B) by striking "Generic Drug User Fee Amendments of 2017" each place it appears and inserting "Generic Drug User Fee Amendments of 2022";

(2) in subsection (b), by striking "2018" and inserting "2023";

(3) in subsection (c)—

(A) by striking "2018" and inserting "2023"; and

(B) by striking "Generic Drug User Fee Amendments of 2017" each place it appears and inserting "Generic Drug User Fee Amendments of 2022"; and

(4) in subsection (f)—

(A) in paragraph (1), by striking "2022" and inserting "2027"; and

(B) in paragraph (5), by striking "January 15, 2022" and inserting "January 15, 2027".

SEC. 304. SUNSET DATES.

(a) Authorization.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41; 379j–42) shall cease to be effective October 1, 2027.

(b) Reporting Requirements.—Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) shall cease to be effective January 31, 2028.

(c) Previous Sunset Provision.—Effective October 1, 2022, subsections (a) and (b) of section 305 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act **(21 U.S.C. 379j–41 et seq.)** shall be assessed for all abbreviated new drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 306. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to abbreviated new drug applications (as defined in such part as of such day) that were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) Short Title.—This title may be cited as the "Biosimilar User Fee Amendments of 2022".

(b) Finding.—Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. DEFINITIONS.

Section 744G of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51) is amended—

(1) in paragraph (1)—

(A) by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington–Arlington–Alexandria, DC–VA–MD–WV";

(B) by striking "October of" and inserting "September of"; and

(C) by striking "October 2011" and inserting "September 2011"; and

(2) in paragraph (4)(B)(iii)—

(A) by striking subclause (II); and

(B) by redesignating subclauses (III) and (IV) as subclauses (II) and (III), respectively.

SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

(a) Types of Fees.—Section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "2018" and inserting "2023";

(2) in paragraph (1)—

(A) in subparagraph (A)—

(i) in clause (iv)(I), by striking "5 days" and inserting "7 days"; and

(ii) in clause (v)(II), by striking "5 days" and inserting "7 days";

(B) in subparagraph (B)—

(i) in clause (i), by inserting ~~"except"~~**", except** that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee or successor shall pay the annual biosimilar biological product development fee"

before the period;

(ii) in clause (iii)—

(I) in subclause (I), by striking "; or" and inserting a semicolon;

(II) in subclause (II), by striking the period and inserting "; or"; and

(III) by adding at the end the following:

"(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).";
and

(iii) in clause (iv), by striking "accepted for filing on or after October 1 of such fiscal year" and inserting "subsequently accepted for filing";

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by striking "shall, if the person seeks to resume participation in such program, pay" and inserting "or who has been administratively removed from such program for a product under subparagraph (E)(v) shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and";

(II) in subclause (I)—

(aa) by striking "5 days" and inserting "7 days"; and

(bb) by inserting "or the date of administrative removal, as applicable" after "discontinued"; and

(III) in subclause (II), by inserting "or the date of administrative removal, as applicable" after "discontinued"; and

(ii) in clause (ii), by inserting ~~"except"~~**", except** that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee or successor shall pay the annual biosimilar biological product development fee" before the period at the end; and

(D) in subparagraph (E), by adding at the end the following:

"(v) ADMINISTRATIVE REMOVAL FROM THE BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of 2 consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.";

(3) in paragraph (2)(D), by inserting "prior to approval" after "withdrawn";

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking "; and" and inserting a semicolon;

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting the following after clause (i):

"(ii) may be dispensed only under prescription pursuant to section 503(b); and"; and

(B) by adding at the end the following:

"(E) MOVEMENT TO DISCONTINUED LIST.—

"(i) WRITTEN REQUEST TO PLACE ON DISCONTINUED LIST.—

"(I) IN GENERAL.—If a written request to place a product on the list of discontinued biosimilar biological products referred to in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary shall consider such product to have been included on such list on the later of—

"(aa) the date such request was received; or

"(bb) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

"(II) WITHDRAWN FROM SALE DEFINED.—For purposes of this clause, a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

"(ii) PRODUCTS REMOVED FROM DISCONTINUED LIST.—If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of such fiscal year, on the list of discontinued biosimilar biological products referred to in subparagraph (A)(iii), and on any subsequent day during such fiscal year the biosimilar biological product does not appear on such list, except as provided in subparagraph (D), each person who is named as the applicant in the biosimilar biological product application shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for such biosimilar biological product. Notwithstanding subparagraph (B), such fee shall be due on the last business day of such fiscal year and shall be paid only once for each product for each fiscal year."; and

(5) by striking paragraph (4).

(b) Fee Revenue Amounts.—Section 744H(b) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 379j–52(b)) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) through (4) as paragraphs (1) through (3), respectively;

(3) in paragraph (1), as so redesignated—

(A) in the paragraph heading, by striking "SUBSEQUENT FISCAL YEARS" and inserting "IN GENERAL";

(B) in the matter preceding subparagraph (A), by striking "2019 through 2022" and inserting "2023 through 2027";

(C) in subparagraph (A), by striking "paragraph (4)" and inserting "paragraph (3)";

(D) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively;

(E) by inserting after subparagraph (B) the following:

"(C) the dollar amount equal to the strategic hiring and retention adjustment (as determined under subsection (c)(2));";

(F) in subparagraph (D), as so redesignated, by striking "subsection (c)(2)); and" and inserting "subsection (c)(3));";

(G) in subparagraph (E), as so redesignated, by striking "subsection (c)(3))." and inserting "subsection (c)(4)); and"; and

(H) by adding at the end the following:

"(F) for fiscal years 2023 and 2024, additional dollar amounts equal to—

"(i) $4,428, 886 for fiscal year 2023; and

"(ii) $320,569 for fiscal year 2024.";

(4) in paragraph (2), as so redesignated—

(A) in the paragraph heading, by striking "; LIMITATIONS ON FEE AMOUNTS";

(B) by striking subparagraph (B); and

(C) by redesignating subaparagraphs (C) and (D) as subparagraphs (B) and (C), respectively; and

(5) by amending paragraph (3), as so redesignated, to read as follows:

"(3) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

"(A) for fiscal year 2023, $43,376,922; and

"(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(4).".

(c) Adjustments; Annual Fee Setting.—Section 744H(c) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 379j–52(c)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking "subsection (b)(2)(B)" and inserting "subsection (b)(1)(B)"; and

(ii) in clause (i), by striking "subsection (b)" and inserting "subsection (b)(1)(A)"; and

(B) in subparagraph (B)(ii), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington–Arlington–Alexandria, DC–VA–MD–WV";

(2) by striking paragraph (4);

(3) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(4) by inserting after paragraph (1) the following:

"(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year beginning in fiscal year 2023, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.";

(5) in paragraph (3), as so redesignated—

(A) in subparagraph (A)—

(i) by striking "Beginning with the fiscal year described in subparagraph (B)(ii)(II)" and inserting "For each fiscal year"; and

(ii) by striking "adjustment under paragraph (1), further increase" and inserting "adjustments under paragraphs (1) and (2), further adjust"; and

(B) by amending subparagraph (B) to read as follows:

"(B) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Biosimilar User Fee Rates for Fiscal Year 2021' (85 Fed. Reg. 47220; August 4, 2020). The workload categories used in forecasting shall include only the activities described in such notice and, as feasible, additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types and the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in forecasting any non-core review activities, including any activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021."; and

(C) in subparagraph (C)—

(i) by striking "subsections (b)(2)(A)" and inserting "subsections (b)(1)(A)";

(ii) by striking "and (b)(2)(B)" and inserting ", (b)(1)(B)"; and

(iii) by inserting ", and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment)" before the period at the end;

(6) by amending paragraph (4), as so redesignated, to read as follows:

"(4) OPERATING RESERVE ADJUSTMENT.—

"(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

"(B) DECREASE.—

"(i) FISCAL YEAR 2023.—For fiscal year 2023, if the Secretary has carryover balances for the process for the review of biosimilar biological product applications in excess of 33 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves.

"(ii) FISCAL YEAR 2024.—For fiscal year 2024, if the Secretary has carryover balances for the process for the review of biosimilar biological product applications in excess of 27 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves.

"(iii) FISCAL YEAR 2025 AND SUBSEQUENT FISCAL YEARS.—For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for the process for the review of biosimilar biological product applications in excess of 21 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves.

"(C) FEDERAL REGISTER NOTICE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5)(B) establishing fee revenue and fees for the fiscal year involved."; and

(7) in paragraph (5), in the matter preceding subparagraph (A), by striking "2018" and inserting "2023".

(d) Crediting and Availability of Fees.—Section 744H(f)(3) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 379j–52(f)(3)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

(e) Written Requests for Waivers and Refunds.—Subsection (h) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is amended to read as follows:

"(h) Written Requests for Waivers and Returns; Disputes Concerning Fees.—To qualify for

consideration for a waiver under subsection (d), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver or return and, except as otherwise specified in this section, such written request shall be submitted to the Secretary not later than 180 days after such fee is due. A request submitted under this paragraph shall include any legal authorities under which the request is made.".

SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) is amended—

(1) by striking "2018" each place it appears and inserting "2023";

(2) by striking "Biosimilar User Fee Amendments of 2017" each place it appears and inserting "Biosimilar User Fee Amendments of 2022";

(3) in subsection (a)(4), by striking "2020" and inserting "2023"; and

(4) in subsection (f), by striking "2022" each place it appears and inserting "2027".

SEC. 405. SUNSET DATES.

(a) Authorization.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51, 379j–52) shall cease to be effective October 1, 2027.

(b) Reporting Requirements.—Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) shall cease to be effective January 31, 2028.

(c) Previous Sunset Provision.—Effective October 1, 2022, subsections (a) and (b) of section 405 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 406. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed for all biosimilar biological product applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 407. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to biosimilar biological product applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE V—IMPROVING REGULATION OF DRUGS AND

BIOLOGICAL PRODUCTS

SEC. 501. ALTERNATIVES TO ANIMAL TESTING.

(a) In General.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (i)—

(A) in paragraph (1)(A), by striking "preclinical tests (including tests on animals)" and inserting "nonclinical tests"; and

(B) in paragraph (2)(B), by striking "animal" and inserting "nonclinical tests"; and

(2) after subsection (y), by inserting the following:

"(z) Nonclinical Test Defined.—For purposes of this section, the term 'nonclinical test' means a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug, and may include animal tests, or non-animal or human biology-based test methods, such as cell-based assays, microphysiological systems, **or bioprinted** or computer models.".

(b) Biosimilar Biological Product Applications.—Item (bb) of section 351(k)(2)(A)(i)(I) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I)) is amended to read as follows:

"(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc)); and".

SEC. 502. SAFER DISPOSAL OF OPIOIDS.

Section 505–1(e)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(e)(4)(B)) is amended by striking "for purposes of rendering drugs nonretrievable (as defined in section 1300.05 of title 21, Code of Federal Regulations (or any successor regulation))".

SEC. 503. CLARIFICATIONS TO EXCLUSIVITY PROVISIONS FOR FIRST INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(6) of the Public Health Service Act (42 U.S.C. 262(k)(6)) is amended—

(1) in the matter preceding subparagraph (A)—

(A) by striking "Upon review of" and inserting "The Secretary shall not make ~~licensure~~ **approval** as an interchangeable biological product effective with respect to";

(B) by striking "relying on" and inserting "that relies on"; and

(C) by striking "the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use"; and

(2) in the flush text that follows subparagraph (C), by striking the period and inserting ", and the term 'first interchangeable biosimilar biological product' means any interchangeable biosimilar biological product that is approved on the first day on which

such a product is approved as interchangeable with the reference product.".

SEC. 504. IMPROVEMENTS TO THE PURPLE BOOK.

(a) In General.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) in subsection (a)—

(A) by striking "The holder of an application approved under subsection (c) or (j) of section 505" and inserting "The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act";

(B) in paragraph (2), by inserting "(in the case of a biological product, the proper name)" after "established name"; and

(C) in paragraph (3), by striking "or abbreviated application number" and inserting ", abbreviated application number, or biologics license application number"; and

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "The holder of an application approved under subsection (c) or (j)" and inserting "The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act";

(B) in paragraph (1), by inserting "(in the case of a biological product, the proper name)" after "established name"; and

(C) in paragraph (2), by striking "or abbreviated application number" and inserting ", abbreviated application number, or biologics license application number".

(b) Additional One-Time Report.—Subsection (c) of section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended to read as follows:

"(c) Additional One-Time Report.—Within 180 days of the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, all holders of applications approved under subsection (a) or (k) of section 351 of the Public Health Service Act shall review the information in the list published under section 351(k)(9)(A) and shall submit a written notice to the Secretary—

"(1) stating that all of the application holder's biological products in the list published under section 351(k)(9)(A) that are not listed as discontinued are available for sale; or

"(2) including the information required pursuant to subsection (a) or (b), as applicable, for each of the application holder's biological products that are in the list published under section 351(k)(9)(A) and not listed as discontinued, but have been discontinued from sale or never have been available for sale.".

(c) Purple Book.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) in subsection (d)—

(A) by striking "or (c), the Secretary" and inserting "or (c)—

"(1) the Secretary";

(B) by striking the period at the end, and inserting "; and"; and

(C) by adding at the end the following:

"(2) the Secretary may identify the application holder's biological products as discontinued in the list published under section 351(k)(9)(A) of the Public Health Service Act, except that the Secretary shall remove from the list in accordance with section 351(k)(9)(B) of such Act any biological product for which a license has been revoked or suspended for reasons of safety, purity, or potency."; and

(2) in subsection (e)—

(A) by inserting after the first sentence the following: "The Secretary shall update the list published under section 351(k)(9)(A) of the Public Health Service Act based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that any biological product for which the license has been revoked or suspended for reasons of safety, purity, or potency shall be removed from the list in accordance with section 351(k)(9)(B) of the Public Health Service Act."; and

(B) in the last sentence—

(i) by striking "updates to the list" and inserting "updates to the lists published under section 505(j)(7)(A) of this Act and section 351(k)(9)(A) of the Public Health Service Act"; and

(ii) by striking "update the list" and inserting "update such lists".

SEC. 505. THERAPEUTIC EQUIVALENCE EVALUATIONS.

Section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)) is amended by adding at the end the following:

"(v)(I) With respect to an application submitted pursuant to subsection (b)(2) for a drug that is subject to section 503(b) for which the sole difference from a listed drug relied upon in the application is a difference in inactive ingredients not permitted under clause (iii) or (iv) of section 314.94(a)(9) of title 21, Code of Federal Regulations (or **any** successor regulations), the Secretary shall make an evaluation with respect to whether such drug is a therapeutic equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) to another approved drug product in the prescription drug product section of the list under this paragraph as follows:

"(aa) With respect to such an application submitted after the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, the evaluation shall be made with respect to a listed drug relied upon in the application ~~under~~ **pursuant to** subsection (b)(2) that is a pharmaceutical equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) to the drug in the application ~~under~~ **pursuant to** subsection (b)(2) at the time of approval of such application or not later than 180 days after the date of such approval, provided that the

request for such ~~a determination~~ **an evaluation** is made in the original application (or in a resubmission to a complete response letter), and all necessary data and information are submitted in the original application (or in a resubmission in response to a complete response letter) for the therapeutic equivalence evaluation, including information to demonstrate bioequivalence, in a form and manner prescribed by the Secretary.

"(bb) With respect to such an application ~~submitted~~ **approved** prior to **or on** the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, ~~with respect to an application approved on or after the date of enactment of such Act,~~ the evaluation shall be made not later than 180 days after receipt of a request for a therapeutic equivalence evaluation submitted as part of a supplement to such application; or with respect to an application that was ~~not approved as of~~ **submitted prior to** the date of enactment of **the Food and Drug Administration Safety and Landmark Advancements Act of 2022 but not approved as of the date of enactment of** such Act, the evaluation shall be made not later than 180 days after the date of approval of such application if a request for such evaluation is submitted **as an amendment** to the application, provided that—

"(AA) such request for a therapeutic ~~equivalent~~ **equivalence** evaluation is being sought with respect to a listed drug relied upon in the application, and the relied upon listed drug is in the prescription drug product section of the list under this paragraph and is a pharmaceutical equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) to the drug for which a therapeutic equivalence evaluation is sought; and

"(BB) the ~~initial submission~~ **amendment or supplement, as applicable,** containing such request, or the relevant application, includes all necessary data and information for the therapeutic equivalence evaluation, including information to demonstrate bioequivalence, in a form and manner prescribed by the Secretary.

"(II) When the Secretary makes an evaluation under subclause (I), the Secretary shall, in revisions made to the list pursuant to clause (ii), include such information for such drug.".

SEC. 506. MODERNIZING ACCELERATED APPROVAL.

(a) In General.—Section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended—

(1) in paragraph (2)—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and adjusting the margins accordingly;

(B) by striking "Approval of a product" and inserting the following:

"(A) IN GENERAL.—Approval of a product";

(C) in clause (i) of such subparagraph (A), as so redesignated, by striking "appropriate postapproval studies" and inserting "an appropriate postapproval study or studies (which may be augmented or supported by real world evidence)"; and

(D) by adding at the end the following:

"(B) STUDIES NOT REQUIRED.—If the Secretary does not require that the sponsor of a product approved under accelerated approval conduct a postapproval study under this paragraph, the Secretary shall publish on the website of the Food and Drug Administration the rationale for why such study is not appropriate or necessary.

"(C) POSTAPPROVAL STUDY CONDITIONS.—Not later than the ~~time~~ **date** of approval of a product under accelerated approval, the Secretary shall specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to such product, which may include enrollment targets, the study protocol, and milestones, including the target date of study completion.

"(D) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may require such study or studies to be underway prior to ~~approval."~~ **approval of the applicable product."**; and

(2) in paragraph (3)—

(A) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively and adjusting the margins accordingly;

(B) by striking "The Secretary may" and inserting the following:

"(A) IN GENERAL.—The Secretary may";

(C) in clause (i) of such subparagraph (A), as so redesignated, by striking "drug with due diligence" and inserting "product with due diligence, including with respect to conditions specified by the Secretary under paragraph (2)(C)";

(D) in clause (iii) of such subparagraph (A), as so redesignated, by inserting "shown to be" after "product is not"; and

(E) by adding at the end the following:

"(B) EXPEDITED PROCEDURES DESCRIBED.—Expedited procedures described in this subparagraph shall consist of, prior to the withdrawal of accelerated approval—

"(i) providing the sponsor with—

"(I) due notice;

"(II) an explanation for the proposed withdrawal;

"(III) an opportunity for a meeting with the Commissioner or the Commissioner's designee; and

"(IV) an opportunity for written appeal to—

"(aa) the Commissioner; or

"(bb) a designee of the Commissioner who has not participated in the ~~proposal~~ **proposed** withdrawal of approval (other than a meeting pursuant to subclause (III)) and is not subordinate of an individual (other than the Commissioner) who participated in such proposed withdrawal;

"(ii) providing an opportunity for public comment on the ~~proposing to withdrawal~~ **proposal to withdraw** approval;

"(iii) the publication of a summary of the public comments received, and the Secretary's response to such comments, on the website of the Food and Drug Administration; and

"(iv) convening and consulting an advisory committee on issues related to the proposed withdrawal, if requested by the sponsor and if no such advisory committee has previously advised the Secretary on such issues with respect to the withdrawal of the product prior to the sponsor's request.".

(b) Reports of Postmarketing Studies.—Section 506B**(a)** of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b(a)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following:

"(2) ACCELERATED APPROVAL.—Notwithstanding paragraph (1), a sponsor of a drug approved ~~under~~ **pursuant to** accelerated approval shall submit to the Secretary a report of the progress of any study required under section 506(c), including progress toward enrollment targets, milestones, and other information as required by the Secretary, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or ~~terminated.".~~ **terminated. The Secretary shall promptly publish on the website of the Food and Drug Administration, in an easily searchable format, the information reported under this paragraph.".**

(c) Enforcement.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

~~* 12 (c) Enforcement.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 824, is further amended by adding at the end the following:~~

~~"(ll)~~**"(fff)** The failure of a sponsor of a product approved under accelerated approval pursuant to section 506(c)—

"(1) to conduct with due diligence any postapproval study required under section 506(c) with respect to such product; or

"(2) to submit timely reports with respect to such product in accordance with section 506B(a)(2).".

(d) Guidance.—

(1) IN GENERAL.—The Secretary of Health and Human Services **(referred to in this section as the "Secretary")** shall issue guidance describing—

(A) how sponsor questions related to the identification of novel surrogate or intermediate clinical endpoints may be addressed in early-stage development meetings with the Food and Drug Administration;

(B) the use of novel clinical trial designs that may be used to conduct appropriate ~~post-approval~~ **postapproval** studies as may be required under section 506(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a);

(C) the expedited procedures described in section 506(c)(3)(B) of the Federal Food,

Drug, and Cosmetic Act; and

(D) considerations related to the use of surrogate or intermediate clinical endpoints that may support the accelerated approval of an application under 506(c)(1)(A), including considerations in evaluating the evidence related to any such endpoints.

(2) FINAL GUIDANCE.—The Secretary shall issue—

(A) ~~a~~ draft guidance under paragraph (1) not later than 18 months after the date of enactment of this Act; and

(B) final guidance not later than 1 year after the close of the public comment period on such draft guidance.

(e) ~~Rare Disease Endpoint Advancement Pilot.—~~ **Accelerated Approval Council.—**

~~* 2 (1) In general.—The Secretary of Health and Human Services shall establish a pilot program under which the Secretary will establish procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints, including surrogate and intermediate endpoints, for drugs intended to treat rare diseases, including through—~~

~~(A) determining eligibility of participants for such program; and~~

~~* 3 (B) developing and implementing a process for applying to, and participating in, such a program.~~

~~* 4 (2) Public workshops.—The Secretary shall conduct up to 3 public workshops, which shall be completed not later than September 30, 2026, to discuss topics relevant to the development of endpoints for rare diseases, which may include discussions about—~~

~~* 5 (A) novel endpoints developed through the pilot program established under this subsection; and~~

~~* 6 (B) as appropriate, the use of real world evidence and real work data to support the validation of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.~~

~~(3) Report.—Not later than September 30, 2027, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the outcomes of the pilot program established under this subsection.~~

~~* 7 (4) Guidance.—Not later than September 30, 2027, the Secretary shall issue guidance describing best practices and strategies for development of efficacy endpoints, including~~

~~surrogate and intermediate endpoints, for rare diseases.~~

~~* 8 (5) Sunset.—The Secretary may not accept any new application or request to participate in the program established by this subsection on or after October 1, 2027.~~

~~(f) Accelerated Approval Council.—~~

(1) GENERAL.—Not later than ~~180 days~~ **1 year** after the date of enactment of this Act, the Secretary ~~of Health and Human Services~~ shall establish an intra-agency coordinating council within the Food and Drug Administration to ensure the consistent and appropriate use of accelerated approval across the Food and Drug Administration, pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)).

(2) MEMBERSHIP.—The members of the Council shall consist of the following senior officials, or a designee of such official, from the Food and Drug Administration and relevant Centers:

(A) The Director of the Center for Drug Evaluation and Research.

(B) The Director of the Center for Biologics Evaluation and Research.

(C) The Director of the Oncology Center of Excellence.

(D) The Director of the Office of New Drugs.

(E) The Director of the Office of Orphan Products Development.

(F) The Director of the Office of Tissues and Advanced Therapies.

(G) The Director of the Office of Medical Policy.

(H) At least 3 directors of review ~~division~~ **divisions or offices** overseeing products approved under accelerated approval, including at least one director ~~of a review division~~ within the Office of Neuroscience.

(3) DUTIES OF THE COUNCIL.—

(A) MEETINGS.—The Council shall convene not fewer than 3 times per calendar year to discuss issues related to accelerated approval, including any relevant cross-disciplinary approaches related to product review with respect to accelerated approval.

(B) POLICY DEVELOPMENT.—The Council shall directly engage with product review teams to support the consistent and appropriate use of accelerated approval across the Food and Drug Administration. Such activities may include—

(i) developing guidance for Food and Drug Administration staff and best practices for, and across, product review teams, including with respect to communication between sponsors and the Food and Drug Administration and the review of products under accelerated approval;

(ii) providing training for product review teams; and

(iii) advising review divisions on product-specific development, review, and withdrawal of products under accelerated approval.

(4) PUBLICATION OF A REPORT.—Not later than 1 year after the date of enactment of this

Act, and annually thereafter, the council shall publish on the public website of the Food and Drug Administration a report on the activities of the council.

~~(g)~~**(f)** Rule of Construction.—Nothing in this section (including the amendments made by this section) shall be construed to affect products approved ~~under~~ **pursuant to section** 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) prior to the date of enactment of this Act.

SEC. 507. RARE DISEASE PILOT PROGRAM.

** 2 ~~(1)~~**(a)** In ~~general. The~~ **General.—The** Secretary of Health and Human Services **(referred to in this section as the "Secretary")** shall establish a pilot program under which the Secretary ~~will establish~~ **establishes** procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints, including surrogate and intermediate endpoints, for drugs intended to treat rare diseases, including through—

(1) determining eligibility of participants for such program; and

** 3 ~~(B)~~**(2)** developing and implementing a process for applying to, and participating in, such a program.

** 4 ~~(2)~~**(b)** Public ~~workshops. The~~ **Workshops.—The** Secretary shall conduct up to 3 public workshops, which shall be completed not later than September 30, 2026, to discuss topics relevant to the development of endpoints for rare diseases, which may include discussions about—

** 5 ~~(A)~~**(1)** novel endpoints developed through the pilot program established under this ~~subsection;~~ **section;** and

** 6 ~~(B)~~**(2)** as appropriate, the use of real world evidence and real ~~work~~ **world** data to support the validation of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

(c) Report.—Not later than September 30, 2026, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the outcomes of the pilot program established under this section.

** 7 ~~(4)~~**(d)** Guidance.—Not later than September 30, 2027, the Secretary shall issue guidance describing best practices and strategies for development of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

** 8 ~~(5)~~**(e)** Sunset.—The Secretary may not accept any new application or request to participate in the program established by this ~~subsection~~ **section** on or after October 1, 2027.

SEC. 508. SUPPORTING REVIEW AND DEVELOPMENT OF DRUGS TO TREAT RARE DISEASES.

(a) GAO Report.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health,

Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report assessing the policies, practices, and programs of the Food and Drug Administration with respect to the review of applications for drugs and biological products intended to treat rare diseases and conditions (as defined in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2))).

(2) CONTENT OF REPORT.—The report under paragraph (1) shall—

(A) describe the activities of the Food and Drug Administration dedicated to the development and review of drugs and biological products intended to treat rare diseases and conditions;

(B) describe challenges with developing and obtaining approval or licensure of drugs and biological products intended to treat rare diseases and conditions, such as challenges related to designing and conducting clinical trials, clinical trial subject recruitment and enrollment, study endpoints, and ensuring data quality, assessing the benefit-risk profile of drugs and biological products intended to treat rare diseases and conditions, and meeting requirements for approval or licensure;

(C) assess the effectiveness of policies and practices of the Food and Drug Administration related to the review of applications for drugs and biological products intended to treat rare diseases and conditions, including—

(i) initiatives to support the development and review of drugs and biological products intended to treat rare diseases and conditions, including initiatives related to regulatory science, clinical trial design, statistical analysis, and other relevant topics;

(ii) consideration of relevant patient-focused drug development data and information, including patient experience data and the views of patients, pursuant to section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c);

(iii) training and other efforts to ensure the expertise of personnel of the Food and Drug Administration regarding the review of applications for drugs and biological products intended to treat rare diseases and conditions; and

(iv) consultations and engagement with stakeholders and external experts pursuant to section 569 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8);

(D) assess the extent to which the Food and Drug Administration is applying the policies and practices described in subparagraph (C) consistently across review divisions, and the factors that influence the extent to which such application is consistent; and

(E) include recommendations to address challenges and deficiencies identified, including recommendations to improve the effectiveness, consistency, and coordination of policies, practices, and programs of the Food and Drug

Administration related to the review of applications for drugs and biological products intended to treat rare diseases and conditions.

(b) FDA Report.—

(1) IN GENERAL.—Not later than March 31, 2026, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report assessing the policies, practices, and programs of the Food and Drug Administration with respect to the review of applications for drugs and biological products intended to treat rare diseases and conditions (as defined in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2))).

(2) CONTENT OF REPORT.—The report under paragraph (1) shall include, with respect to the period of fiscal years 2023 through 2025, broken down by fiscal year and by the responsible review division of the Food and Drug Administration—

(A) the number of drugs that have been designated as a drug for a rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb);

(B) the number of applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a drug designated under section 526 for a rare disease or condition that were submitted, the number of such applications that were approved, and the average size of the affected population in the United States upon which the designation pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) was granted for each such submitted and approved application;

(C) the number of applications for a drug or biological product for which the sponsor requested written recommendations pursuant to section 525 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa), and the number of such applications for which the sponsor received such written recommendations;

(D) the number of applications for which the Secretary consulted experts pursuant to section 569(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c); and

(E) the number of applications for which the Secretary allowed the sponsor to rely upon data and information pursuant to section 529A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff–1).

(3) CLARIFICATION.—Nothing in this subsection shall be construed to authorize the disclosure of confidential commercial information or other information considered proprietary or trade secret, as prohibited under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) or section 1905 of title 18, United States Code.

(c) Guidance.—Not later than 9 months after the date of enactment of this Act, the Secretary shall publish final guidance related to the draft guidance titled, "Rare Diseases:

Common Issues in Drug Development" issued on February 1, 2019.

SEC. 509. GENERIC DRUG LABELING CHANGES.

Section 505(j)(10)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended by striking clauses (i) through (iii) and inserting the following:

"(i) a revision to the labeling of the listed drug has been approved by the Secretary within 90 days of when the application is otherwise eligible for approval under this subsection;

"(ii) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after approval under this subsection of the application;

"(iii) the labeling revision described under clause (i) does not include a change to the 'Warnings' section of the labeling; and".

TITLE VI—OTHER REAUTHORIZATIONS

SEC. 601. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIP.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 602. REAUTHORIZATION OF THE BEST PHARMACEUTICALS FOR CHILDREN PROGRAM.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 603. REAUTHORIZATION OF THE HUMANITARIAN DEVICE EXEMPTION INCENTIVE.

Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking "2022" and inserting "2027".

SEC. 604. REAUTHORIZATION OF THE PEDIATRIC DEVICE CONSORTIA PROGRAM.

Section 305(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note) is amended by striking "$5,250,000 for each of fiscal years 2018 through 2022" and inserting "$7,000,000 for each of fiscal years 2023 through 2027".

SEC. 605. REAUTHORIZATION OF PROVISION PERTAINING TO DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)) is amended by—

(1) in paragraph (1)(A)(ii)(II), by adding "(other than bioavailability studies)" after "any clinical investigations"; and

(2) in paragraph (4), by striking "October 1, 2022" and inserting "October 1, 2027".

SEC. 606. REAUTHORIZATION OF ORPHAN DRUG GRANTS.

Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 607. REAUTHORIZATION OF CERTAIN DEVICE INSPECTIONS.

Section 704(g)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by striking "2022" and inserting "2027".

TITLE VII—ENHANCING FDA HIRING AUTHORITIES

SEC. 701. ENHANCING FDA HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

Section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3a) is amended—

(1) in subsection (a)—

(A) by inserting ", including cross-cutting operational positions," after "professional positions"; and

(B) by inserting "and the regulation of food" after "medical products"; and

(2) in subsection (d)(1)—

(A) in the matter preceding subparagraph (A)—

(i) by striking "the 21st Century Cures Act" and inserting "the Food and Drug Administration Safety and Landmark Advancements Act of 2022"; and

(ii) by striking "that examines the extent" and all that follows through ", including" and inserting "that addresses";

(B) in subparagraph (A)—

(i) by inserting "updated" before "analysis"; and

(ii) by striking "; and" and inserting a semicolon;

(C) by redesignating subparagraph (B) as subparagraph (C);

(D) by inserting after subparagraph (A) the following:

"(B) an analysis of how the Secretary has used the authorities provided under this section, and a plan for how the Secretary will use the authority under this section, and other applicable hiring authorities, for employees of the Food and Drug Administration; and"; and

(E) in **the matter preceding clause (i) of** subparagraph (C), as so redesignated, by striking "a recruitment" and inserting "an updated recruitment".

SEC. 702. STRATEGIC WORKFORCE PLAN AND REPORT.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting after section 714A the following:

"SEC. 714B. STRATEGIC WORKFORCE PLAN AND REPORT.

"(a) In General.—Not later than September 30, 2023, and at least every 4 years thereafter, the Secretary shall develop and submit to the appropriate committees of Congress and post on the website of the Food and Drug Administration, a coordinated strategy and report to provide direction for the activities and programs of the Secretary to recruit, hire, train, develop, and retain the workforce needed to fulfill the public health mission of the Food and Drug Administration, including to facilitate collaboration across centers, to keep pace with new biomedical, technological, and scientific advancements, and support the development, review, and regulation of medical products. Each such report shall be known as the 'Food and Drug Administration Strategic Workforce Plan'.

"(b) Use of the Food and Drug Administration Strategic Workforce Plan.—Each center within the Food and Drug Administration shall develop and update, as appropriate, a strategic plan that will be informed by the Food and Drug Administration Strategic Workforce Plan developed and updated under this subsection.

"(c) Contents of the Food and Drug Administration Strategic Workforce Plan.—Each Food and Drug Administration Strategic Workforce Plan under subsection (a) shall—

"(1) include agency-wide strategic goals and priorities for recruiting, hiring, training, developing, and retaining a qualified workforce for the Food and Drug Administration;

"(2) establish specific activities the Secretary will take to achieve its strategic goals and priorities and address the workforce needs of the Food and Drug Administration in the forthcoming fiscal years;

"(3) identify challenges and risks the Secretary will face in meeting its strategic goals and priorities, and the activities the Secretary will undertake to overcome those challenges and mitigate those risks;

"(4) establish metrics and milestones that the Secretary will use to measure progress in achieving its strategic goals and priorities; and

"(5) define functions, capabilities, and gaps in such workforce and identify strategies to recruit, hire, train, develop, and retain such workforce.

"(d) Considerations.—In developing each Food and Drug Administration Strategic Workforce Plan under subsection (a), the Secretary shall consider—

"(1) the number of employees, employee expertise, and employing center of employees, including senior leadership and non-senior leadership employees, eligible for retirement;

"(2) the vacancy and turnover rates for employees with different types of expertise and from different centers, including any changes or trends related to such rates;

"(3) the results of the Federal Employee Viewpoint Survey for employees of the Food and Drug Administration, including any changes or trends related to such results;

"(4) rates of pay for different types of positions, including rates for different types of expertise within the same field (such as differences in pay between different medical specialists), and how such rates of pay impact the ability of the Secretary to achieve strategic goals and priorities; and

"(5) the statutory hiring authorities used to hire Food and Drug Administration employees, and the time to hire across different hiring authorities.

"(e) Evaluation of Progress.—Each Food and Drug Administration Strategic Workforce Plan issued pursuant to subsection (a), with the exception of the first such Food and Drug Administration Strategic Workforce Plan, shall include an evaluation of the progress the Secretary has made, based on the metrics, benchmarks, and other milestones that measure successful recruitment, hiring, training, development, and retention activities; and whether such actions improved the capacity of the Food and Drug Administration to achieve the strategic goals and priorities set forth in the previous Food and Drug Administration Strategic Workforce Plan.

"(f) Additional Considerations.—The Food and Drug Administration Strategic Workforce Plan issued in fiscal year 2023 shall address the effect of the COVID–19 pandemic on hiring, retention, and other workforce challenges for the Food and Drug Administration, including protecting such workforce during public health emergencies.".

TITLE VIII—ADVANCING REGULATION OF COSMETICS, DIETARY SUPPLEMENTS, AND ~~LABORATORY DEVELOPED~~ **IN VITRO CLINICAL** TESTS

Subtitle A—Cosmetics

SEC. 801. SHORT TITLE.

This subtitle may be cited as the "Modernization of Cosmetics Regulation Act of 2022".

SEC. 802. AMENDMENTS TO COSMETIC REQUIREMENTS.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amended by adding at the end the following:

"SEC. 604. DEFINITIONS.

"In this chapter:

"(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a cosmetic product that is adverse.

"(2) COSMETIC PRODUCT.—The term 'cosmetic product' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

"(3) FACILITY.—

"(A) IN GENERAL.—The term 'facility' includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

"(B) Such term does not include any of the following:

"(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.

"(ii) Cosmetic product retailers, including individual sales representatives, direct sellers **(as defined in section 3508(b)(2) of the Internal Revenue Code of 1986)**, retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.

"(iii) Hospitals, physicians' offices, and health care clinics.

"(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

"(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.

"(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

"(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.

"(viii) An establishment that solely performs one or more of the following with respect to cosmetic products:

"(I) Labeling.

"(II) Relabeling.

"(III) Packaging.

"(IV) Repackaging.

"(V) Holding.

"(VI) Distributing.

"(C) CLARIFICATION.—For the purposes of subparagraph (B)(viii), the terms 'packaging' and 'repackaging' do not include filling a product container with a cosmetic product.

"(4) RESPONSIBLE PERSON.—The term 'responsible person' means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of this Act or section 4(a) of the Fair Packaging and Labeling Act.

"(5) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' means an adverse event that—

"(A) results in—

"(i) death;

"(ii) a life-threatening experience;

"(iii) inpatient hospitalization;

"(iv) a persistent or significant disability or incapacity;

"(v) a congenital anomaly or birth defect; or

"(vi) significant disfigurement (including serious and persistent rashes or infections, second- or third-degree burns, significant hair loss, or permanent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or

"(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

"SEC. 605. ADVERSE EVENTS.

"(a) Serious Adverse Event Reporting Requirements.—The responsible person shall submit to the Secretary any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person.

"(b) Submission of Reports.—

"(1) SERIOUS ADVERSE EVENT REPORT.—The responsible person shall submit to the Secretary a serious adverse event report accompanied by a copy of the label on or within the retail packaging of such cosmetic product no later than 15 business days after the report is received by the responsible person.

"(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new and material medical information, related to a serious adverse event report submitted to the Secretary in accordance with paragraph (1), that is received by the responsible person within 1 year of the initial report to the Secretary, no later than 15 business days after such information is received by such responsible person.

"(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to enable responsible persons to submit a single report that includes duplicate reports of, or new medical information related to, a serious adverse event.

"(c) Exemptions.—The Secretary may establish by regulation an exemption to any of the

requirements of this section if the Secretary determines that such exemption would have no significant adverse effect on public health.

"(d) Contact Information.—The responsible person shall receive reports of adverse events through the domestic address, domestic telephone number, or electronic contact information included on the label in accordance with section 609(a).

"(e) Maintenance and Inspection of Adverse Event Records.—

"(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event associated with the use, in the United States, of a cosmetic product manufactured or distributed by such person received by such person, for a period of 6 years.

"(2) INSPECTION.—

"(A) IN GENERAL.— The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

"(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services who has—

"(i) appropriate credentials, as determined by the Secretary; and

"(ii) been duly designated by the Secretary to have access to the records required under this section.

"(f) Fragrance and Flavor Ingredients.—If the Secretary has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under this section, the Secretary may request in writing a ~~complete list~~ **list of ingredients or categories** of ingredients in the specific fragrances or flavors in the cosmetic product, from the responsible person. The responsible person shall ensure that the requested information is submitted to the Secretary within 30 days of such request. ~~Information~~ **In response to a request under section 552 of title 5, United States Code, information** submitted to the Secretary under this subsection ~~that is confidential commercial or trade secret information shall be exempt from disclosure under section 552~~ **shall be withheld under section 552(b)(3)** of title 5, United States Code.

"(g) Protected Information.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection ~~(a)(2)~~**(b)(2)**, or an adverse event report, or any new information, voluntarily submitted to the Secretary shall be considered to be—

"(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

"(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly

referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

"(h) Effect of Section.—

"(1) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

"(2) PERSONALLY IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

"(A) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

"(B) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

"(3) USE OF REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with this section.

"(4) RULE OF CONSTRUCTION.—The submission of any report in compliance with this section shall not be construed as an admission that the cosmetic product involved caused or contributed to the relevant adverse event.

"SEC. 606. GOOD MANUFACTURING PRACTICE.

"(a) In General.—The Secretary shall by regulation establish good manufacturing practices for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601. Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this paragraph during an inspection conducted under section 704.

"(b) Considerations.—In establishing regulations for good manufacturing practices under this section, the Secretary shall take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses, and may include longer compliance times for smaller businesses. Before issuing regulations to implement subsection (a), the Secretary shall consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by the Secretary.

"(c) Timeframe.—The Secretary shall publish a notice of proposed rulemaking not later than 2

years after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022 and shall publish a final such rule not later than 3 years after such date of enactment.

"SEC. 607. REGISTRATION AND PRODUCT LISTING.

"(a) Submission of Registration.—

"(1) INITIAL REGISTRATION.—

"(A) EXISTING FACILITIES.—Every person that, on the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after date of enactment of such Act.

"(B) NEW FACILITIES.—Every person that owns or operates a facility that first engages, after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary such facility within 60 days of first engaging in such activity or 60 days after the deadline for registration under subparagraph (A), whichever is later.

"(2) BIENNIAL RENEWAL OF REGISTRATION.—A person required to register a facility under paragraph (1) shall renew such registrations with the Secretary biennially.

"(3) CONTRACT MANUFACTURERS.—If a facility manufactures or processes cosmetic products on behalf of a responsible person, the Secretary shall require only a single registration for such facility even if such facility is manufacturing or processing its own cosmetic products or cosmetic products on behalf of more than one responsible person. Such single registration may be submitted to the Secretary by such facility or any responsible person whose products are manufactured or processed at such facility.

"(4) UPDATES TO CONTENT.—A person that is required to register under subsection (a)(1) shall notify the Secretary within 60 days of any changes to information required under subsection (b)(2).

"(5) ABBREVIATED RENEWAL REGISTRATIONS.—The Secretary shall provide for an abbreviated registration renewal process for any person that owns or operates a facility that has not been required to submit updates under paragraph (4) for a registered facility since submission of the most recent registration of such facility under paragraph (1) or (2).

"(b) Format; Contents of Registration.—

"(1) IN GENERAL.—Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe.

"(2) CONTENTS.—The registration under subsection (a) shall contain—

"(A) the facility's name, physical address, email address, and telephone number;

"(B) with respect to any foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information;

"(C) the facility registration number, if any, previously assigned by the Secretary

under subsection (d);

"(D) all brand names under which cosmetic products manufactured or processed in the facility are sold; and

"(E) the product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

"(c) Cosmetic Product Listing.—

"(1) IN GENERAL.—For each cosmetic product, the responsible person shall submit~~, or ensure is submitted,~~ to the Secretary a cosmetic product listing, **or ensure that such submission is made,** at such time and in such manner as the Secretary may prescribe.

"(2) COSMETIC PRODUCT LISTING.—The responsible person of a cosmetic product that is marketed on the date of enactment of the Modernization of Cosmetics Regulation Act of 2022 shall submit to the Secretary a cosmetic product listing not later than 1 year after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, or for a cosmetic product that is first marketed after the date of enactment of such Act, within 120 days of marketing such product in interstate commerce. Thereafter, any updates to such listing shall be made annually, consistent with paragraphs (4) and (5).

"(3) ABBREVIATED RENEWAL.—The Secretary shall provide for an abbreviated process for the renewal of any cosmetic product listing under this subsection with respect to which there has been no change since the responsible person submitted the previous listing.

"(4) CONTENTS OF LISTING.—

"(A) IN GENERAL.—Each such cosmetic product listing shall include—

"(i) the facility registration number of each facility where the cosmetic product is manufactured or processed;

"(ii) the name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;

"(iii) the applicable cosmetic category or categories for the cosmetic product;

"(iv) a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name ~~adopted in regulations promulgated by the Secretary, if any~~**, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations)**, or by the common or usual name of the ingredient; and

"(v) the product listing number, if any previously assigned by the Secretary under subsection (d).

"(B) FLEXIBLE LISTINGS.—A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

"(5) UPDATES TO CONTENT.—A responsible person that is required to submit a cosmetic product listing shall submit any updates to such cosmetic product listing annually.

"(6) SUBMISSION.—A responsible person may submit product listing information as part of a facility registration or separately.

"(d) Facility Registration and Product Listing Numbers.—At the time of the initial registration of any facility under subsection (a)(1) or initial listing of any cosmetic product under (c)(1), the Secretary shall assign a facility registration number to the facility and a product listing number to each cosmetic product. The Secretary shall not make such product listing number publicly available.

"(e) ~~Confidentiality.—Information submitted to the Secretary under this section that is confidential commercial or trade secret information shall be exempt from disclosure~~ **Confidentiality.—In response to a request** under section 552 of title 5, United States Code, ~~including all~~ information ~~submitted under~~ **described in** subsection (b)(2)(D) or (c)(4)(A)(i) **that is derived from a registration or listing under this section shall be withheld under section 552(b)(3) of title 5, United States Code**.

"(f) Suspensions.—

"(1) SUSPENSION OF REGISTRATION OF A FACILITY.—The Secretary may suspend the registration of a facility if the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

"(2) NOTICE OF SUSPENSION.—Before suspending a facility registration under this section, the Secretary shall provide—

"(A) notice to the facility registrant of the cosmetic product or other responsible person, as appropriate, of the intent to suspend the facility registration, which shall specify the basis of the determination by the Secretary that the facility **registration** should be suspended; and

"(B) an opportunity, within 5 business days of the notice provided under subparagraph (A), for the responsible person to provide a plan for addressing the reasons for possible suspension of the facility registration.

"(3) HEARING ON SUSPENSION.—The Secretary shall provide the registrant subject to an order under paragraph (1) or (2) with an opportunity for an informal hearing, to be held as soon as possible but not later than 5 business days after the issuance of the order, or such other time period agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to the suspension should be reinstated. The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

"(4) POST-HEARING CORRECTIVE ACTION PLAN.—If, after providing opportunity for an informal hearing under paragraph (3), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan not later than 14 business days after the submission of the corrective action plan or such other time period as determined by

the Secretary, in consultation with the registrant.

"(5) VACATING OF ORDER; REINSTATEMENT.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions, the Secretary shall promptly vacate the suspension and reinstate the registration of the facility.

"(6) EFFECT OF SUSPENSION.—If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the United States cosmetic products from such facility.

"(7) NO DELEGATION.—The authority conferred by this section to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

"SEC. 608. SAFETY SUBSTANTIATION.

"(a) Substantiation of Safety.—A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.

"(b) Coal-Tar Hair Dye.—Subsection (a) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 601(a). A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

"(c) Definitions.—For purposes of this section:

"(1) ADEQUATE SUBSTANTIATION OF SAFETY.—The term 'adequate substantiation of safety' means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

"(2) SAFE.—The term 'safe' means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof.

"SEC. 609. LABELING.

"(a) General Requirement.—Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product.

"(b) Fragrance Allergens.—The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in such cosmetic product. Substances that are fragrance allergens for purposes of this subsection shall be determined by the Secretary by regulation. The Secretary shall issue a notice of proposed rulemaking promulgating the regulation implementing

this requirement not later than 18 months after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, and not later than 180 days after the date on which the public comment period on the proposed rulemaking closes, shall issue a final rulemaking. In promulgating regulations implementing this subsection, the Secretary shall consider international, State, and local requirements for allergen disclosure, including the substance and format of requirements in the European Union, and may establish threshold levels of amounts of substances subject to disclosure pursuant to such regulations.

"(c) Cosmetic Products for Professional Use.—

"(1) DEFINITION OF PROFESSIONAL.—For purposes of this subsection, the term 'professional' means an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

"(2) PROFESSIONAL USE LABELING.—A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that—

"(A) contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and

"(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this Act and section 4(a) of the Fair Packaging and Labeling Act.

"SEC. 610. RECORDS.

"(a) In General.—If the Secretary has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, and any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans, each responsible person and facility shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans. This subsection shall not be construed to extend to recipes or formulas for cosmetics, financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this Act), research data (other than safety substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales).

"(b) ~~Protection of Sensitive Information.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.~~

~~"(c)~~ Rule of Construction.—Nothing in this section shall be construed to limit the authority of the Secretary to inspect records or require establishment and maintenance of records under any other provision of this Act, including section 605 or 606.

"SEC. 611. MANDATORY RECALL AUTHORITY.

"(a) In General.—If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary (if so prescribed), the Secretary may, by order, require, as the Secretary ~~deems~~ **determines** necessary, such person to immediately cease distribution of such article.

"(b) Hearing.—The Secretary shall provide the responsible person who is subject to an order under subsection (a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order.

"(c) Order Resolution.—After an order is issued according to the process under subsections (a) and (b), the Secretary shall, except as provided in subsection (d)—

"(1) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

"(2) continue the order ceasing distribution of the cosmetic until a date specified in such order; or

"(3) amend the order to require a recall of the cosmetic, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

"(d) Action Following Order.—Any person who is subject to an order pursuant to paragraph (2) or (3) of subsection (c) shall immediately cease distribution of or recall, as applicable, the cosmetic and provide notification as required by such order.

"(e) Notice to Persons Affected.—If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to subsection (a) or an amended order pursuant to paragraph (2) or (3) of subsection (c) to provide either a notice of a recall order for, or an order to cease distribution of, such cosmetic, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public.

"(f) Public Notification.—In conducting a recall under this section, the Secretary shall—

"(1) ensure that a press release is published regarding the recall, and that alerts and public notices are issued, as appropriate, in order to provide notification—

"(A) of the recall to consumers and retailers to whom such cosmetic was, or may have been, distributed; and

"(B) that includes, at a minimum—

"(i) the name of the cosmetic subject to the recall;

"(ii) a description of the risk associated with such article; and

"(iii) to the extent practicable, information for consumers about similar cosmetics that are not affected by the recall; and

"(2) ensure publication, as appropriate, on the website of the Food and Drug Administration of an image of the cosmetic that is the subject of the press release described in paragraph (1), if available.

"(g) No Delegation.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

"(h) Effect.—Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this chapter.

"SEC. 612. SMALL BUSINESSES.

"(a) In General.—Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and not subject to the requirements of section 606 or 607.

"(b) Requirements Applicable to All Manufacturers and Processors of Cosmetics.—The exemptions under subsection (a) shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

"(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

"(2) Cosmetic products that are injected.

"(3) Cosmetic products that are intended for internal use.

"(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

"SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FACILITIES.

"(a) In General.—Notwithstanding any other provision of law, except as provided in subsection (b), a cosmetic product or facility that is also subject to the requirements of chapter V shall be exempt from the requirements of sections 605, 606, 607, 608, 609(a), 610, and 611.

"(b) Exception.—A facility described in subsection (a) that also manufactures or processes cosmetic products that are not subject to the requirements of chapter V shall not be exempt from the requirements of sections 605, 606, 607, 608, 609(a), 610, and 611, with respect to such cosmetic products.

"SEC. 614. PREEMPTION.

"(a) In General.—No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this chapter with respect to registration and product listing, good manufacturing practice, recordkeeping, recalls,

adverse event reporting, or safety substantiation.

"(b) Limitation.—Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a). Notwithstanding subsection (a), nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in ~~an~~ **a** cosmetic product.

"(c) Savings.—Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law.

"(d) Rule of Construction.—Nothing in this section shall be construed to amend, expand, or limit the provisions under section 752.".

SEC. 803. ENFORCEMENT AND CONFORMING AMENDMENTS.

(a) In General.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) ~~is~~ **, as amended by section 506, is further** amended—

(A) by adding at the end the following:

~~"(fff)~~**"(ggg)** The failure to register or submit listing information in accordance with section 607.

~~"(ggg)~~**"(hhh)** The refusal or failure to follow an order under section 611."; and

(B) in paragraph (d), by striking "or 564" and inserting ", 564, or 607".

(2) ADULTERATED PRODUCTS.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amended by adding at the end the following:

"(f) If it has been manufactured or processed under conditions that do not meet good manufacturing practice regulations, as prescribed by the Food and Drug Administration in accordance with section 606.

"(g) If it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in section 608(c).".

(3) MISBRANDED COSMETICS.—Section 602(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362(b)) is amended—

(A) by striking "and (2)" and inserting "(2)"; and

(B) by inserting after "numerical count" the following: "; and (3) the information required under section 609".

(4) ADVERSE EVENT REPORTING.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(A) in section 301(e) (21 U.S.C. 331(e))—

(i) by striking "564, 703" and inserting "564, 605, 703"; and

(ii) by striking "564, 760" and inserting "564, 605, 611, 760";

(B) in section 301(ii) (21 U.S.C. 331(ii))—

(i) by striking "760 or 761) or" and inserting "604, 760, or 761) or"; and

(ii) by inserting "or required under section 605(a)" after "report (as defined under section 760 or 761";

(C) in section 801(a) (21 U.S.C. 381(a))—

(i) by striking "under section 760 or 761" and inserting "under section 605, 760, or 761";

(ii) by striking "defined in such section 760 or 761" and inserting "defined in section 604, 760, or 761";

(iii) by striking "of such section 760 or 761" and inserting "of such section 605, 760, or 761"; and

(iv) by striking "described in such section 760 or 761" and inserting "described in such section 605, 760, or 761"; and

(D) in section 801(b) (21 U.S.C. 381(b))—

(i) by striking "requirements of sections 760 or 761," and inserting "requirements of section 605, 760, or 761";

(ii) by striking "as defined in section 760 or 761" and inserting "as defined in section 604, 760, or 761"; and

(iii) by striking "with section 760 or 761" and inserting "with section 605, 760, or 761".

(b) Effective ~~Date.—The~~ **Dates.—**

(1) IN GENERAL.—The amendments made by subsection (a) shall take effect on the date that is 1 year after the date of enactment of this Act.

(2) LABELING REQUIREMENT.—Section 609(a) of the Federal Food, Drug, and Cosmetic Act, as added by section 802, shall take effect on the date that is 2 years after the date of enactment of this Act.

(c) Confidentiality.—

(1) IN GENERAL.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential commercial information that is obtained by the Secretary of Health and Human Services pursuant to this subtitle, including the amendments made by this subtitle.

(2) CLARIFICATION.—Nothing in this subtitle, including the amendments made by this subtitle, shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) or section 1905 of title 18, United States Code, or that is subject to withholding under section 552(b)(4) of title 5, United States Code.

SEC. 804. RECORDS INSPECTION.

Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by inserting after the second sentence the following: "In the case of a facility (as defined in section 604) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 605, 606, and 610, when the standard for records inspection under such section applies.".

SEC. 805. TALC-CONTAINING COSMETICS.

The Secretary of Health and Human Services—

(1) not later than one year after the date of enactment of this Act, shall promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products; and

(2) not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.

SEC. 806. PFAS IN COSMETICS.

(a) In General.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall assess the use of perfluoroalkyl and polyfluoroalkyl substances in cosmetic products and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use. In conducting such assessment, the Secretary may, as appropriate, consult with the National Center for Toxicological Research.

(b) Report.—Not later than ~~2~~ **3** years after enactment of this Act, the Secretary shall publish on the website of the Food and Drug Administration a report summarizing the results of the assessment conducted under subsection (a).

SEC. 807. **SENSE OF THE SENATE ON ANIMAL TESTING.**

It is the sense of the Senate that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances.

SEC. 808. FUNDING.

There is authorized to be appropriated $14,200,000 for fiscal year 2023, $25,960,000 for fiscal year 2024, and $41,890,000 for each of ~~the~~ fiscal years 2025 through 2027, for purposes of conducting the activities under this subtitle (including the amendments made by this subtitle) and hiring personnel required to carry out this subtitle (including the amendments made by this subtitle).

Subtitle B—Dietary Supplements

SEC. 811. REGULATION OF DIETARY SUPPLEMENTS.

(a) In General.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding after section 403C of such Act (21 U.S.C. 343–3) the following:

"SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIREMENT.

"(a) In General.—Beginning on the date specified in subsection (b)(4), each dietary supplement **marketed in the United States** shall be listed with the Secretary in accordance with this section. Each such listing shall include, with respect to the dietary supplement, the information specified in subsection (b)(1).

"(b) Requirements.—

"(1) IN GENERAL.—The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 403(e)(1)) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the 'responsible person'), or if the responsible person is a foreign entity, the United States agent of such person, shall submit to the Secretary in accordance with this section the following information for a dietary supplement that is marketed:

"(A) Any name of the dietary supplement and the statement of identity, including brand name and specified flavors, if applicable.

"(B) The name and address of the responsible person and the name and email address of the owner, operator, or agent in charge of the responsible person.

"(C) The name, domestic address, and email address for the United States agent, if the responsible person is a foreign entity.

"(D) The business name and ~~mailing~~ **full** address of all locations at which the responsible person manufactures, packages, labels, or holds the dietary supplement.

"(E) A list of all ingredients in each such dietary supplement required under sections 101.4 and 101.36, title 21, Code of Federal Regulations (or any successor regulations) to appear on the label of a dietary supplement, including—

"(i) where applicable, ingredients in a proprietary blend as described in section 101.36(c) of title 21, Code of Federal Regulations (or any successor regulations);

"(ii) the amount per serving of each listed dietary ingredient;

"(iii) if required by section 101.36 of title 21, Code of Federal Regulations (or any successor regulations), the percent of the daily value of each listed dietary ingredient; and

"(iv) the amount per serving of dietary ingredients within a proprietary blend.

"(F) The number of servings per container for each container size ~~of the identical formulation~~.

"(G) The directions for use.

"(H) Warnings, notice, and safe handling statements, as required by section 101.17 of title 21, Code of Federal Regulations (or any successor regulations).

"(I) Allergen statements for major food allergens (pursuant to sections 403(w) and 403(x)).

"(J) The form of the dietary supplement (such as tablets, capsules**, powders, liquids, softgels, and gummies)**~~)~~.

"(K) Any health claims or structure or function claims.

"(L) The dietary supplement product listing number for the ~~product~~ **dietary supplement** provided by the Secretary in accordance with subsection (c) ~~for that product~~.

"(2) FORMAT.—The Secretary may require that a listing submitted under paragraph (1) be submitted in an electronic format. Upon receipt of a complete listing under paragraph (1), the Secretary shall promptly notify the responsible person of the receipt of such listing.

"(3) LISTING CONTENT.—A single listing submission for a dietary supplement under paragraph (1) may include multiple dietary supplements with identical formulations **and forms**, or formulations **of the same form,** that differ only with respect to color, ~~additives~~ **excipients**, or flavorings, whether offered in a single package size or in multiple package sizes.

"(4) TIMING.—

"(A) IN GENERAL.—

"(i) DIETARY SUPPLEMENTS ON THE MARKET.—In the case of a dietary supplement that is being offered in interstate commerce on or before January 1, 2024, a listing for each such dietary supplement introduced or delivered for introduction into interstate commerce shall be submitted by the responsible person to the Secretary under this subsection not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022.

"(ii) NEW DIETARY SUPPLEMENTS.—In the case of a dietary supplement that is not being offered in interstate commerce on or before January 1, 2024, a listing for each such dietary supplement introduced or delivered for introduction into interstate commerce that has not been included in any listing previously submitted by the responsible person to the Secretary under this subsection shall be submitted to the Secretary at the time of introduction into interstate commerce.

"(B) DISCONTINUED DIETARY SUPPLEMENTS.—The responsible person shall notify the Secretary within one year of the date of discontinuance of a dietary supplement required to be listed with the Secretary under paragraph (1) for which the responsible person has discontinued commercial marketing.

"(C) CHANGES TO EXISTING LISTINGS.—The responsible person shall submit to the Secretary a change or modification to listing information submitted under paragraph (1) included on the label for a dietary supplement at the time the dietary supplement

with the change or modification is introduced into interstate commerce.

"(5) ADDITIONAL INFORMATION.—The responsible person shall provide upon request from the Secretary, within 10 calendar days of such request, the full business name and physical and mailing address from which the responsible person receives a dietary ingredient or combination of dietary ingredients that the responsible person uses in the manufacture of the dietary supplement or, if applicable, from which the responsible person receives the dietary supplement.

"(c) Product Listing Number and Dietary Supplement Electronic Database.—

"(1) DIETARY SUPPLEMENT PRODUCT LISTING NUMBER.—The Secretary shall provide each dietary supplement listed in accordance with subsection (b)(1) a dietary supplement product listing number, which may apply to multiple dietary supplements with identical formulations, or formulations that differ only with respect to color, ~~additives~~ **excipients**, or flavorings, including dietary supplements offered in a single package size or in multiple package sizes. The Secretary shall provide a process for a responsible person to reserve dietary supplement listing numbers in advance of listing under subsection (b)(1).

"(2) ELECTRONIC DATABASE.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, the Secretary shall establish and maintain an electronic database that is publicly available and contains information submitted under subsection (b)(1) (except for the information submitted under subparagraphs (D) and (E)(iv) of such subsection). The Secretary shall make such information maintained in the electronic database publicly searchable, including by dietary supplement product listing number, and by any field of information or combination of fields of information provided under subsection (b)(1).

"(3) CONFIDENTIAL INFORMATION.—In response to a request under section 552 of title 5, United States Code, information described in subparagraph (D) or (E)(iv) of subsection (b)(1) that is derived from a listing under this section shall be withheld under section 552(b)(3) of title 5, United States Code.

"(d) Rule of Construction.—Nothing in this section shall be construed—

"(1) to limit the authority of the Secretary to inspect or copy records or to require the establishment and maintenance of records under any other provision of this Act; ~~or~~

"(2) to authorize the disclosure of ~~trade secret or confidential commercial information subject to section 552(b)(4) of title 5~~ **information that is prohibited from disclosure under section 301(j) of this Act or section 1905 of title 18**, United States Code, ~~as prohibited under section 301(j) of this Act or section 1905 of title 18, United States Code, including information provided to the Secretary under subsection (b)(1)(D) or (b)(1)(E)(iv).~~ **or that is subject to withholding under section 552(b)(4) of title 5, United States Code; or**

"(3) to grant the Secretary authority to require the approval of a dietary supplement prior to marketing.

"(e) Authorization of Appropriations.—There is authorized to be appropriated $7,498,080 for fiscal year 2023, and $6,300,000 for each of fiscal years 2024 through 2027, for purposes of

conducting the activities under this section and hiring personnel required to carry out this section.".

(b) Guidance.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish final guidance related to the draft guidance titled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for ~~Industry; Availability" (81 Fed. Reg. 53486;~~ **Industry", issued** August 12, 2016~~)~~, consistent with section 403D of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) Inspections for Certain Dietary Supplements.—The Secretary of Health and Human Services shall direct resources to inspections of facilities, suppliers, and dietary supplement types that present a high risk to public health (as identified by the Secretary).

(d) Misbranding.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

"(z) If it is a dietary supplement for which a responsible person **or the United States agent of such a person** is required under section 403D to file a listing, file a change to an existing listing, or provide additional information to the Secretary, and such person **or agent** has failed to comply with any such requirements under section 403D with respect to such dietary supplement.".

(e) New Prohibited Act.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 803(a), is further amended by adding at the end the following:

~~"(hhh)~~**"(iii)** The introduction or delivery for introduction into interstate commerce of any product marketed as a dietary supplement that does not meet the definition of a dietary supplement under section 201(ff).

~~"(iii)~~**"(jjj)** The introduction or delivery for introduction into interstate commerce of a dietary supplement that has been prepared, packed, or held using the assistance of, or at the direction of, a person debarred under section 306.".

Subtitle C—In Vitro Clinical Tests

SEC. 821. SHORT TITLE~~; TABLE OF CONTENTS~~.

(a) Short Title.—This subtitle may be cited as the ~~"Food and Drug Administration Safety and Landmark Advancements~~**"Verifying Accurate Leading-edge IVCT Development** Act of 2022" or the "VALID Act of 2022".

~~(b) Table of Contents.—The table of contents of this subtitle is as follows:~~

~~subchapter c—in vitro clinical tests~~

~~Sec.821.Short title; table of contents.~~

~~Sec.822.Definitions.~~

~~Sec.823.Regulation of in vitro clinical tests.~~

~~“subchapter j—in vitro clinical tests~~

~~“SUBCHAPTER J. In Vitro Clinical Tests~~

~~“Sec.587.Definitions.~~

~~“Sec.587A.Regulation of in vitro clinical tests.~~

~~“Sec.587B.Premarket review.~~

~~“Sec.587C.Exemptions.~~

~~“Sec.587D.Technology certification.~~

~~“Sec.587E.Mitigating measures.~~

~~“Sec.587F.Regulatory pathway designation.~~

~~“Sec.587G.Grandfathered in vitro clinical tests.~~

~~“Sec.587H.Advisory committees.~~

~~“Sec.587I.Breakthrough in vitro clinical tests.~~

~~“Sec.587J.Registration and listing.~~

~~“Sec.587K.Test design and quality requirements.~~

~~“Sec.587L.Labeling requirements.~~

~~“Sec.587M.Adverse event reporting.~~

~~“Sec.587N.Corrections and removals.~~

~~“Sec.587O.Restricted in vitro clinical tests.~~

~~“Sec.587P.Appeals.~~

~~“Sec.587Q.Accredited persons.~~

~~“Sec.587R.Recognized standards.~~

~~“Sec.587S.Investigational use.~~

~~"Sec.587T.Collaborative communities for in vitro clinical tests.~~

~~"Sec.587U.Comprehensive test information system.~~

~~"Sec.587V.Preemption.~~

~~"Sec.587W.Adulteration.~~

~~"Sec.587X.Misbranding.~~

~~"Sec.587Y.Postmarket surveillance.~~

~~"Sec.587Z.Electronic format for submissions.~~

~~"Sec.587AA.Postmarket remedies.~~

~~"Sec.587BB.Applicability.~~

~~"Sec.587CC.Judicial review.~~

~~Sec.824.Enforcement and other provisions.~~

~~Sec.825.Transition.~~

~~Sec.826.Emergency use authorization.~~

~~Sec.827.Antimicrobial susceptibility tests.~~

~~Sec.828.Combination products.~~

~~Sec.829.Resources.~~

SEC. 822. DEFINITIONS.

(a) In General.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) by adding at the end the following:

"(ss)(1) The term 'in vitro clinical test' means an article specified in subparagraph (2) that is intended ~~by its developer (as defined in section 587)~~ to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body for the purpose of—

"(A) identifying or diagnosing a disease or condition;

"(B) providing information for diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing, or monitoring a disease or condition, including by making a determination of an individual's state of health; or

"(C) selecting, monitoring, or informing therapy or treatment for a disease or condition.

"(2) An article specified in this subparagraph is—

"(A) a test kit;

"(B) a test system;

"(C) a test protocol or laboratory test protocol;

"(D) an instrument (as defined in section 587(11));

"(E) a specimen receptacle (as defined in section ~~587(17))~~ **587(16))**;

"(F) software, excluding software that is excluded by section 520(o) from the definition of a device under section 201(h), that—

"(i) is a component or part of another in vitro clinical test or analyzes, processes, or interprets a signal or pattern from another in vitro clinical test; and

"(ii) does not analyze, process, or interpret a signal, pattern, or medical image from a device; and

"(G) subject to subparagraph (3), a component or part of a test, a test protocol, an instrument, an article, or software described in any of clauses (A) through (D) of such subparagraph, whether alone or in combination, including reagents, calibrators, and controls.

"(3) Notwithstanding subparagraph (2)(G), an article intended to be used as a component or part of an in vitro clinical test described in subparagraph (1) is excluded from the definition in subparagraph (1) if the article consists of any of the following:

"(A) Blood, blood components, or human cells or tissues, from the time of acquisition, donation, or recovery of such article, including determination of donor eligibility, as applicable, until such time as the article is released as a component or part of an in vitro clinical test by the establishment that collected such article.

"(B) An article used for invasive sampling, a needle, or a lancet, except to the extent such article, needle, or lancet is an integral component of an article for holding, storing, or transporting a specimen.

"(C) General purpose laboratory **equipment.";** ~~equipment, including certain pre-analytical equipment, as determined by the Secretary.~~

~~"(D) An article used solely for personal protection during the administering, conducting, or otherwise performing of test activities.";~~

(2) by adding at the end of section 201(g) the following:

"(3) The term 'drug' does not include an in vitro clinical test."; and

(3) in section 201(h)(1), in the matter following clause (C), by striking "section 520(o)" and inserting "section 520(o) or an in vitro clinical test".

(b) Exclusion From Definition of Biological Product.—Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended—

(1) by striking "(1) The term 'biological product' means" and inserting "(1)(A) The term

'biological product' means"; and

(2) by adding at the end the following:

"(B) The term 'biological product' does not include an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act.".

(c) In Vitro Clinical Test Definition.—In this ~~Act~~ **subtitle**, the term "in vitro clinical test" has the meaning given such term in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

SEC. 823. REGULATION OF IN VITRO CLINICAL TESTS.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by amending the heading of chapter V to read as follows: "DRUGS, DEVICES, AND IN VITRO CLINICAL TESTS"; and

(2) by adding at the end of chapter V the following:

"Subchapter J—In Vitro Clinical Tests

"SEC. 587. DEFINITIONS.

"In this subchapter:

"(1) ANALYTICAL VALIDITY.—The term 'analytical validity' means, with respect to an in vitro clinical test, the ability of the in vitro clinical test, to identify, measure, detect, calculate, or analyze (or assist in such identification, measurement, detection, calculation, or analysis of) one or more analytes, biomarkers, substances, or other targets intended to be identified, measured, detected, calculated, or analyzed by the test.

"(2) APPLICABLE STANDARD.—The term 'applicable standard', with respect to an in vitro clinical test, means a reasonable assurance of analytical and clinical validity for its indications for use, and a reasonable assurance of safety for individuals who come into contact with such in vitro clinical test, except that such term, with respect to specimen receptacles and test instruments, means a reasonable assurance of analytical validity for its indications for use and safety for individuals who come into contact with such specimen receptacle or test instrument.

"(3) CLINICAL USE.—The term 'clinical use' means the operation, application, or functioning of an in vitro clinical test for the purpose for which it is intended as described in section 201(ss)(1).

"(4) CLINICAL VALIDITY.—The term 'clinical validity' means the ability of an in vitro clinical test to achieve the purpose for which it is intended as described in section 201(ss)(1).

"(5) COMPONENT OR PART.—The term 'component or part' means a substance, piece, part, raw material, software, firmware, labeling, or assembly, including reagents, that is intended ~~by the developer~~ to be included as an aspect of an in vitro clinical test described in section 201(ss)(1).

"(6) DEVELOP.—The term 'develop', with respect to an in vitro clinical test, means—

"(A) designing, validating, producing, manufacturing, remanufacturing, labeling, advertising, propagating, **importing,** or assembling an in vitro clinical test;

"(B) modifying an in vitro clinical test, including modifying the indications for use of the in vitro clinical test, or modifying an article to be ~~in~~ an in vitro clinical test; or

"(C) establishing a test system as described or included in a test protocol developed by another entity unless such test protocol is listed as an in vitro clinical test in the comprehensive test information system established under section 587T by that other entity.

"(7) DEVELOPER.—The term 'developer' means a person who engages in development as described in paragraph (6), except the term does not include a laboratory that—

"(A) is certified by the Secretary under section 353 of the Public Health Service Act; and

"(B) assembles for use solely within that laboratory, without otherwise developing, an in vitro clinical test appropriately listed in the comprehensive test information system established under section 587T by a different person.

"(8) FIRST-OF-A-KIND.—The term 'first-of-a-kind', with respect to an in vitro clinical test, means that such test has any novel combination of the elements specified in paragraph (10) that differs from in vitro clinical tests that already are legally available in the United States, except for such tests offered under section 587C(a)(3), 587C(a)(4), or 587G.

"(9) HIGH-RISK.—The term 'high-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means that an undetected inaccurate result from such test, or such category of tests, when used as intended—

"(A)(i) has the substantial likelihood to result in serious or irreversible harm or death to a patient or patients, or would otherwise cause serious harm to the public health; or

"(ii) is reasonably likely to result in the absence, significant delay, or discontinuation of life-supporting or life-sustaining medical treatment; and

"(B) sufficient mitigating measures are not able to be established and applied to prevent, mitigate, or detect the inaccurate result, or otherwise mitigate the risk resulting from an undetected inaccurate result described in subparagraph (A), such that the test would be moderate-risk or low-risk.

"(10) INDICATIONS FOR USE.—The term 'indications for use', with respect to an in vitro clinical test, means the following elements:

"(A) Substance or substances measured by the in vitro clinical test, such as an analyte, protein, or pathogen.

"(B) Test method.

"(C) Test purpose or purposes, as described in section 201(ss)(1).

"(D) Diseases or conditions for which the in vitro clinical test is intended for use, including intended patient populations.

"(E) Context of use, such as in a clinical laboratory, in a health care facility, prescription home use, over-the-counter use, or direct-to-consumer testing.

"(11) INSTRUMENT.—

"(A) IN GENERAL.—The term 'instrument' means an analytical or pre-analytical instrument.

"(B) ANALYTIC INSTRUMENT.—The term 'analytic instrument' means an in vitro clinical test that is hardware intended by the hardware developer to be used with one or more other in vitro clinical tests to generate a clinical test result, including software used to effectuate the functionality of the hardware.

"(C) PRE-ANALYTICAL INSTRUMENT.—The term 'pre-analytical instrument' means an in vitro clinical test that is hardware intended by the ~~hardware's~~ **hardware** developer solely to generate an output for use exclusively with one or more analytical instruments as defined in subparagraph (B) and which does not itself generate a clinical test result. Such term may include software used to effectuate the hardware's functionality.

"(12) INSTRUMENT FAMILY.—The term 'instrument family' means more than one instrument developed by the same developer for which the developer demonstrates and documents, with respect to all such instruments, that all—

"(A) have the same basic architecture, design, and performance characteristics;

"(B) have the same indications for use and capabilities;

"(C) share the same measurement principles, detection methods, and reaction conditions, as applicable; and

"(D) produce the same or similar analytical results from samples of the same specimen type or types.

"(13) **LABORATORY OPERATIONS.—The term 'laboratory operations'—**

"(A) means the conduct of a laboratory examination or other laboratory procedure on materials derived from the human body, including the conduct of an in vitro clinical test and associated activities within or under the oversight of a laboratory and not related to the design of an in vitro clinical test; and

"(B) includes—

"(i) performing pre-analytical and post-analytical processes for an in vitro clinical test;

"(ii) standard operating procedures and the conduct thereof; and

"(iii) preparing reagents or other test materials that do not meet the definition of an in vitro clinical test for clinical use under section 201(ss).

"(14) LOW-RISK.—The term 'low-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means that an undetected inaccurate result from such in vitro clinical test, or such category of in vitro clinical tests, when used as intended—

"(A) would cause only minimal or immediately reversible harm, and would lead to only a remote risk of adverse patient impact or adverse public health impact; or

"(B) sufficient mitigating measures are able to be established and applied such that

the in vitro clinical test meets the standard described in subparagraph (A).

~~"(14)~~**"(15)** MITIGATING MEASURES.—The term 'mitigating measures'—

"(A) means controls, standards, and other requirements that the Secretary determines, based on evidence, are necessary—

"(i) for an in vitro clinical test, or a category of in vitro clinical tests, to meet the applicable standard; or

"(ii) to mitigate the risk of harm ensuing from an undetected inaccurate result or misinterpretation of a result; and

"(B) may include, as required by the Secretary, as appropriate, applicable requirements regarding labeling, conformance to performance standards and consensus standards, performance testing, submission of clinical data, advertising, website posting of information, clinical studies, postmarket surveillance, user comprehension studies, training, and confirmatory laboratory, clinical findings, ~~or testing.~~ **the role of a health professional in the testing process, or testing.**

~~"(15)~~**"(16)** MODERATE-RISK.—The term 'moderate-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means **a test or category of tests—**

"(A) that, when used as intended, ~~such test or category of tests—~~

~~"(A)~~ meets the criteria specified in paragraph (9)**(A)** for classification as high-risk, but one or more mitigating measures are able to be established and applied to prevent or detect an inaccurate result or otherwise sufficiently mitigate such risk, but are not sufficient such that the test is low-risk ~~; or~~ **under the criteria in paragraph (13); or**

~~"(B)(i)~~**"(B) for which, when used as intended—**

"(i) an undetected inaccurate result ~~for the intended use of the test~~ would cause only non-life-threatening harm, harm that is medically reversible, or the absence, significant delay, or discontinuation of necessary treatment that is not life-supporting or life-sustaining; and

"(ii) mitigating measures are not able to be established and applied to prevent or detect such inaccurate result or otherwise sufficiently mitigate the risk of such inaccurate result such that the test would be low-risk **under the criteria in paragraph (13).**

"(17).

~~"(16)~~ SPECIMEN RECEPTACLE.—The term 'specimen receptacle' means an in vitro clinical test intended for taking, collecting, holding, storing, or transporting of specimens derived from the human body or for in vitro examination for purposes described in subparagraph (A) or (B) of section 201(ss)(1).

~~"(17)~~**"(18)** TECHNOLOGY.—The term 'technology'—

"(A) means a set of control mechanisms, energy sources, or operating principles—

"(i) that do not differ significantly among multiple in vitro clinical tests; and

"(ii) for which design and development (including analytical and clinical

validation, as applicable) of the tests would be addressed in a similar manner or through similar procedures; and

"(B) may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture, next generation sequencing, nephlometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, slide-based technology, spectroscopy, and any other technology, as the Secretary determines appropriate.

~~"(18)~~**"(19)** TEST.—The term 'test', unless otherwise provided, means an in vitro clinical test.

~~"(19)~~**"(20)** VALID SCIENTIFIC EVIDENCE.—The term 'valid scientific evidence'—

"(A) means, with respect to an in vitro clinical test, evidence that—

"(i) has been generated and evaluated by persons qualified by training or experience to do so, using procedures generally accepted by other persons so qualified; and

"(ii) forms an appropriate basis for concluding by qualified experts whether the applicable standard has been met by the in vitro clinical test; and

"(B) may include evidence described in subparagraph (A) consisting of—

"(i) peer-reviewed literature;

"(ii) clinical guidelines;

"(iii) reports of significant human experience with an in vitro clinical test;

"(iv) bench studies;

"(v) case studies or histories;

"(vi) clinical data;

"(vii) consensus standards;

"(viii) reference standards;

"(ix) data registries;

"(x) postmarket data;

"(xi) real world data;

"(xii) clinical trials; and

"(xiii) data collected in countries other than the United States if such data are demonstrated to be appropriate for the purpose of making a regulatory determination under this subchapter.

"SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.

"(a) In General.—No person shall introduce or deliver for introduction into interstate commerce any in vitro clinical test, unless—

"(1) an approval of an application filed pursuant to subsection (a) or (b) of section 587B is effective with respect to such in vitro clinical test;

"(2) **the in vitro clinical test is offered under** a technology certification order ~~is~~ in effect under section 587D~~;~~**(b)(1);** or

"(3) the test is exempt under sections 587C or 587G from the requirements of section 587B.

"(b) Transfer or Sale of In Vitro Clinical Tests.—

"(1) TRANSFER AND ASSUMPTION OF REGULATORY OBLIGATIONS.—If ownership of an in vitro clinical test is sold or transferred in such manner that the developer transfers the regulatory submissions and obligations applicable under this subchapter with respect to the test, the transferee or purchaser becomes the developer of the test and shall have all regulatory obligations applicable to such a test under this subchapter. The transferee or purchaser shall update the registration and listing information under section 587J for the in vitro clinical test.

"(2) TRANSFER OR SALE OF PREMARKET APPROVAL.—

"(A) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells the approval of the in vitro clinical test, the transferor or seller shall—

"(i) submit a notice of the transfer or sale to the Secretary and update the registration and listing information under section 587J for the in vitro clinical test; and

"(ii) submit a supplement to an application if required under section 587B(h).

"(B) EFFECTIVE DATE OF APPROVAL TRANSFER.—A transfer or sale described in subparagraph (A) shall become effective upon completion of a transfer or sale described in paragraph (1) or the approval of a supplement to an application under section 587B(h) if required, whichever is later. The transferee or purchaser shall update the registration and listing information under section 587J for the in vitro clinical test within 15 calendar days of the effective date of the transfer or sale.

"(3) TRANSFER OR SALE OF TECHNOLOGY CERTIFICATION.—

"(A) REQUIREMENTS FOR TRANSFER OR SALE OF TECHNOLOGY CERTIFICATION.—An unexpired technology certification can be transferred or sold if the transferee or purchaser—

"(i) is an eligible person under section 587D(a)(2); and

"(ii) maintains, upon such transfer or sale, test design and quality requirements, processes and procedures under the scope of technology certification, and scope of the technology certification identified in the applicable technology certification order.

"(B) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells a technology certification order that has not expired, the transferor or seller shall submit

a notice of the transfer or sale to the Secretary and shall update the registration and listing information under section 587J for all in vitro clinical tests covered by the technology certification.

"(C) EFFECTIVE DATE OF TECHNOLOGY CERTIFICATION TRANSFER.—The transfer of a technology certification shall become effective upon completion of a transfer or sale described in subparagraph (A). The transferee or purchaser shall update the registration and listing information under section 587J for the in vitro clinical test within 30 calendar days of the effective date of the technology certification transfer.

"(D) NEW TECHNOLOGY CERTIFICATION REQUIRED.—If the requirements of subparagraph (A)(ii) are not met, the technology certification order may not be transferred and the transferee or purchaser of an in vitro clinical test is required to submit an application for technology certification and obtain a technology certification order prior to offering the test for clinical use.

"(c) Regulations.—The Secretary may issue regulations to implement this subchapter.

"SEC. 587B. PREMARKET REVIEW.

"(a) Application.—

"(1) FILING.—Any developer may file with the Secretary an application for premarket approval of an in vitro clinical test under this subsection.

"(2) TRANSPARENCY AND PREDICTABILITY.—If a developer files a premarket application under this section and provides any additional documentation required under section 587D, the in vitro clinical test that is the subject of the premarket application may be utilized as the representative in vitro clinical test reviewed by the Secretary to support a technology certification order under section 587D.

"(3) APPLICATION CONTENT.—An application submitted under paragraph (1) shall include the following, in such format as the Secretary specifies:

"(A) General information regarding the in vitro clinical test, including—

"(i) the name and address of the applicant;

"(ii) the table of contents for the application and the identification of the information the applicant claims as trade secret or confidential commercial or financial information;

"(iii) a description of the test's design and intended use, including the indications for use; and

"(iv) a description regarding test function and performance characteristics.

"(B) A summary of the data and information in the application for the in vitro clinical test, including—

"(i) a brief description of the foreign and domestic marketing history of the test, if any, including a list of all countries in which the test has been marketed and a list of all countries in which the test has been withdrawn from marketing for any reason related to the ability of the in vitro clinical test to meet the applicable

standard, if known by the applicant;

"(ii) a description of benefit and risk considerations related to the in vitro clinical test, including a description of any applicable adverse effects of the test on health and how such adverse effects have been, or will be, mitigated;

"(iii) a risk assessment of the test; and

"(iv) a description of how the data and information in the application constitute valid scientific evidence and support a showing that the test meets the applicable standard under section 587(2).

"(C) The signature of the developer filing the premarket application or an authorized representative.

"(D) A bibliography of applicable published reports relied upon by the applicant and a description of any studies conducted, including any unpublished studies related to such test, that are known or that should reasonably be known to the applicant, and a description of data and information relevant to the evaluation of whether the test meets the applicable standard.

"(E) Applicable information regarding the methods used in, and the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality requirements under section 587K.

"(F) Information demonstrating compliance with any relevant and applicable—

"(i) mitigating measures under section 587E; and

"(ii) standards established or recognized under section 514 prior to the date of enactment of the VALID Act of 2022, or, after applicable standards are established or recognized under section 587Q, with such standards.

"(G) Valid scientific evidence to support that the test meets the applicable standard, which shall include—

"(i) summary information for all supporting validation studies performed, including a description of the objective of the study, a description of the experimental design of the study, a description of any limitations of the study, a brief description of how the data were collected and analyzed, a brief description of the results of each study, and conclusions drawn from each study;

"(ii) ~~new~~ raw data for each study, which may include, as applicable, tabulations of data and results ~~as required under section 814.20(b)(6)(ii) of title 21, Code of Federal Regulations (or any successor regulations)~~; and

"(iii) for nonclinical laboratory studies involving the test, if applicable, a statement that studies were conducted in compliance with applicable good laboratory practices.

"(H) To the extent the application seeks authorization to make modifications to the test within the scope of the approval that are not otherwise permitted without premarket review under this subchapter, a proposed change protocol that includes validation procedures and acceptance criteria for anticipated modifications that could

be made to the test within the scope of the approval.

"(I) Proposed labeling, in accordance with the requirements of section 587L.

"(J) Such other data or information as the Secretary may require in accordance with the least burdensome requirements under section 587AA(c).

"(4) GUIDANCE FOR PREMARKET AND ABBREVIATED PREMARKET APPLICATIONS.—In accordance with section 825 of the VALID Act of 2022, the Secretary shall issue draft guidance detailing the information to be provided in a premarket application and abbreviated premarket application under this section. The Secretary shall issue final guidance detailing the information to be provided in a premarket application and abbreviated premarket application under this section not later than 1 year prior to the effective date of such Act.

"(5) REFUSE TO FILE A PREMARKET OR ABBREVIATED PREMARKET APPLICATION.—The Secretary may refuse to file an application under this section only for lack of completeness or legibility of the application. If, after receipt of an application under this section, the Secretary refuses to file such an application, the Secretary shall provide to the developer, within ~~60~~ **45** calendar days of receipt of such application **submitted under this subsection or within 30 calendar days of receipt of an application submitted under subsection (b)**, a description of the reason for such refusal, and identify the information required, if any, to allow for the filing of the application.

"(6) SUBSTANTIVE REVIEW FOR DEFICIENT APPLICATION.—If, after receipt of an application under this section, the Secretary determines that any portion of such application is materially deficient, the Secretary shall provide to the applicant a description of such material deficiencies and the information required to resolve such deficiencies.

"(7) INSPECTIONS.—With respect to an application under paragraph (1), preapproval inspections authorized by an employee of the Food and Drug Administration or a person accredited under section 587Q need not occur unless requested by the Secretary.

"(b) Abbreviated Premarket Review.—

"(1) IN GENERAL.—Any developer may file with the Secretary an application for abbreviated premarket approval for—

"(A) an instrument;

"(B) a specimen receptacle;

"(C) an in vitro clinical test that is moderate-risk; or

"(D) an in vitro clinical test that is determined by the Secretary to be eligible for abbreviated premarket review under section 587F(a)(1)(B).

"(2) APPLICATION CONTENT.—An application under paragraph (1) shall include—

"(A) the information required for applications submitted under subsection ~~(a)(2)~~**(a)(3)**, except that applications under paragraph (1) need not include—

"(i) quality requirement information; or

"(ii) raw data, unless explicitly requested by the Secretary; and

"(B) data, as applicable, to support software validation, electromagnetic compatibility, and electrical safety, and information demonstrating compliance with maintaining quality systems documentation.

"(3) SAFETY INFORMATION.—The developer of an in vitro clinical test specimen receptacle reviewed under this subsection shall maintain safety information for such specimen receptacle.

"(4) INSPECTIONS.—With respect to an application under paragraph (1), preapproval inspections authorized by an employee of the Food and Drug Administration or a person accredited under section 587Q need not occur unless requested by the Secretary.

"(c) Instruments and Instrument Families.—

"(1) IN GENERAL.—A developer of an instrument family shall file with the Secretary an application for premarket approval of one version of an instrument under this subsection. Any modified versions of the instrument that generate a new instrument within the same instrument family shall be exempt from premarket review requirements of this section, provided that the developer of such instrument or instrument family—

"(A) maintains documentation that the new instrument is part of the instrument family, as defined in section 587;

"(B) performs, documents, and maintains a risk assessment (as described in subsection ~~(a)(2)(B)(iv))~~**(a)(3)(B)(iii))** of the new instrument compared to the instrument approved under subsection (b) and no new risks are identified;

"(C) performs, documents, and maintains validation and verification activities for the new instrument;

"(D) makes such documentation available to the Secretary upon request; and

"(E) registers and lists the new instrument in accordance with section 587J.

"(2) TEST KITS AND TEST PROTOCOLS.—A test kit or test protocol that is approved under this section for use on an approved instrument or an instrument exempt from premarket review, including an instrument within an instrument family under this section, a submission under this section shall not be required for such test kit or test protocol in order for it to be used on a new instrument within its instrument family, provided that—

"(A) use of the test kit or test protocol with the new instrument does not—

"(i) change the claims for the test kit or test protocol, except as applicable, claims regarding an instrument or instruments that can be used with such test kit or test protocol;

"(ii) adversely affect performance of the test kit or test protocol; or

"(iii) cause the test kit or test protocol to no longer conform with performance standards required under section 587R or comply with any applicable mitigating measures under section 587E, conditions of approval under subsection (e)(2)(B), or restrictions under section 587O;

"(B) the test developer does not identify any new risks for the test kit or test protocol when using the new instrument;

"(C) the test developer validates the use of the new instrument with the test kit or test protocol and maintains validation documentation;

"(D) the test kit or test protocol is not intended for use—

"(i) ~~at the point of care setting or~~ in settings for which a certificate of waiver is in effect under section 353 of the Public Health Service Act;

"(ii) without a prescription;

"(iii) at home; or

"(iv) in testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products;

"(E) the test developer makes the documentation described under subparagraph (C) available to the Secretary upon request; and

"(F) the test developer updates the listing information for the test kit or test protocol, as applicable.

"(d) Amendments to an Application.—An applicant shall amend an application submitted under subsection (a), (b), or (f) if the applicant becomes aware of information that could reasonably affect an evaluation under subsection (e) of whether the approval standard has been met.

"(e) Action on an Application for Premarket Approval.—

"(1) REVIEW.—

"(A) DISPOSITION.—As promptly as possible, but not later than 90 calendar days after an application under subsection (a) is accepted for submission (unless the Secretary determines that an extension is necessary to review one or more major amendments to the application), or not later than 60 calendar days after an application under subsection (b) is accepted for submission or a supplemental application under subsection (f) is accepted for submission, the Secretary, after considering any applicable report and recommendations pursuant to advisory committees under section 587H, shall issue an order approving the application, unless the Secretary finds that the grounds for approval in paragraph (2) are not met.

"(B) RELIANCE ON PROPOSED LABELING.—In determining whether to approve or deny an application under paragraph (1), the Secretary shall rely on the indications for use included in the proposed labeling, provided that such labeling is not false or misleading based on a fair evaluation of all material facts.

"(2) APPROVAL OF AN APPLICATION.—

"(A) IN GENERAL.—The Secretary shall approve an application submitted under subsection (a) or (b) with respect to an in vitro clinical test if the Secretary finds that the applicable standard is met, and—

"(i) the applicant is in compliance with applicable quality requirements in section 587K;

"(ii) the application does not contain a false statement or misrepresentation of material fact;

"(iii) based on a fair evaluation of all material facts, the proposed labeling is truthful and non-misleading and complies with the requirements of section 587L;

"(iv) the applicant permits, if requested, authorized employees of the Food and Drug Administration and persons accredited under section 587Q an opportunity to inspect pursuant to section 704;

"(v) the test conforms with any applicable performance standards required under section 587R and any applicable mitigating measures under section 587E;

"(vi) all nonclinical laboratory studies and clinical investigations involving human subjects that are described in the application were conducted in a manner that meets the applicable requirements of this subchapter; and

"(vii) other data and information the Secretary may require under subsection ~~(a)(2)(K)~~**(a)(3)(J)** support approval.

"(B) CONDITIONS OF APPROVAL.—An order approving an application pursuant to this section may require reasonable conditions of approval for the in vitro clinical test, which may include conformance with applicable mitigating measures under section 587E, restrictions under section 587O, and performance standards under section 587R.

"(C) PUBLICATION.—The Secretary shall publish an order for each application approved pursuant to this paragraph on the public website of the Food and Drug Administration and make publicly available a summary of the data used to approve such application~~, except to the extent the Secretary determines that such order —~~**. In making the order and summary publicly available, the Secretary shall not disclose any information that—**

~~"(i) contains commercially confidential~~ **"(i) is confidential commercial information** or trade secret information ~~; or~~ **subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; or**

~~"(ii) if published, would present a risk to~~**"(ii) could compromise** national security.

"(3) REVIEW OF DENIALS.—An applicant whose application submitted under this section has been denied approval under this subsection may, by petition filed not more than 60 calendar days after the date on which the applicant receives notice of such denial, obtain review of the denial in accordance with section 587P.

"(f) Supplements to an Approved Application.—

"(1) RISK ANALYSIS.—Prior to implementing any modification to an in vitro clinical test, the holder of the application approved under subsection ~~(a) or (b)~~**(e)** for such test shall perform risk analyses in accordance with this subsection, unless such modification is included in the change protocol submitted by the applicant and approved under this section or exempt under section 587C.

"(2) SUPPLEMENT REQUIREMENT.—

"(A) IN GENERAL.—If the holder of an application of an approved in vitro clinical test makes a modification to such in vitro clinical test, except as provided in subparagraph (C), or otherwise specified by the Secretary, the holder of the application

approved under subsection (e) for an in vitro clinical test shall submit a supplemental application to the Secretary. The holder of the application may not implement such modification to the in vitro clinical test until such supplemental application is approved. The information required in a supplemental application is limited to what is needed to support the change.

"(B) ADJUSTMENTS TO CHANGE PROTOCOL.—The holder of an approved application may submit under this paragraph a supplemental application to modify the change protocol of the test at any time after the application is submitted under subsection (a) or (b).

"(C) EXCEPTIONS.—Notwithstanding subparagraphs (A) and (B), and so long as the holder of an approved application submitted under subsection (a) or (b) for an in vitro clinical test does not add a manufacturing site, or change activities at an existing manufacturing site, with respect to the test, the holder of an approved application may, without submission of a supplemental application, implement the following modifications to the test:

"(i) Modifications in accordance with an approved change protocol under subsection (a)(3)(H).

"(ii) Modifications that are exempt under section ~~587C(b)~~ **587C(a)(6)**.

"(iii) Labeling changes that are appropriate to address a safety concern, except such labeling changes that include any of the following~~,~~ remain subject to subparagraph (A):

"(I) A change to the indications for use of the test.

"(II) A change to the performance claims made with respect to the test.

"(III) A change that adversely affects performance of the test.

"(D) REPORTING FOR CERTAIN MODIFICATIONS MADE PURSUANT TO A CHANGE PROTOCOL.—The holder of an application approved under subsection (e), with an approved change protocol under subsection (a)(2)(H) for such in vitro clinical test shall—

"(i) report any modification to such test made pursuant to such change protocol approved under subsection ~~(a)(2)(H)~~**(a)(3)(H)** in a submission under section 587J(c)(2)(B); and

"(ii) include in such report—

"(I) a description of the modification;

"(II) the rationale for implementing such modification; and

"(III) as applicable, a summary of the evidence supporting that the test, as modified, meets the applicable standard, complies with performance standards required under section 587Q, and complies with any mitigating measures established under section 587E and any restrictions under section 587O.

"(E) REPORTING FOR CERTAIN SAFETY RELATED LABELING CHANGES.—The holder of

the application for an in vitro clinical test approved under subsection ~~(a) or (b) pursuant to subsection~~(e) shall—

"(i) report to the Secretary any modification to the test described in subparagraph (C)(iii) not more than 30 days after the date on which the test, with the ~~modifications~~ **modification**, is introduced into interstate commerce; and

"(ii) include in the report—

"(I) a description of the change or changes;

"(II) the rationale for implementing such change or changes; and

"(III) a description of how the change or changes were evaluated.

"(3) CONTENTS OF SUPPLEMENT.—Unless otherwise specified by the Secretary, a supplement under this subsection shall include—

"(A) for modifications other than manufacturing site changes requiring a supplement—

"(i) a description of the modification;

"(ii) data relevant to the modification to demonstrate that the applicable standard is met, not to exceed data requirements for the original submission;

"(iii) acceptance criteria; and

"(iv) any revised labeling; and

"(B) for manufacturing site changes—

"(i) the information listed in subparagraph (A); and

"(ii) information regarding the methods used in, or the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality requirements under section 587K.

"(4) ADDITIONAL DATA.—The Secretary may require, when necessary, data to evaluate a modification to an in vitro clinical test that is in addition to the data otherwise required under the preceding paragraphs if the data request is in accordance with the least burdensome requirements under section 587AA(c).

"(5) CONDITIONS OF APPROVAL.—In an order approving a supplement under this subsection, the Secretary may require conditions of approval for the in vitro clinical test, including compliance with restrictions under section 587O and conformance to performance standards under section 587R.

"(6) APPROVAL.—The Secretary shall approve a supplement under this subsection if—

"(A) the data demonstrate that the modified in vitro clinical test meets the applicable standard; and

"(B) the holder of the application approved under subsection (e) for the test has demonstrated compliance with applicable quality and inspection requirements, as applicable and appropriate.

"(7) PUBLICATION.—The Secretary shall publish on the public website of the Food and

Drug Administration notice of any order approving a supplement under this subsection~~,—~~ ~~except that such publication shall exclude—~~

~~"(A) commercial confidential or trade secret information; and~~

~~"(B) any other information that the Secretary determines to relate to national security or countermeasures or to be restricted from disclosure pursuant to another provision of law.~~ **provided that doing so does not disclose any information that—**

"(A) is trade secret or confidential commercial or financial information; or

"(B) could compromise national security.

"(8) REVIEW OF DENIAL.—An applicant whose supplement under this subsection has been denied approval may, by petition filed on or before the 60th calendar day after the date upon which the applicant receives notice of such denial, obtain review of the denial in accordance with section 587P.

"(g) Withdrawal and Temporary Suspension of Approval.—

"(1) ORDER WITHDRAWING APPROVAL.—

"(A) IN GENERAL.—The Secretary may, after providing due notice and an opportunity for an informal hearing to the holder of an approved application for an in vitro clinical test under this section, issue an order withdrawing approval of the application if the Secretary finds that—

"(i) the grounds for approval under subsection (e) are no longer met;

"(ii) there is a reasonable likelihood that the test would cause death or serious adverse health consequences, including by causing the absence, significant delay, or discontinuation of life-saving or life sustaining medical treatment;

"(iii) the holder of the approved application—

"(I) has failed to, or repeatedly or deliberately failed to, maintain records to make reports, as required under section 587M;

"(II) has refused to permit access to, or copying or verification of such records, as required under section 704;

"(III) has not complied with the requirements of section 587K; or

"(IV) has not complied with any mitigating measure required under section 587E or restriction under section 587O; or

"(iv) the labeling of such in vitro clinical test, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact.

"(B) CONTENT.—An order under subparagraph (A) withdrawing approval of an application shall state each ground for withdrawal and shall notify the holder of such application 60 calendar days prior to issuing such order.

"(C) PUBLICATION.—The Secretary shall publish any order under subparagraph (A) on the public website of the Food and Drug Administration~~, except that such~~

~~publication shall exclude—~~

~~"(i) commercial confidential or trade secret information; and~~ **provided that doing so does not disclose—**

"(i) any information that is trade secret or confidential commercial or financial information; or

"(ii) any other information that the Secretary determines, if published, ~~would present a risk to~~ **could compromise** national security.

"(2) ORDER OF TEMPORARY SUSPENSION.—If, after providing due notice and an opportunity for an informal hearing to the holder of an approved application for an in vitro clinical test under this section, the Secretary determines, based on scientific evidence, that there is a reasonable likelihood that the in vitro clinical test would cause death or serious adverse health consequences, such as by causing the absence, significant delay, or discontinuation of life-saving or life-sustaining medical treatment, the Secretary shall, by order, temporarily suspend the approval of the application. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw approval of such application.

"(3) APPEAL WITHDRAWING APPROVAL AND ORDERS OF TEMPORARY SUSPENSIONS.—An order of withdrawal or an order of temporary suspension may be appealed under 587P.

"SEC. 587C. EXEMPTIONS.

"(a) In General.—The following in vitro clinical tests are exempt from premarket review under section 587B, and may be lawfully marketed subject to other applicable requirements of this Act:

"(1) TESTS EXEMPT FROM SECTION 510(K).—

"(A) EXEMPTION.—An in vitro clinical test is exempt from premarket review under section 587B and may be lawfully marketed subject to the other applicable requirements of this Act, if the developer of the in vitro clinical test—

"(i) maintains documentation demonstrating that the test meets and continues to meet the criteria set forth in subparagraph (B); and

"(ii) makes such documentation available to the Secretary upon request.

"(B) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as specified in subparagraph (A) if such test—

"(i)(I)**(aa)** was offered for clinical use prior to the date of enactment of the VALID Act of 2022; **and**

"(bb)~~"(II)~~ immediately prior to such date of enactment was exempt pursuant to subsection (l) or (m)(2) of section 510 from the requirements for submission of a report under section 510(k); or

~~"(III)(aa)~~**"(II)(aa)** was not offered for clinical use prior to such date of enactment;

"(bb) is not an instrument; and

"(cc) falls within a category of tests that was exempt from the requirements for submission of a report under section 510(k) as of such date of enactment (including class II devices and excluding class I devices described in section 510(l));

"(ii) meets the applicable standard as described in section 587(2);

"(iii) is not offered with labeling and advertising that is false or misleading; and

"(iv) is not likely to cause or contribute to serious adverse health consequences.

"(C) EFFECT ON SPECIAL CONTROLS.—For any in vitro clinical test, or category of in vitro clinical tests, that is exempt from premarket review based on the criteria in subparagraph (B), any special control that applied to a device within a predecessor category immediately prior to the date of enactment of the VALID Act of 2022 shall be deemed a mitigating measure applicable under section 587E to an in vitro clinical test within the successor category, except to the extent such mitigating measure is withdrawn or changed in accordance with section 587E.

"(D) NEAR-PATIENT TESTING.—Not later than 1 year after the date of enactment of the VALID Act of 2022, the Secretary shall issue draft guidance indicating categories of tests that shall be exempt from premarket review under section 587B when offered for near-patient testing (point of care), which were not exempt from submission of a report under section 510(k) pursuant to subsection (l) or (m)(2) of section 510 and regulations imposing limitations on exemption for in vitro devices intended for near-patient testing (point of care).

"(2) LOW-RISK TESTS.—

"(A) EXEMPTION.—An in vitro clinical test is exempt from premarket review under section 587B and may be lawfully marketed subject to the other applicable requirements of this Act, including section 587J(b)~~(6)~~, if such test meets the definition of low-risk under section 587 and if the developer of the test—

"(i) maintains documentation demonstrating that the in vitro clinical test meets and continues to meet the criteria set forth in ~~paragraph (2);~~ **subparagraph (B);** and

"(ii) makes such documentation available to the Secretary upon request.

"(B) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as specified in subparagraph (A) if—

"(i) the in vitro clinical test meets the applicable standard as described in 587(2);

"(ii) the labeling and advertising are not false or misleading;

"(iii) the in vitro clinical test is not likely to cause or contribute to serious adverse health consequences; and

"(iv) the in vitro clinical test ~~is listed pursuant to section 587J or~~ falls within a category of tests listed as described in subparagraph (C).

"(C) LIST OF LOW-RISK TESTS.—

"(i) IN GENERAL.—The Secretary shall maintain, and make publicly available on the website of the Food and Drug Administration, a list of in vitro clinical tests, and categories of in vitro clinical tests, that are low-risk in vitro clinical tests for purposes of the exemption under this paragraph.

"(ii) INCLUSION.—The list under clause (i) shall consist of—

"(I) all in vitro clinical tests and categories of in vitro clinical tests that are exempt from premarket review pursuant to ~~subsection (d)~~ **paragraph** (1) or ~~(d)(3);~~ **this paragraph;** and

"(II) all in vitro clinical tests and categories of in vitro clinical tests that are designated by the Secretary pursuant to subparagraph ~~(C)~~**(D)** as low-risk for purposes of this paragraph.

"(D) DESIGNATION OF TESTS AND CATEGORIES.—Without regard to subchapter II of chapter 5 of title 5, United States Code, the Secretary may designate, in addition to the tests and categories described in subparagraph (C)(i), additional in vitro clinical tests, and categories of in vitro clinical tests, as low-risk in vitro clinical tests for purposes of the exemption under this paragraph. The Secretary may make such a designation on the Secretary's own initiative or in response to a request by a developer pursuant to subsection (a) or (b) of section 587F. In making such a designation for a test or category of tests, the Secretary shall consider—

"(i) whether the test, or category of tests, is low-risk;

"(ii) the existence of and ability to develop mitigating measures sufficient for such test category to meet the low-risk standard; and

"(iii) such other factors as the Secretary determines to be appropriate for the protection of the public health.

"(3) HUMANITARIAN TEST EXEMPTION.—

"(A) IN GENERAL.—An in vitro clinical test that meets the criteria under subparagraph (B) is exempt from premarket review under section 587B and may be lawfully offered subject to the other applicable requirements of this subchapter, if the developer of the test—

"(i) maintains documentation (which may include literature citations in specialized medical journals, textbooks, specialized medical society proceedings, and governmental statistics publications, or, if no such studies or literature citations exist, credible conclusions from appropriate research or surveys) demonstrating that such test meets and continues to meet the criteria described in this subsection; and

"(ii) makes such documentation available to the Secretary upon request.

"(B) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as described in subparagraph (A) if—

"(i) the in vitro clinical test is intended by the developer for use for a diagnostic purpose for a disease or condition that affects not more than 10,000 (or such other higher number determined by the Secretary) individuals in the United States per

year; ~~and~~

"(ii) the in vitro clinical test meets the applicable standard described in section 587(2);

"(iii) the labeling and advertising for the in vitro clinical test are not false or misleading;

"(iv) the in vitro clinical test is not likely to cause or contribute to serious **adverse** health consequences; and

"(v) the in vitro clinical test is not intended for screening.

"(C) EXCEPTION FOR CERTAIN TESTS.—An in vitro clinical test intended to inform the use of a specific individual or specific type of biological product, drug, or device shall be eligible for an exemption from premarket review under this subsection only if, the developer submits a request under ~~subsection (m)~~ **section 587F(e)** for informal feedback and the Secretary determines that such in vitro clinical test is eligible for an exemption from premarket review under this subsection.

"(4) CUSTOM TESTS AND LOW-VOLUME TESTS.—An in vitro clinical test is exempt from premarket review under section 587B, quality requirements under section 587K, and listing requirements under section 587J, and may be lawfully marketed subject to the other applicable requirements of this Act, if—

"(A) such in vitro clinical test—

"(i) is a test protocol performed for not more than 5 patients per year (or such other higher number determined by the Secretary), in a laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

"(I) meets the requirements to perform tests of high-complexity in which the test protocol was developed; or

"(II) meets the requirements to perform tests of high-complexity within the same corporate organization and having common ownership by the same parent corporation as the laboratory in which such test protocol was developed; or

"(ii) is an in vitro clinical test developed or modified to diagnose a unique pathology or physical condition of a specific patient or patients, upon order of a health professional or other specially qualified person designated under regulations, for which no other in vitro clinical test is commercially available in the United States, and is—

"(I) not intended for use with respect to more than 5 (or such other higher number determined by the Secretary) other patients; and

"(II) after the development of such test, not included in any test menu or template test report or other promotional materials, and is not otherwise advertised; and

"(B) the developer of the in vitro clinical test—

"(i) maintains documentation demonstrating that such test meets the applicable criteria described in subparagraph (A);

"(ii) makes such documentation, such as a prescription order requesting the custom test for an individual patient, available to the Secretary upon request; and

"(iii) informs the Secretary, on an annual basis, in a manner prescribed by the Secretary by guidance, that such test was offered.

"(5) IN VITRO CLINICAL TESTS UNDER A TECHNOLOGY CERTIFICATION ORDER.—An in vitro clinical test that is within the scope of a technology certification order, as described in section 587D(a), is exempt from premarket review under section 587B.".

"(6) MODIFIED TESTS.—

"(A) IN GENERAL.—An in vitro clinical test that is modified is exempt from premarket review under section 587B if—

"(i)~~(I)~~ the modification is made by—

~~"(aa)~~**"(I)** the developer that obtained premarket approval for the unmodified version of the test under section 587B; or

~~"(bb)~~**"(II)** a clinical laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements for performing high complexity testing, to a lawfully offered in vitro clinical test, including another developer's lawfully offered in vitro clinical test, excluding investigational in vitro clinical tests offered under section 587S, and the modified test is performed—

~~"(AA)~~**"(aa)** in the same clinical laboratory in which it was developed for which a certification is still in effect under section 353 that meets the requirements to perform tests of high complexity;

~~"(BB)~~**"(bb)** by another clinical laboratory for which a certificate is in effect under section 353 that meets the requirements to perform tests of high complexity, is within the same corporate organization, and has common ownership by the same parent corporation as the laboratory in which the test was developed; or

~~"(CC)~~**"(cc)** by a clinical laboratory for which a certificate is in effect under section 353 that meets the requirements to perform tests of high complexity and is within a public health laboratory network coordinated ~~f~~or managed ~~l~~ by the Centers for Disease Control and Prevention, if the test was developed by the Centers for Disease Control and Prevention or another laboratory within such public health laboratory network; ~~or~~ **and**

~~"(II)~~**"(ii)** the modification does not—

~~"(aa)~~**"(I)** constitute a significant change to the indications for use;

~~"(bb)~~**"(II)** cause the test to no longer comply with applicable mitigating measures under section 587E or restrictions under section 587O;

"~~(cc)~~**"(III)** significantly **and adversely** change performance claims or significantly and adversely change performance, unless provided for under an approved change protocol under section ~~587(a)(2)(H);~~ **587B(a)(3)(H);** or

"~~(dd)~~**"(IV)** constitute an adverse change in the safety of the in vitro clinical test for individuals who come in contact with the in vitro clinical test;

~~"(ii)~~**"(iii)** the test meets the applicable standard as described in section 587(2);

~~"(iii)~~**"(iv)** the labeling and advertising are not false or misleading; and

~~"(iv)~~**"(v)** the test is not likely to cause or contribute to serious adverse health consequences.

"(B) CERTAIN MODIFICATIONS.—A modification to extend specimen stability is exempt from premarket review under section 587B if the modified test meets the requirements in clauses ~~(iii)~~**(ii)** through ~~(v)~~**(iv)** of subparagraph (A).

"(C) MODIFICATIONS UNDER A CHANGE PROTOCOL.—Notwithstanding subparagraph (A), a modification made under a change protocol pursuant to subsection (a)(2)(H) of section 587B is exempt from review under such section.

"(D) DOCUMENTATION.—A person who modifies an in vitro clinical test in a manner that is a modification described in subparagraph (A) shall—

"(i) document the modification that was made and the basis for determining that the modification, considering the changes individually and collectively, is a type of modification described in subparagraph (A), (B), or (C); and

"(ii) provide such documentation to the Secretary upon request or inspection.

"(E) GUIDANCE.—Not later than 30 months after the date of enactment of the VALID Act of 2022, the Secretary shall issue guidance regarding the in vitro clinical tests that are modified and exempt from premarket review under section 587B pursuant to this paragraph.

"(b) Manual Tests.—

"(1) EXEMPTION.—An in vitro clinical test is exempt from all requirements of this subchapter if the output of such in vitro clinical test is the result of direct, manual observation, without the use of automated instrumentation or software for intermediate or final interpretation, by a qualified laboratory professional, and such in vitro clinical test—

"(A) is ~~designed,~~ developed~~,~~ and used within a single clinical laboratory for which a certificate is in effect under section 353 of the Public Health Service Act that meets the requirements under section 353 for performing high-complexity testing;

"(B) is not a specimen receptacle, instrument, or an in vitro clinical test that includes an instrument or specimen receptacle that is not approved under or exempt from section 587B;

"(C) is not a high-risk test, or is a high-risk test that the Secretary has determined meets at least one condition in paragraph (2) and is otherwise appropriate for this exemption; and

"(D) is not intended for testing donors, donations, or recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products.

"(2) HIGH-RISK TEST LIMITATION OR CONDITION.—A high-risk test may be exempt under paragraph (1) from the requirements of this subchapter only if—

"(A) no ~~component~~ **components** or ~~part~~ **parts** of such test, including any reagent, is introduced into interstate commerce under the exemption under ~~paragraph (5)~~ **subsection (e)**, and any article for taking or deriving specimens from the human body used in conjunction with the test remains subject to the requirements of this subchapter; or

"(B) the test has been developed in accordance with the applicable test design and quality requirements under section ~~587J~~ **587K**.

"(c) Public Health Surveillance Activities.—

"(1) IN GENERAL.—The provisions of this subchapter shall not apply to a test intended by the developer to be used solely for public health surveillance activities.

"(2) EXCLUSION.—An in vitro clinical test used for public health surveillance activities is not excluded from the provisions of this subchapter pursuant to this subsection if such test is intended for use in making clinical decisions for individual patients.

"(d) General Laboratory Equipment.—Any instrument that does not produce an analytical result, and that functions as a component of pre-analytical procedures related to in vitro clinical tests, is not subject to the requirements of this subchapter, provided that the instrument is operating in a clinical laboratory that is certified under section 353 of the Public Health Service Act.

"(e) Components and Parts.—

"(1) IN GENERAL.—Subject to paragraph (2), a component or part described in section ~~201(ss)(2)(E)~~ **201(ss)(2)(G)** is—

"(A) exempt from the requirements of this subchapter if it is intended for further development as described in paragraph (3); or

"(B) subject to the requirements of this subchapter and regulated based on its risk when used as intended by the developer, notwithstanding its subsequent use by a developer as a component, part, or raw material of another in vitro clinical test.

"(2) INAPPLICABILITY TO OTHER TESTS.—Notwithstanding paragraph (1), an in vitro clinical test that is described in section 201(ss)(1)(B) and that uses a component or part described in such subparagraph shall be subject to the requirements of this subchapter, unless the test is otherwise exempt under this section.

"(3) FURTHER DEVELOPMENT.—A component, part, or raw material (as described in paragraph (1)) is intended for further development (for purposes of such paragraph) if—

"(A) it is intended solely for use in the development of another in vitro clinical test; and

"(B) in the case of such a test that is introduced or delivered for introduction into interstate commerce after the date of enactment of the VALID Act of 2022, the

labeling of such test bears the following statement: 'This product is intended solely for further development of an in vitro clinical test and is exempt from FDA regulation. This product must be evaluated by the in vitro clinical test developer if it is used with or in the development of an in vitro clinical test.'.

"(f) General Exemption Authority.—The Secretary may, by order published in the Federal Register following notice and an opportunity for comment, exempt a class of persons from any section under this subchapter upon a finding that such exemption is appropriate for the protection of the public health and other relevant considerations.

"(g) Exemption.—An in vitro clinical test that is intended solely for use in forensic analysis or law enforcement activity is exempt from the requirements of this subchapter. An in vitro clinical test that is intended for use in making clinical decisions for individual patients, or whose individually identifiable results may be reported back to an individual patient or the patient's health care provider, even if also intended for forensic analysis or law enforcement purposes, is not intended solely for forensic analysis or law enforcement for purposes of this subsection.

"(h) Revocation.—

"(1) IN GENERAL.—The Secretary may revoke any exemption **under this section** with respect to in vitro clinical tests with the same indications for use if new clinical information indicates that the exemption of an in vitro clinical test or tests from premarket review under section 587B has a reasonable probability of severe adverse health consequences, including the absence, delay, or discontinuation of appropriate medical treatment.

"(2) PROCESS.—Any action under paragraph (1) shall be made by publication of a notice of such proposed action on the website of the Food and Drug Administration, the consideration of comments to a public docket on such proposal, and publication of a final action on such website within 60 calendar days of the close of the comment period posted to such public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

"(i) Pre-Analytical Instrument.—A pre-analytical instrument is exempt from premarket review under section 587B and may be lawfully offered subject to the other applicable requirements of this Act, if either of the following applies:

"(1) Such instrument provides additional information regarding the sample or performs an action on the sample but is not preparing or processing the sample and does not perform any function of an analytical instrument. Such types of pre-analytical instruments include barcode readers, sample movers, and sample identifiers.

"(2) Such instrument processes or prepares the sample prior to use on an analytical instrument, does not perform any function of an analytical instrument, and does not select, isolate, or prepare a part of a sample based on specific properties. Such types of pre-analytical instruments may include sample mixers, DNA extractors and those used to dilute samples.

"SEC. 587D. TECHNOLOGY CERTIFICATION.

"(a) Definitions.—In this section:

"(1) ELIGIBLE IN VITRO CLINICAL TEST.—The term 'eligible in vitro clinical test' means an

in vitro clinical test that is not—

"(A) a component or part of an in vitro clinical test as described in section ~~201(ss)(2)(E);~~ **201(ss)(2)(G) unless it is a component or part and is regulated based on its own risk under section 587C(e)(1)(B) or as part of an otherwise eligible in vitro clinical test;**

"(B) an instrument under section ~~201(ss)(2)(B)~~ **201(ss)(2)(D)** or an in vitro clinical test that includes an instrument that **is subject to section 587B, but** is not approved under, or exempt from, section 587B;

"(C) a specimen receptacle under section ~~201(ss)(2)(C)~~ **201(ss)(2)(E)** or an in vitro clinical test that includes a specimen receptacle that **is subject to section 587B, but** is not approved under, or exempt from, section 587B;

"(D) an in vitro clinical test, including reagents used in such tests, intended for use for testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products;

"(E) high-risk;

"(F) a combination product unless such test has been determined to be eligible to be introduced into interstate commerce under a technology certification order pursuant to the regulatory pathway designation process described in section 587F, or as described in subsection (k); or

"(G) a first-of-a-kind in vitro clinical test, unless such test has been determined to be eligible to be introduced into interstate commerce under a technology certification order pursuant to the regulatory pathway designation process described in section 587F, or as described in subsection (k).

"(2) ELIGIBLE PERSON.—The term 'eligible person' means an in vitro clinical test developer unless such developer—

"(A) is a laboratory subject to section 353 of the Public Health Service Act and does not have in effect a certificate applicable to the category of laboratory examination or other procedure;

"(B) was a laboratory, or an owner or operator or any employee of a laboratory, found to have committed a significant violation of section 353 of the Public Health Service Act that resulted in a suspended, revoked, or limited certificate within the 2-year period preceding the date of the submission of the application for a technology certificate under subsection (c) and such violation has not been resolved; or

"(C) has been found to have submitted information to the Secretary, or otherwise disseminated information, that—

"(i) made false or misleading statements relevant to the requirements of this subchapter; or

"(ii) violated any requirement of this Act, where such violation exposed individuals to serious risk of illness, injury, or death, unless—

"(I) such violation has been resolved; or

"(II) such violation is not pertinent to any in vitro clinical test within the scope of the technology certification that such developer seeks.

"(b) Applicability.—

"(1) IN GENERAL.—An in vitro clinical test is not subject to section 587B and may be introduced into interstate commerce if the in vitro clinical test—

"(A) is an eligible in vitro clinical test;

"(B) is developed by an eligible person;

"(C) falls within the scope of a technology certification order issued under this section and that is in effect;

"(D) complies with the conditions of the technology certification order, including with applicable mitigating measures under section 587E, restrictions under section 587O, and performance standards under section 587R; and

"(E) meets the applicable standard described in section 587(2).

"(2) SCOPE.—

"(A) IN GENERAL.—Subject to subparagraph (B), the scope of a technology certification order issued under this section shall apply to **one or more technologies with** multiple in vitro clinical tests utilizing ~~the~~ **a** technology ~~do~~ **that does** not significantly differ in control mechanisms, energy sources, or operating principles and for which development, including design, and analytical and clinical validation, of the in vitro clinical tests would be addressed through similar procedures, and be no broader than—

"(i) a single technology type; or

"(ii) a fixed combination of technologies.

"(B) TECHNOLOGY TYPE.—A technology type described in this paragraph may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture, next generation sequencing, nephlometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, slide-based technology, spectroscopy, and any other technology, as the Secretary determines appropriate.

"(c) Application for Technology Certification.—

"(1) IN GENERAL.—A developer seeking a technology certification order shall submit an application under this subsection, which shall contain the information specified under paragraph (2).

"(2) CONTENT OF APPLICATION.—A developer that submits an application for a technology certification shall include all necessary information to make a showing that all eligible in vitro clinical tests developed within the scope of the technology certification order will meet the applicable standard, including—

"(A) the name and address of the developer;

"(B) a table of contents for the application and the identification of the information the developer claims as trade secret or confidential commercial or financial information;

"(C) the signature of the individual filing the application or an authorized representative;

"(D) a statement identifying the scope of the proposed technology certification intended to be introduced into interstate commerce under the application;

"(E) information establishing that the developer submitting the application is an eligible person;

"(F) quality procedures showing that eligible in vitro clinical tests covered under the technology certification will conform to the applicable quality requirements of section 587K with respect to—

"(i) design controls, including related purchasing controls and acceptance activities;

"(ii) complaint investigation, adverse event reporting, and corrections and removals; and

"(iii) process validation, as applicable;

"(G) procedures for analytical and clinical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a showing ~~of analytical validity of~~ **that** eligible in vitro clinical tests within the proposed scope of the technology certification order ~~that is~~ **are** analytically and clinically valid;

"(H) procedures that provide a showing that in vitro clinical tests covered by the proposed scope of the technology certification order will be safe for individuals who come into contact with in vitro clinical tests covered by such order;

"(I) a proposed listing submission under section 587J(b) for in vitro clinical tests that the developer intends to introduce into interstate commerce upon receiving a technology certification order, which shall not be construed to limit the developer from introducing additional tests not included in such submission under the same technology certification order;

"(J) information concerning one or more representative in vitro clinical tests, including—

"(i) a test within the scope of the technology certification application with the appropriate analytical complexity at the time of the submission of the application under this section to serve as the representative test ~~and validate and run within the developer's stated scope~~;

"(ii) the information specified in subsection (a) or (b) of section 587B, as applicable, for the representative in vitro clinical test or tests, including information and data required pursuant to subsection (a)(2)(G) of section 587B, unless the Secretary determines that such information is not necessary;

"(iii) a summary of a risk assessment of the in vitro clinical test;

"(iv) an explanation of the choice of the representative in vitro clinical test or tests for the technology certification application and how such test adequately demonstrates the range of procedures that the developer includes in the application under subparagraphs (F), (G), (H), and (I); and

"(v) a brief explanation of the ways in which the procedures included in the application under subparagraphs (F), (G), (H), and (I) have been applied to the representative in vitro clinical test or tests; and

"(K) such other information necessary to make a determination on a technology certification application as the Secretary may determine necessary.

"(3) REFERENCE TO EXISTING APPLICATIONS.—With respect to the content requirements in the technology certification application described in paragraph (2), a developer may incorporate by reference any content of an application previously submitted by the developer.

"(d) Action on an Application for Technology Certification.—

"(1) SECRETARY RESPONSE.—

"(A) IN GENERAL.—As promptly as practicable, and not later than 90 days after receipt of an application under subsection (c), the Secretary shall—

"(i) issue a technology certification order granting the application, which shall specify the scope of the technology certification, if the Secretary finds that all of the grounds in paragraph (3) are met; or

"(ii) deny the application if the Secretary finds (and sets forth the basis of such finding as part of or accompanying such denial) that one or more grounds for granting the application specified in paragraph (3) are not met.

"(B) EXTENSION.—The timeline described in subparagraph (A) may be extended by mutual agreement between the Secretary and the applicant.

"(2) DEFICIENT APPLICATIONS.—

"(A) IN GENERAL.—If, after receipt of an application under this section, the Secretary determines that any portion of such application is deficient, the Secretary, not later than 60 days after receipt of such application, shall provide to the applicant a description of such deficiencies and identify the information required to resolve such deficiencies.

"(B) CONVERTING TO PREMARKET APPLICATIONS.—When responding to the deficiency letter, the developer may convert the application for technology certification under subsection (c) into a premarket application under section 587B.

"(3) TECHNOLOGY CERTIFICATION ORDER.—The Secretary shall issue an order granting a technology certification under this section if, on the basis of the information submitted to the Secretary as part of the application and any other information with respect to such applicant, the Secretary finds that—

"(A) there is a showing that in vitro clinical tests within the scope of the technology

certification order will meet the applicable standard;

"(B) the methods used in, and the facilities or controls used for, the development of eligible in vitro clinical tests covered by the proposed scope of the technology certification conform to the applicable requirements of section 587K with respect to—

"(i) design controls, including related purchasing controls and acceptance activities;

"(ii) complaint investigation, adverse event reporting, and corrections and removals; and

"(iii) process validation, as applicable;

"(C) based on a fair evaluation of all material facts, the applicant's proposed labeling and advertising are not false or misleading in any particular;

"(D) the application does not contain a false statement of material fact;

"(E) there is a showing that the representative in vitro clinical test or tests—

"(i) meet the applicable standard; and

"(ii) reasonably represent the range of procedures required to be submitted in the application;

"(F) the applicant has agreed to permit, upon request, authorized employees of the Food and Drug Administration or persons accredited, or recognized under this Act, an opportunity to inspect at a reasonable time and in a reasonable manner the facilities and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, including all things (including records, files, papers, and controls) bearing on whether an in vitro clinical test is adulterated, misbranded, or otherwise in violation of this Act, and permits such authorized employees or persons accredited under this Act to view and to copy and verify all records pertinent to the application and the in vitro clinical test; and

"(G) based on other data and information the Secretary may require under subsection (c)(2)(K), the Secretary finds that such data and information support granting a technology certification order.

"(4) REVIEW OF DENIALS.—An applicant whose application has been denied under this subsection may obtain review of such denial under section 587P.

"(e) Supplements.—

"(1) SUPPLEMENTAL APPLICATIONS.—

"(A) IN GENERAL.—With respect to any of the following changes related to an in vitro clinical test under a technology certification order, a supplemental application to a technology certification order shall be submitted by the holder of the technology certification order describing such proposed changes, prior to introducing the in vitro clinical test that is the subject of the technology certification order into interstate commerce—

"(i) any significant change to the procedures provided in support of the application for technology certification submitted under subparagraph (G) or (H)

of subsection (c)(2); or

"(ii) any significant change to the procedures provided in support of the application for technology certification submitted under subparagraph (F) of subsection (c)(2).

"(B) SECRETARY ACTION ON SUPPLEMENTAL APPLICATIONS.—Any action by the Secretary on a supplemental application shall be in accordance with subsection (d), and any order resulting from such supplement shall be treated as an amendment to a technology certification order.

"(2) CONTENT OF APPLICATION.—

"(A) IN GENERAL.—A supplemental application for a change to an in vitro clinical test under a technology certification order shall—

"(i) contain all necessary information to make a showing that any in vitro clinical test affected by such change that is within the scope of the technology certification order will meet the applicable standard; and

"(ii) be limited to such information that is needed to support the change.

"(B) CONTENT.—Unless otherwise specified by the Secretary, a supplemental application under this subsection shall include—

"(i) a description of the change, including a rationale for implementing such change;

"(ii) a description of how the change was evaluated;

"(iii) data from a representative in vitro clinical test or tests that supports a showing that, in using the modified procedure or procedures, all eligible in vitro clinical tests within the scope of the technology certification will meet the applicable standard;

"(iv) as applicable, information to demonstrate that the modified procedure or procedures submitted under subsection (c)(2)(F) continue to conform to applicable requirements under section 587K; and

"(v) any other information requested by the Secretary.

"(3) CHANGES IN RESPONSE TO A PUBLIC HEALTH RISK.—

"(A) IN GENERAL.—If the holder of a technology certification makes a change to an in vitro clinical test or tests to address a potential risk to public health by adding a new specification or test method, such holder may immediately implement such change and shall submit a notification for such change to the Secretary within 30 days.

"(B) CONTENT.—Any notification to the Secretary under this paragraph shall include—

"(i) a summary of the relevant change;

"(ii) the rationale for implementing such change;

"(iii)(I) if such a change necessitates a change to the procedures reviewed as part of the granted technology certification order, the modified procedures; or

"(II) if the procedures were not changed, an explanation as to why they were not changed; and

"(iv) if such a change necessitates a change to the procedures reviewed as part of the granted technology certification order, data from a representative in vitro clinical test or tests that support a showing that, in using the modified procedures, all eligible in vitro clinical tests within the scope of the technology certification will meet the applicable standard.

"(f) Temporary Hold.—

"(1) IN GENERAL.—Subject to the process specified in paragraph (2), and based on one or more findings under paragraph (4), the Secretary may issue a temporary hold prohibiting any holder of a technology certification order issued under this section from introducing into interstate commerce an in vitro clinical test that was not previously the subject of a listing under section 587J. The temporary hold shall identify the grounds for the temporary hold under paragraph (4) and the rationale for such finding.

"(2) PROCESS FOR ISSUING A TEMPORARY HOLD.—If the Secretary makes a finding that a temporary hold may be warranted based on one or more grounds specified in paragraph (4), the Secretary shall promptly notify the holder of the technology certification order of such finding and provide 30 calendar days for the developer to come into compliance with or otherwise resolve the finding.

"(3) WRITTEN REQUESTS.—Any written request to the Secretary from the holder of a technology certification order that a temporary hold under paragraph (1) be removed shall receive a decision, in writing and specifying the reasons therefore, within 90 days after receipt of such request. Any such request shall include information to support the removal of the temporary hold.

"(4) GROUNDS FOR TEMPORARY HOLD.—The Secretary may initiate a temporary hold under this subsection upon a finding that the holder of a technology certification order—

"(A) is not in compliance with the conditions of the technology certification order pursuant to subsection (b)(1)(D);

"(B) offers one or more in vitro clinical tests with advertising or labeling that is false or misleading;

"(C) has reported a correction or removal of an in vitro clinical test that is offered under a technology certification order under this section and has failed to demonstrate that the issue or issues causing the correction or removal does not adversely impact the ability of other in vitro clinical tests offered under the same technology certification order to meet the applicable standard; or

"(D) has introduced into interstate commerce an in vitro clinical test under a technology certification order and such test is adulterated or misbranded, based on a determination by the Secretary, and has failed to demonstrate that the issue or issues causing the adulteration or misbranding does not adversely impact the ability of other in vitro clinical tests offered under the same technology certification granted under this section to meet the applicable standard.

"(g) Withdrawal.—The Secretary may, after due notice and opportunity for an informal

hearing, issue an order withdrawing a technology certification order including all tests introduced into interstate commerce under the technology certification order if the Secretary finds that—

"(1) the application, supplement, or report under subsection (h) contains false or misleading information or fails to reveal a material fact;

"(2) such holder fails to correct false or misleading labeling or advertising upon the request of the Secretary;

"(3) in connection with a technology certification, the holder provides false or misleading information to the Secretary; or

"(4) the holder of such technology certification order fails to correct the grounds for a temporary hold within a timeframe specified in the temporary hold order.

"(h) Reports to Congress.—

"(1) IN GENERAL.—Not later than 1 year after the effective date of the VALID Act of 2022, and annually thereafter for the next 4 years, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the website of the Food and Drug Administration, a report containing the information described in paragraph (2).

"(2) CONTENT.—

"(A) IN GENERAL.—Each report under paragraph (1) shall address, at a minimum—

"(i) the total number of applications for technology certifications filed, ~~granted,~~ **issued,** withdrawn**,** and denied;

"(ii) the total number of technology certification orders the Secretary put on temporary hold under subsection (h) and the number of technology certification orders withdrawn under subsection (i);

"(iii) the types of technologies for which the Secretary ~~granted~~ **issued** technology certification orders;

"(iv) the total number of holders of technology certification orders that are in effect; and

"(v) the total number of in vitro clinical test categories that required premarket review under section 587B that were redesignated as eligible in vitro clinical tests under this section.

"(B) FINAL REPORT.—The fifth report submitted under paragraph (1) shall include a summary of, and responses to, comments raised in the docket.

"(C) PERFORMANCE REPORTS.—The reports required under this section may be issued with performance reports as required under section 829 of the VALID Act of 2022.

"(i) Public Meeting and Input.—

"(1) PUBLIC DOCKET.—Not later than 30 days after the date of enactment of the VALID

Act of 2022, the Secretary shall establish a public docket to receive comments concerning recommendations for implementation of this section, including criteria and procedures for subsections (c) through (h). The public docket shall remain open for at least 1 year after the establishment of the public docket.

"(2) PUBLIC MEETING.—Not later than 180 days after the date of enactment of the VALID Act of 2022, the Secretary shall convene a public meeting to which stakeholders from organizations representing patients and consumers, academia, and the in vitro clinical test industry are invited to discuss the technology certification process including application requirements, inspections, alignment with third-party accreditors, and the definition of the term 'technology' under section 587.

"(j) Regulations.—The Secretary shall issue regulations regarding the technology certification process, including describing criteria or procedures relating to technology certification under this section, which shall be subject to public comment for a minimum of 60 days from issuance prior to finalizing such regulations after considering the comments received. The regulation shall include an outline of the application process, opportunities to meet with officials of the Food and Drug Administration, and plans to streamline inspections.

"(k) Notification.—

"(1) IN GENERAL.—Notwithstanding subsection (a)(1), a first-of-a-kind in vitro clinical test or a combination product that meets the definition of a moderate-risk test under section 587A may be introduced into interstate commerce under a technology certification order that has been issued by the Secretary, subject to other applicable requirements if—

"(A) the developer provides notification to the Secretary 60 days prior to introducing such tests into interstate commerce that includes information demonstrating that the test is moderate-risk and within the scope of the applicable technology certification order; and

"(B) the Secretary has not issued a notification to the developer under paragraph (2) before such time has elapsed.

"(2) NOTIFICATION FROM SECRETARY.—The Secretary shall issue a notification to the developer that such test may not be introduced into interstate commerce under such order if the Secretary determines that—

"(A) such test—

"(i) does not meet the definition of a moderate-risk test under section 587A;

"(ii) is not eligible to be introduced into interstate commerce under ~~the referenced technology certification order issued by the Secretary~~ **any of subparagraphs (A) through (E) of subsection (a)(1)**; or

"(iii) is not eligible ~~for~~ **to be introduced into interstate commerce under the referenced** technology certification **order issued by the Secretary because it is not within the scope of the technology certification order** under subsection (b)(2); or

"(B) based on the information included in the notification submitted by the developer pursuant to this subsection, there is insufficient information for the Secretary

to make the determinations described in clauses (i), (ii), and (iii) of subparagraph (A).

"SEC. 587E. MITIGATING MEASURES.

"(a) Establishment of Mitigating Measures.—

"(1) ESTABLISHING, CHANGING, OR WITHDRAWING.—

"(A) ESTABLISHMENT.—The Secretary may establish and require, on the basis of evidence, mitigating measures for any in vitro clinical test or category of in vitro clinical tests with the same indications for use that is introduced or delivered for introduction into interstate commerce after the establishment of such mitigating measures.

"(B) METHODS OF ESTABLISHMENT.—The Secretary may establish mitigating measures—

"(i) under the process set forth in subparagraph (D);

"(ii) as provided under section 587F; or

"(iii) through a premarket approval or technology certification order, which may establish mitigating measures for an individual in vitro clinical test or a category of in vitro clinical tests.

"(C) METHODS OF CHANGE OR WITHDRAWAL.—The Secretary may change or withdraw mitigating measures—

"(i) under the process set forth in subparagraph (D); or

"(ii) as provided under section 587F.

"(D) PROCESS FOR ESTABLISHMENT, CHANGE, OR WITHDRAWAL.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person—

"(i) establish, change, or withdraw mitigating measures for an in vitro clinical test or category of in vitro clinical tests by—

"(I) publishing a proposed order in the Federal Register;

"(II) providing an opportunity for public comment for a period of not less than 30 60 calendar days; and

"(III) after consideration of any comments submitted, publishing a final order in the Federal Register that responds to the comments submitted, and which shall include a reasonable transition period.

"(E) EFFECT OF MITIGATING MEASURES ON GRANDFATHERED TESTS.—A mitigating measure shall not be required by the Secretary for an in vitro clinical test subject to section 587G(a)~~, unless otherwise provided under section 587F~~.

"(2) IN VITRO CLINICAL TESTS PREVIOUSLY CLEARED OR EXEMPT AS DEVICES WITH SPECIAL CONTROLS.—

"(A) IN GENERAL.—Any special controls applicable to an in vitro clinical test previously cleared or exempt under section 510(k), or classified under section

513(f)(2) prior to date of enactment of the VALID Act of 2022, including any such special controls established during the period beginning on the date of enactment of the VALID Act of 2022 and ending on the effective date of such Act (as described in section 5(b) of such Act)—

"(i) shall continue to apply to such in vitro clinical test after such effective date; and

"(ii) are deemed to be mitigating measures as of the effective date specified in section 825(a)(1)(A) of the VALID Act of 2022.

"(B) CHANGES.—Notwithstanding subparagraph (A), the Secretary may establish, change, or withdraw mitigating measures for such tests or category of tests using the procedures under paragraph (1).

"(b) Documentation.—

"(1) IN VITRO CLINICAL TESTS SUBJECT TO PREMARKET REVIEW.—The developer of an in vitro clinical test subject to premarket review under section 587B and to which mitigating measures apply shall—

"(A) in accordance with section 587B(c)(2)(G)(i), submit documentation to the Secretary as part of the application for the test under subsection (c) or (d) of section 587B demonstrating that such mitigating measures have been met;

"(B) if such application is approved, maintain documentation demonstrating that such mitigating measures continue to be met following a test modification by the developer; and

"(C) make such documentation available to the Secretary upon request or inspection.

"(2) OTHER TESTS.—The developer of an in vitro clinical test that is offered under a technology certification order or other exemption from premarket review under section 587B and to which mitigating measures apply shall—

"(A) maintain documentation in accordance with the applicable quality requirements under section 587J demonstrating that such mitigating measures continue to be met following a test modification by the developer;

"(B) make such documentation available to the Secretary upon request or inspection; and

"(C) include in the performance summary for such test a brief description of how such mitigating measures are met, if applicable.

"SEC. 587F. REGULATORY PATHWAY DESIGNATION.

"(a) Pathway Determinations.—

"(1) IN GENERAL.—After considering available evidence with respect to an in vitro clinical test or category of in vitro clinical tests with the same intended use, including the identification, establishment, and implementation of mitigating measures under section 587E, as appropriate, the Secretary may, upon the initiative of the Secretary or upon request of a developer, determine that—

"(A) such in vitro clinical test is high-risk and subject to premarket review under section 587B;

"(B) such in vitro clinical tests, including a first-of-a-kind test, is moderate-risk and subject to abbreviated premarket review under section ~~587B(d)~~ **587B(b)** or technology certification under section ~~587D(b)(2);~~ **587D(a)(1);** or

"(C) such in vitro clinical test, including a first-of-a-kind test is low-risk or otherwise exempt from premarket review under section 587B.

"(2) REQUESTS.—

"(A) SUBMISSIONS BY DEVELOPERS.—

"(i) ~~SPECIAL~~ **ABBREVIATED** PREMARKET REVIEW; TECHNOLOGY CERTIFICATION.—A developer submitting a request that the Secretary make a determination as described in paragraph (1)(B) shall submit information to support that the in vitro clinical test is moderate-risk or propose mitigating measures, if applicable, that would support such a determination.

"(ii) LOW-RISK; EXEMPT FROM PREMARKET REVIEW.—A developer submitting a request that the Secretary make a determination as described in paragraph (1)(C) shall submit information that the in vitro clinical test is low-risk, or otherwise appropriate for exemption from premarket review under section 587B and propose mitigating measures, if applicable, that would support such a determination.

"(B) RESPONSE BY THE ~~SECRETARY.—AFTER~~ **SECRETARY.—Not later than 30 days after** receiving a request under clause (i) or (ii) of subparagraph (A), the Secretary shall provide a timely response describing whether or not the Secretary will initiate the process for making a determination under paragraph (1)(B) or (1)(C) as described in paragraph (4).

"(3) SUFFICIENCY OF MITIGATING MEASURES.—When determining whether mitigating measures for an in vitro clinical test, or category of in vitro clinical tests, are sufficient to make such test moderate-risk or low-risk, the Secretary shall take into account the following:

"(A) The degree to which the technology for the intended use of the in vitro clinical test is well-characterized, taking into consideration factors that include one or more of the following:

"(i) Peer-reviewed literature.

"(ii) Practice guidelines.

"(iii) Consensus standards.

"(iv) Recognized standards of care.

"(v) Use of such technology, including historical use.

"(vi) Multiple scientific publications by different authors.

"(vii) Adoption by the scientific or clinical community.

"(viii) Real world evidence.

"(B) Whether the criteria for performance of the test are well-established to be sufficient for the intended use.

"(C) The clinical circumstances under which the in vitro clinical test is used, including whether the in vitro clinical test is the sole determinate for the diagnosis or treatment of the targeted disease, and the availability of other tests (such as confirmatory or adjunctive tests) or relevant material standards.

"(D) Whether such mitigating measures sufficiently mitigate the risk of harm such that the test or category of tests is moderate-risk or low-risk.

"(4) PROCESS.—

"(A) IN GENERAL.—For a test that is not first-of-a-kind, any action under paragraph (1) shall be made by publication of a notice of such proposed action on the website of the Food and Drug Administration, the consideration of comments to a public docket on such proposal, and publication of a final action on such website within 60 calendar days of the close of the comment period posted to such public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

"(B) PROCESS FOR FIRST-OF-A-KIND TEST.—In the case of an in vitro clinical test that is first-of-a-kind, the process is as follows:

"(i) Any determination that the test is subject to premarket approval or abbreviated premarket review under subparagraph (A) or (B) of paragraph (1) shall be published on the website of the Food and Drug Administration, notwithstanding subclause II of chapter 5 of title 5, United States Code, only after the in vitro clinical test is approved under section 587B. Until that time, the determination shall not be binding on other in vitro clinical tests.

"(ii) Any determination other than those made under clause (i) shall be made by publication of a notice of final action on the website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

"(5) NO EFFECT ON GRANDFATHERING DETERMINATIONS.—A determination under paragraph (1) shall have no effect on the applicability of section 587G to an in vitro clinical tests.

"(b) Transition Period.—Upon a decision by the Secretary to change a regulatory pathway designation, or reclassifies an in vitro clinical test, or category of in vitro clinical tests, the Secretary shall provide an appropriate transition period with respect to any new requirements.

"(c) Appeals.—A decision by the Secretary under this section shall be deemed a significant decision subject to appeal under section 587P.

"(d) Advisory Committee.—The Secretary may request recommendations from an advisory committee under section 587H pursuant to carrying out this section.

"(e) Request for Informal Feedback.—Before submitting a premarket application or technology certification application for an in vitro clinical test—

"(1) the developer of the test may submit to the Secretary a written request for a meeting, conference, or written feedback to discuss and provide information relating to the regulation of such in vitro clinical test which may include—

"(A) the submission process and the type and amount of evidence expected to demonstrate the applicable standard;

"(B) which regulatory pathway is appropriate for an in vitro clinical test; and

"(C) an investigation plan for an in vitro clinical test, including a clinical protocol; and

"(2) upon receipt of such a request, the Secretary shall—

"(A) if a meeting is requested—

"(i) within 60 calendar days after such receipt, or within such time period as may be agreed to by the developer, meet or confer with the developer submitting the request; and

"(ii) within 15 calendar days after such meeting or conference, provide to the developer a written record or response describing the issues discussed and conclusions reached in the meeting or conference; and

"(B) if written feedback is requested, provide feedback to the requestor within 75 days after such receipt.

"SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.

"(a) In General.—Subject to subsection (d), an in vitro clinical test is exempt from the requirements of this subchapter specified in subsection (b) if—

"(1) the test was first offered for clinical use**, and was not intended solely for investigational use,** before the date of enactment of the VALID Act of 2022;

"(2) the **test** was developed by a clinical laboratory for which a certificate was in effect under section 353 of the Public Health Service Act that meets the requirements for performing tests of high complexity;

"(3) the test is performed—

"(A) in the same clinical laboratory in which the test was developed for which a certification is still in effect under section 353 of the Public Health Service Act that meets the requirements to perform tests of high complexity;

"(B) by another clinical laboratory for which a certificate is in effect under section 353 of such Act that meets the requirements to perform tests of high complexity, and that is within the same corporate organization and having common ownership by the same parent corporation as the laboratory in which the test was developed; or

"(C) in the case of a test that was developed by the Centers for Disease Control and Prevention or another laboratory **in** a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, by a clinical laboratory for which a certificate is in effect under section 353 of such Act that meets the

requirements to perform tests of high complexity, and that is within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention;

"(4) the test does not have in effect an approval under section 515, a clearance under section 510(k), an authorization under section 513(f)(2), or an exemption under section 520(m), or licensure under section 351 of the Public Health Service Act;

"(5) any modification to the test on or after the date of enactment of the VALID Act of 2022 **is** made by the initial developer ~~and conform~~**, conforms** with section 587C(a)(6)(A)(ii)**,** and does not meet the ~~criterial~~ **criteria** in subsection (d)(1);

"(6) ~~the test is not for investigational use;~~ **when used as an investigational in vitro clinical test, such test complies with section 587S, as applicable;**

"(7) the test is offered with an order from an authorized person as required under section 353 of the Public Health Service Act, and was offered with a prescription required under section 809.30(f) of title 21, Code of Federal Regulations prior to the effective date of this subchapter;

"(8) the test is not for use with home specimen collection, unless the specimen is collected with a collection container, receptacle, or kit that—

"(A) has been approved, cleared, or authorized by the Secretary for home specimen collection and the collection is performed pursuant to the approved, cleared, or authorized labeling, including any indication for use as prescription use or over-the-counter use, or

"(B) is exempt from premarket review and its use is consistent with applicable limitations on the exemption;

"(9) **the test** is not a specimen receptacle or instrument**;**

"(10) each test report ~~template~~ for the test bears a statement that reads as follows: 'This in vitro clinical test ~~has not been reviewed by the Food and Drug Administration.';~~ **was introduced into commerce prior to the application of the VALID Act and is exempt from FDA premarket review.';** and

"(11) the developer of the test—

"(A) maintains documentation demonstrating that the test meets and continues to meet the criteria set forth in this subsection; and

"(B) makes such documentation available to the Secretary upon request.

"(b) Exemptions Applicable to Grandfathered Tests.—An in vitro clinical test that meets the criteria specified in subsection (a) is exempt from premarket review under 587B, labeling requirements under 587L, and test design requirements and quality requirements under 587K, and may be lawfully offered subject to the other applicable requirements of this Act.

"(c) Modifications.—In the case of an in vitro clinical test that meets the criteria specified in subsection (a), such test continues to qualify for the exemptions described in subsection (b) if the test is modified and the modification is ~~not~~ of a type described in subsection (a)(5), and the person modifying such in vitro clinical test—

"(1) documents each such modification and maintains documentation of the basis for such determination;

"(2) provides such documentation relating to the change to the Secretary upon request or inspection; and

"(3) does not modify the in vitro clinical test such that it no longer meets the criteria under subsection (a).

"(d) Request for Information.—

"(1) CRITERIA.—The criteria described in this paragraph are any of the following:

"(A) There is ~~insufficient~~ **a lack of** valid scientific evidence to support that the **in vitro clinical** test is analytically valid or clinically valid.

"(B) Such in vitro clinical test is being offered by its developer with any false or misleading analytical or clinical claims.

"(C) It is probable that such in vitro clinical test will cause serious adverse health consequences.

"(2) PROCESS.—

"(A) WRITTEN REQUEST FOR INFORMATION.—The Secretary may issue a written request to a developer identifying specific scientific concerns, based on credible information, with an in vitro clinical test, which indicate that one or more of the criteria described in paragraph (1) apply to such in vitro clinical ~~tests~~ **test**. Such written request shall include specific information requests pertaining to such criteria.

"(B) DEADLINE FOR SUBMITTING INFORMATION.—Not later than 45 days after receiving a request for information under subparagraph (A)—

"(i) the developer of an in vitro clinical test—

"(I) may seek a teleconference prior to the submission of information under ~~clause (ii)~~ **subclause (II)** to discuss the Secretary's request; and

"(II) shall submit the information requested pursuant to subparagraph (A) ~~within 30 days of receipt of such request~~**, and may include in such submission a request for a teleconference**; and

"(ii) the Secretary shall—

"(I) schedule a teleconference requested under clause (i)(I); and

"(II) hold a teleconference ~~so~~ **if** requested within 10 days of the Secretary's receipt of the information ~~requested~~ **submitted** under clause (i)(II).

"(C) REVIEW DEADLINE.—Upon receiving a submission under subparagraph (B), the Secretary shall—

"(i) review the submitted information within 45 calendar days of such receipt, which may include communication with the developer; and

"(ii) determine whether the criteria listed in paragraph (1) apply to the in vitro

clinical test and communicate such determination to the developer as described in subparagraph (D).

"(D) COMMUNICATION AND RESULTS OF DETERMINATION.—The Secretary shall notify the developer, in writing, of the Secretary's determination under subparagraph (C), as follows:

"(i) If the Secretary determines that none of the criteria listed in paragraph (1) apply to the in vitro clinical test, such test shall be exempt from relevant requirements of this subchapter, as set forth in subsection (b), subject to applicable limitation.

"(ii) If the Secretary determines that one or more of the criteria listed in subparagraph (1) apply to the test but such a determination may be resolved within a reasonable time, and the test has not been previously subject to this subsection on the basis of the same or substantially similar scientific concerns identified in the written request issued under paragraph (d)(2)(A)—

"(I) the Secretary shall notify the developer of such a determination and allow the developer to seek a teleconference to discuss the finding;

"(II) the developer shall submit information demonstrating resolution of the determination within 15 days of receiving the notification; and

"(III) the Secretary shall make a determination within 30 days of the submission of information as to whether the criteria under paragraph (1) apply to the test.

"(iii) If the Secretary determines that none of the criteria listed in paragraph (1) apply to the test, such test shall be exempt from relevant requirements of the subchapter as set forth in subsection (b), subject to applicable limitations.

"(iv) If the Secretary determines that one or more of the criteria listed in paragraph (1) apply to the in vitro clinical test, such test is not exempt as set forth in this section and shall not be offered unless approved under section 587B, **or, upon a determination by the Secretary pursuant to section 587F,** offered under a technology certification order under section 587D~~,~~ or offered as a low-risk test. ~~upon a determination by the Secretary pursuant to section 587F.~~

"(v) If the Secretary determines that one or more of the criteria listed in paragraph (1) apply to the in vitro clinical test and clause (ii) does not apply, the in vitro clinical test is not exempt as set forth in section and shall not be offered unless approved under section 587B, **or upon a determination by the Secretary pursuant to section 587F,** offered under a technology certification order under section 587D~~,~~ or offered as a low-risk test ~~upon a determination by the Secretary pursuant to section 587F~~.

"SEC. 587H. ADVISORY COMMITTEES.

"(a) In General.—The Secretary may establish advisory committees or use advisory committee panels of experts established before the date of enactment of the VALID Act of 2022 (including a device classification panel under section 513) for the purposes of providing expert scientific

advice and making recommendations related to—

"(1) the approval of an application for an in vitro clinical test submitted under this subchapter, including for evaluating, as applicable, the analytical validity, clinical validity, and safety of in vitro clinical tests;

"(2) the potential effectiveness of mitigating measures for a determination of the applicable regulatory pathway under section 587F(b) or risk evaluation for an in vitro clinical test or tests;

"(3) quality requirements under section 587K or applying such requirements to in vitro clinical tests developed or imported by developers;

"(4) appeals under section 587P; or

"(5) such other purposes as the Secretary determines appropriate.

"(b) Appointments.—

"(1) VOTING MEMBERS.—The Secretary shall appoint to each committee established under subsection (a), as voting members, individuals who are qualified by training and experience to evaluate in vitro clinical tests referred to the committee for the purposes specified in subsection (a), including individuals with, to the extent feasible, scientific expertise in the development of such in vitro clinical tests, laboratory operations, and the use of in vitro clinical tests. The Secretary shall designate one member of each committee to serve as chair.

"(2) NONVOTING MEMBERS.—In addition to the individuals appointed pursuant to paragraph (1), the Secretary shall appoint to each committee established under subsection (a), as nonvoting members—

"(A) a representative of consumer interests; and

"(B) a representative of interests of in vitro clinical test developers not directly affected by the matter to be brought before the committee.

"(3) LIMITATION.—No individual who is a regular full-time employee of the United States and engaged in the administration of this Act may be a member of any advisory committee established under subsection (a).

"(4) EDUCATION AND TRAINING.—The Secretary shall, as appropriate, provide education and training to each new committee member before such member participates in a committee's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to committee meetings.

"(5) MEETINGS.—The Secretary shall ensure that scientific advisory committees meet regularly and at appropriate intervals so that any matter to be reviewed by such a committee can be presented to the committee not more than 60 calendar days after the matter is ready for such review. Meetings of the committee may be held using electronic or telephonic communication to convene the meetings.

"(6) COMPENSATION.—Members of an advisory committee established under subsection (a), while attending meetings or conferences or otherwise engaged in the business of the

advisory committee—

"(A) shall be entitled to receive compensation at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above level GS–15 of the General Schedule; and

"(B) may be allowed travel expenses as authorized by section 5703 of title 5, United States Code, for employees serving intermittently in the Government service.

"(c) Guidance.—The Secretary may issue guidance on the policies and procedures governing advisory committees established under subsection (a).

"SEC. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.

"(a) In General.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the review of, in vitro clinical tests that represent breakthrough technologies.

"(b) Establishment of Program.—The Secretary shall establish a program to expedite the development of, and provide for the priority review of, in vitro clinical tests.

"(c) Eligibility.—The program developed under subsection (b) shall be available for any in vitro clinical test that—

"(1) provides or enables more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions compared to existing approved or cleared ~~alternatives~~ **in vitro clinical tests**, including an in vitro clinical test offered under a technology certification order; and

"(2) is a test—

"(A) that represents a breakthrough technology;

"(B) for which no approved or cleared alternative in vitro clinical test exists, including no in vitro clinical test offered under a technology certification order;

"(C) that offers a clinically meaningful advantage over ~~any~~ existing alternative in vitro clinical ~~test~~ **tests** that ~~is~~ **are** approved or cleared (including ~~any~~ in vitro clinical ~~test~~ **tests** offered under a technology certification order), including the potential to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

"(D) the availability of which is in the best interest of patients or public health.

"(d) Designation.—

"(1) REQUEST.—To receive breakthrough designation under this section, an applicant may request that the Secretary designate the in vitro clinical test for expedited development and priority review. Any such request for designation may be made at any time prior to, or at the time of, the submission of an application under section 587B or 587D, and shall include information demonstrating that the test meets the criteria described in subsection

(c).

"(2) DETERMINATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether the in vitro clinical test that is the subject of the request meets the criteria described in subsection (c). If the Secretary determines that the test meets the criteria, the Secretary shall designate the test for expedited development and priority review.

"(3) REVIEW.—Review of a request under paragraph (1) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

"(4) WITHDRAWAL.—

"(A) IN GENERAL.—The designation of an in vitro clinical test under this subsection is deemed to be withdrawn, and such in vitro clinical test shall no longer be eligible for designation under this section, if an application for approval for such test under section 587B or 587D is denied. Such test shall be eligible for breakthrough designation upon a new request for such designation.

"(B) EXCEPTION.—The Secretary may not withdraw a designation granted under this subsection based on the subsequent approval or technology certification of another in vitro clinical test that—

"(i) is designated under this section; or

"(ii) was given priority review under section 515B.

"(e) Actions.—For purposes of expediting the development and review of in vitro clinical tests under this section, the Secretary may take the actions and additional actions set forth in paragraphs (1) and (2), respectively, of section 515B(e) when reviewing such tests. Any reference or authorization in section 515B(e) with respect to a device shall be deemed a reference or authorization with respect to an in vitro clinical test for purposes of this section.

"(f) Guidance.—Not later than the date specified for final guidance under section 825 of the VALID Act of 2022, the Secretary shall issue final guidance on the implementation of this section. Such guidance shall—

"(1) set forth the process by which a person may seek a designation under subsection (d);

"(2) provide a template for request under subsection (d);

"(3) identify the criteria the Secretary will use in evaluating a request for designation; and

"(4) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review in vitro clinical tests designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(g) Rules of Construction.—Nothing in this section shall be construed to affect—

"(1) the criteria and standards for evaluating an application pursuant to section 587B or 587D, including the recognition of valid scientific evidence as described in section ~~587(17)~~ **587(20)** and consideration and application of the least burdensome means described under section 587AA(c);

"(2) the authority of the Secretary with respect to clinical holds under section ~~587R~~ **587S**;

"(3) the authority of the Secretary to act on an application pursuant to section 587B before completion of an establishment inspection, as the Secretary determines appropriate; or

"(4) the authority of the Secretary with respect to postmarket surveillance under ~~sections 587L(d) and 587Y~~ **section 587X**.

"SEC. 587J. REGISTRATION AND LISTING.

"(a) Registration Requirement.—

"(1) IN GENERAL.—Each person described in subsection (b)(1) shall—

"(A) during the period beginning on October 1 and ending on December 31 of each year, register with the Secretary the name of such person, places of business of such person, all establishments engaged in the activities specified under this paragraph, the establishment registration number of each such establishment, and a point of contact for each such establishment, including an electronic point of contact; and

"(B) submit an initial registration containing the information required under subparagraph (A) not later than—

"(i) the effective date of this section if such establishment is engaged in any activity described in subsection (b)(1) on such effective date, unless the Secretary establishes by guidance a date later than such implementation date for all or a category of such establishments; or

"(ii) 30 days prior to engaging in any activity described in subsection (b)(1), if such establishment is not engaged in any activity described in this paragraph on such effective date.

"(2) REGISTRATION NUMBERS.—The Secretary may assign a registration number to any person or an establishment registration number to any establishment registered in accordance with this section. Registration information shall be made publicly available by publication on the website maintained by the Food and Drug Administration, in accordance with subsection (d).

"(3) INSPECTION.—Each person or establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

"(b) Listing Information for In Vitro Clinical Tests.—

"(1) IN GENERAL.—Each person who—

"(A) is a developer; and

"(B) introduces or proposes to begin the introduction or delivery for introduction into interstate commerce through an exemption under subsection (a)(1), (a)(2), (a)(3), or (g) of section 587C or section 587G or through the filing of an application under section 587B or section 587D,

shall submit a listing to the Secretary containing the information described in paragraph (2), (4), or (5), as applicable, in accordance with the applicable schedule described under

subsection (c). Such listing shall be prepared in such form and manner as the Secretary may specify in guidance. Listing information shall be submitted through the comprehensive test information system in accordance with section 587T, as appropriate.

"(2) SUBMISSIONS.—Each developer submitting a listing under paragraph (1) shall electronically submit to the comprehensive test information system described in section 587T the following information, as applicable, for each in vitro clinical test for which such person is a developer in the form and manner prescribed by the Secretary, taking into account **the** least burdensome ~~principles~~ **requirements under section 587AA(c)**:

"(A) Name of the establishment and its establishment registration number.

"(B) Contact information for the official correspondent for the listing.

"(C) Name (common name and trade name, if applicable) of the in vitro clinical test and its test listing number (when available).

"(D) The certificate number for any laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements to perform high-complexity testing and that is the developer of the in vitro clinical test, and the certificate number under such section for any laboratory that is performing the test, is within the same corporate organization, and has common ownership by the same parent corporation.

"(E) Whether the in vitro clinical test is, as applicable, offered as a test approved under section 587B, cleared to be offered under a granted technology certification order, or offered as an exempt in vitro clinical test under section ~~587A~~ **587C of 587G**.

"(F) Indications for use information under section 587(10).

"(G) A brief summary of the analytical and clinical performance of the in vitro clinical test, and as applicable, the lot release criteria.

"(H) A brief description of conformance with any applicable mitigating measures, restrictions, and standards.

"(I) Representative labeling for the in vitro clinical test, as appropriate.

"(3) TEST LISTING NUMBER.—The Secretary may assign a test listing number to each in vitro clinical test that is the subject of a listing under this section. The process for assigning test listing numbers may be established through guidance, and may include the recognition of standards, formats, or conventions developed by a third-party organization.

"(4) ABBREVIATED LISTING.—A person who is not a developer but is otherwise required to register pursuant to subsection (a) shall submit an abbreviated listing to the Secretary containing the information described in subparagraphs (A) through (C) of paragraph (2), and the name of the developer. The information shall be submitted in accordance with the applicable schedule described under subsection (c). Such abbreviated listing shall be prepared in such form and manner as the Secretary may specify through guidance. Listing information shall be submitted to the comprehensive test information system in accordance with section 587T, as appropriate.

"(5) GRANDFATHERED TESTS.—A developer offering a test that is a grandfathered in vitro clinical test under section 587G(a) shall submit listing information required under

subparagraphs (A) through (F) of paragraph (2), and may submit a statement of the performance specifications for such in vitro clinical tests.

"(6) EXEMPT TESTS.—A developer of an in vitro clinical test who introduces or proposes to begin the introduction or delivery for introduction into interstate commerce that is otherwise exempt from the requirement to submit listing information pursuant to an exemption under section 587C may submit listing information under this subsection.

"(c) Timelines for Submission of Listing Information.—

"(1) IN GENERAL.—The timelines for submission of registration and listing under subsections (a) and (b) are as follows:

"(A) For an in vitro clinical test that was listed as a device under section 510(j) prior to the effective date of this section, a person shall maintain a device listing under section 510 until such time as the system for submitting the listing information required under subsection (b) becomes available and thereafter shall submit the listing information not later than the later of 1 year after the system for submitting the listing under this section becomes available or the effective date of this section.

"(B) For an in vitro clinical test that is subject to grandfathering under section 587G(a) a person shall submit the listing information required under subsection (b)(5) not later that the later of 1 year after the system for submitting the listing under this section becomes available or the effective date of this section.

"(C) For an in vitro clinical test that is not described in subparagraph (A) or (B), a person shall submit the required listing information as follows:

"(i) For an in vitro clinical test that is not exempt from premarket approval under section 587B, a person shall submit the required listing information, prior to offering the in vitro clinical test and not later than 30 business days after the date of approval of the premarket approval application.

"(ii) For an in vitro clinical test that is exempt from premarket review under section 587C, the required listing information shall be submitted prior to offering the in vitro clinical test.

"(2) UPDATES.—

"(A) UPDATES AFTER CHANGES.—Each developer required to submit listing information under this section shall update such information within 10 business days of any change that causes any previously listed information to be inaccurate or incomplete.

"(B) ANNUAL UPDATES.—Each developer required to submit listing information under this section shall update its information annually during the period beginning on October 1 and ending on December 31 of each year.

"(d) Public Availability of Listing Information.—

"(1) IN GENERAL.—Listing information submitted pursuant to this section shall be made publicly available on the website of the Food and Drug Administration in accordance with paragraph (3).

"(2) CONFIDENTIALITY.—Listing information for an in vitro clinical test that is subject to premarket approval or technology certification shall remain confidential until such date as the in vitro clinical test receives the applicable premarket approval or the developer receives a technology certification order and for subsequent tests introduced under a technology certification order until their introduction.

"(3) EXCEPTIONS FROM PUBLIC AVAILABILITY REQUIREMENTS.—The public listing requirements of this subsection shall not apply to any registration and listing information submitted under subsection (a) or (b), if the Secretary determines that such information—

"(A) is a trade secret or confidential commercial **or financial** information; or

"(B) if posted, would present a risk to national security.

"(e) Submission of Information by Accredited Persons.—If agreed upon by the developer, the information required under this section may be submitted by a person accredited under section 587Q.

"SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.

"(a) Applicability.—

"(1) IN GENERAL.—Each developer and each other person required to register under section ~~587I(b)(1)~~ **587J(b)(1)** shall establish and maintain quality requirements in accordance with the applicable requirements set forth in subsection (b).

"(2) CERTIFIED LABORATORY REQUIREMENTS.—A developer shall establish and maintain quality requirement under subsection (b)(2) or (b)(3), as applicable, if such developer is a clinical laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

"(A) is certified to perform high-complexity testing;

"(B) develops an in vitro clinical test that is for use only—

"(i) within the laboratory certified by the Secretary under such section 353 in which such test was developed; or

"(ii) within another laboratory certified by the Secretary under such section 353 if such laboratory is—

"(I) within the same corporate organization and has common ownership by the same parent corporation as the laboratory in which the test was developed; or

"(II) within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, if the test is developed by a public health laboratory or the Centers for Disease Control and Prevention; and

"(C) does not manufacture, produce, or distribute in vitro clinical tests other than laboratory test protocols.

"(3) REGULATIONS.—The Secretary shall promulgate quality system regulations

implementing this section. In promulgating such regulations under this section, the Secretary shall consider whether, and to what extent, international harmonization is appropriate.

"(4) QUALITY SYSTEMS FOR HYBRID DEVELOPERS OF BOTH LABORATORY TEST PROTOCOLS AND OTHER IN VITRO CLINICAL TESTS.—An entity that develops both finished products and laboratory test protocols and other in vitro clinical tests shall comply with subsection (b)(1) for activities related to the development of any in vitro clinical test that is not a laboratory test protocol ~~product~~ and with subsection (b)(2) or (b)(3), as applicable, for activities related to the development of any laboratory test protocol.

"(b) Quality Requirements.—

"(1) IN GENERAL.—The quality requirements applicable under this section shall—

"(A) avoid duplication of regulations **and guidance** under section 353 of the Public Health Service Act;

~~and~~**"(B) not apply to laboratory operations; and**

~~"(B) shall~~**"(C)** include the following, as applicable, subject to ~~subparagraph~~ **subparagraphs** (A) **and (B)** and paragraphs (2) and (3)—

"(i) management responsibilities;

"(ii) quality audits;

"(iii) personnel;

"(iv) design controls;

"(v) document controls;

"(vi) purchasing controls;

"(vii) identification and traceability;

"(viii) production and process controls;

"(ix) acceptance activities;

"(x) nonconforming in vitro clinical tests;

"(xi) corrective and preventive action;

"(xii) labeling and packaging controls;

"(xiii) handling, storage, distribution, and installation;

"(xiv) complaints and records;

"(xv) servicing; and

"(xvi) statistical techniques.

"(2) EXCEPTION FOR LABORATORY TEST PROTOCOLS.—Developers that are developing test protocols for use as described in subsection (a)(2)(B)(i) are exempt from the requirements under paragraph ~~(1)(B)~~**(1)(C)** except for the requirements described in clauses (iv), ~~(vi),~~(ix), (xi), and (xiv) of such paragraph.

"(3) QUALITY REQUIREMENTS FOR CERTAIN LABORATORIES DISTRIBUTING LABORATORY TEST PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC HEALTH NETWORKS.—Quality requirements applicable to the developer who is distributing a laboratory test protocol as described in subsection (a)(2)(B)(ii) shall consist of the following:

"(A) Clauses (iv), ~~(vi),~~(ix), (xi), (xiv), (xii) of paragraph (1)(B).

"(B) The requirement to maintain records of the laboratories to which the laboratory test protocol is distributed.

"(c) Regulations.—In implementing quality requirements for test developers that participate in international audit programs under this section, the Secretary shall—

"(1) for purposes of facilitating international harmonization, consider whether the developer participates in an international audit program in which the United States participates and recognizes compliance with, or conformance to, such standards recognized by the Secretary; and

"(2) ensure a least burdensome approach described in section 587AA(c) by leveraging, to the extent applicable, the quality assurance requirements applicable to developers certified by the Secretary under section 353 of the Public Health Service Act.

"SEC. 587L. LABELING REQUIREMENTS.

"(a) In General.—An in vitro clinical test shall bear or be accompanied by labeling, as applicable, that meets the requirements set forth in subsections (b) and (c), unless such test is exempt under subsection (d) or (e).

"(b) Labels.—

"(1) IN GENERAL.—The label of an in vitro clinical test, shall meet the requirements set forth in paragraph (2) if there is an immediate container to which the label is applied.

"(2) REGULATIONS.—The label of an in vitro clinical test shall state the name and place of business of its developer and meet the requirements set forth in regulations promulgated in accordance with this section.

"(c) Labeling.—

"(1) IN GENERAL.—Labeling of an in vitro clinical test, including labeling in the form of a package insert, website, standalone laboratory reference document, or other similar document shall include—

"(A) adequate directions for use and shall meet the requirements set forth in regulations promulgated under this section, except as provided in subsection (d) or (e); and

"(B) the information described in paragraph (2), as applicable.

"(2) CONTENT.—Labeling of an in vitro clinical test shall include—

"(A) the test listing number that was provided to the developer at the time of listing;

"(B) information to facilitate reporting an adverse event;

"(C) information regarding accessing the performance summary data displayed in

the listing database for the test;

"(D) the indications ~~of~~ **for** use of the in vitro clinical test; and

"(E) any warnings, contraindications, or limitations.

"(3) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make all of the information described in paragraph (2) with respect to each in vitro clinical test available to the public, as applicable, in accordance with section 587T, except to the extent that the Secretary determines that such information—

"(A) is trade secret or confidential commercial **or financial** information; or

"(B) if posted, ~~would present a risk to~~ **could compromise** national security.

"(4) ADDITIONAL REQUIREMENTS.—Labeling for an in vitro clinical test used for immunohematology testing shall meet the applicable requirements set forth in part 660 of title 21, Code of Federal Regulations (or any successor regulations), related to the labeling of blood grouping reagents, reagent red blood cells, and anti-human globulin.

"(d) Exemptions and Alternative Requirements.—

"(1) IN GENERAL.—

"(A) IN GENERAL.—With respect to an in vitro clinical test that meets the criteria of subparagraph (B), the 'state in one place' regulations under section 809.10(b) of title 21, Code of Federal Regulations (or any successor regulations) may be satisfied by the laboratory posting such information on its website or in multiple documents, if such documents are maintained and accessible in one place.

"(B) APPLICABLE TESTS.—An in vitro clinical test meets the criteria of this subparagraph if such test is—

"(i) developed by a laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements to perform tests of high-complexity; and

"(ii) performed in—

"(I) the same laboratory in which such test was developed; or

"(II) by another laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

"(aa) meets the requirements to perform tests of high complexity; and

"(bb) is under common ownership and control as the laboratory that developed the test.

"(2) TEST INSTRUMENT LABELING.—Unless the instrument is the entire test system, the labeling for an instrument is not required to bear the information indicated in paragraphs (3), (4), (5), (7), (8), (9), (10), (11), (12), and (13) of section 809.10(b) of title 21, Code of Federal Regulations (or any successor regulations).

"(3) REAGENT LABELING.—For purposes of compliance with subsection (c)(1), the labeling for a reagent intended for use as a replacement in an in vitro clinical test may be limited to that information necessary to identify the reagent adequately and to describe its

proper use in the test.

"(4) INVESTIGATIONAL USE.—A shipment or other delivery of an in vitro clinical test for investigational use pursuant to section 587S shall be exempt from the labeling requirements of subsections (b) and (c)(1) and from any standard promulgated through regulations, except as required under section 353 of the Public Health Service Act or section 587R of this Act.

"(5) GENERAL PURPOSE LABORATORY REAGENTS.—The labeling of general purpose laboratory reagents (such as hydrochloric acid) whose uses are generally known by persons trained in their use need not bear the directions for use required by subsection (c)(1)(A).

"(6) OVER-THE-COUNTER TEST SPECIMEN RECEPTACLE LABELING.—The labeling for over-the-counter test specimen receptacles for drugs of abuse testing shall bear the name and place of business of the developer included in the registration under section 587J and any information specified in applicable regulations promulgated under this section, in language appropriate for the intended users.

"(e) Tests in the Strategic National Stockpile.—

"(1) IN GENERAL.—The Secretary may grant an exception or alternative to any provision listed in this section, unless explicitly required by a statutory provision outside this subchapter, for specified lots, batches, or other units of an in vitro clinical test, if the Secretary determines that compliance with such labeling requirement could adversely affect the availability of such products that are, or will be, included in the Strategic National Stockpile under section 319F–2 of the Public Health Service Act.

"(2) REGULATIONS.—The Secretary may issue regulations amending section 809.11 of title 21, Code of Federal Regulations (or any successor regulation) to apply in full or in part to in vitro clinical tests and in vitro clinical test developers.

"(f) Regulations.—The Secretary shall issue or revise regulations related to standardized, general content and format for in vitro clinical test labeling pursuant to this subsection.

"SEC. 587M. ADVERSE EVENT REPORTING.

"(a) In General.—Each in vitro clinical test developer shall establish and maintain a system for establishing and maintaining records of adverse events and reporting adverse events in accordance with this section.

"(b) Submission of Individual Reports.—A developer shall submit an individual adverse event not later than 5 calendar days after the developer receives or becomes aware of an adverse event that reasonably suggests that an in vitro clinical test may—

"(1) have caused or contributed to a patient or user death; or

"(2) present an imminent threat to public health.

"(c) Submission of Quarterly Reports.—As applicable, a developer shall submit quarterly reports that include any in vitro clinical test errors and serious injuries that occurred during the applicable quarter. Such quarterly reports shall be submitted not later than the end of the quarter following the quarter in which the developer receives or becomes aware of such adverse events.

"(d) Definitions.—For the purposes of this section—

"(1) the term 'in vitro clinical test error' means a failure of an in vitro clinical test to meet its performance specifications, or to otherwise perform as intended by the developer, including an inaccurate result resulting from such failure; and

"(2) the term 'serious injury' means—

"(A) a significant delay in a diagnosis that results in the absence, delay, or discontinuation of critical medical treatment or that irreversibly or seriously and negatively alters the course of a disease or condition; or

"(B) an injury that—

"(i) is life threatening;

"(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

"(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

"(e) Regulations.—The Secretary shall promulgate regulations to implement this section.

"SEC. 587N. CORRECTIONS AND REMOVALS.

"(a) Regulations.—The Secretary shall promulgate regulations, or amend existing regulations, as appropriate, to implement this section.

"(b) Reports of Corrections and Removals.—

"(1) IN GENERAL.—Each in vitro clinical test developer shall report to the Secretary any correction or removal of an in vitro clinical test undertaken by such developer if the correction or removal was undertaken—

"(A) to reduce the risk to health posed by the in vitro clinical test; or

"(B) to remedy a violation of this Act caused by the in vitro clinical test which may present a risk to health.

"(2) EXCEPTION FOR IN VITRO CLINICAL TESTS OFFERED UNDER A TECHNOLOGY CERTIFICATION ORDER.—For any eligible test offered under a technology certification order under section 587D, a correction and removal report for any correction or removal of an in vitro clinical test should demonstrate that the issue or issues causing the correction or removal do not adversely impact the ability of other in vitro clinical tests offered under the same technology certification order to meet the applicable standard.

"(c) Timing.—A developer shall submit any report required under this subsection to the Secretary within 15 business days of initiating such correction or removal.

"(d) Recordkeeping.—A developer of an in vitro clinical test that undertakes a correction or removal of an in vitro clinical test which is not required to be reported under this subsection shall keep a record of such correction or removal.

"(e) Recall Communications.—Upon the ~~voluntary~~ reporting of a correction or removal by the developer—

"(1) the Secretary shall classify such correction or removal under this section within ~~15~~

45 calendar days; and

"(2) not later than ~~45~~ **70** calendar days after the developer or other responsible party notifies the Secretary that it has completed a recall action, the Secretary shall provide the developer or other responsible party with a written statement closing the recall action or stating the reasons the Secretary cannot close the recall at that time.

"SEC. 587O. RESTRICTED IN VITRO CLINICAL TESTS.

"(a) Applicability.—

"(1) IN GENERAL.—For the types of in vitro clinical tests described in paragraph (3)**,** the Secretary may require, in issuing an approval of an in vitro clinical test under section 587B, granting a technology certification order under section 587D, or in issuing a determination under section 587F(a), or by issuing a regulation, that such test, or category of tests, be restricted to sale, distribution, or use upon such conditions as the Secretary may prescribe under paragraph (2).

"(2) CONDITIONS.— The Secretary may prescribe conditions under this section, based on available evidence, with respect to an in vitro clinical test described in paragraph (3), that are determined to be needed due to the potential for harmful effect of such test (including any resulting absence, significant delay, or discontinuation of appropriate medical treatment), and are necessary to ensure that the test meets the applicable standard.

"(3) IN VITRO CLINICAL TESTS SUBJECT TO RESTRICTIONS.—The restrictions or conditions authorized under this section may be applied by the Secretary to any high-risk or moderate-risk in vitro clinical test, prescription home-use in vitro clinical test, direct-to-consumer in vitro clinical test, or over-the-counter in vitro clinical test.

"(b) Labeling and Advertising of a Restricted in Vitro Clinical Test.—The labeling and advertising of an in vitro clinical test to which restrictions apply under subsection (a) shall bear such appropriate statements of the restrictions as the Secretary may prescribe in an approval under section 587B, an order under section 587D, a determination under section 587F(a), or in regulation, as applicable.

"(c) Device Restrictions.—An in vitro clinical test that was offered as a restricted device prior to the date of enactment of this subchapter—

"(1) shall continue to comply with the applicable restrictions under section 515 or section 520(e) until ~~the~~ this subchapter takes effect; and

"(2) except for in vitro clinical tests required to meet **the requirements of** section 809.30 of title 21, Code of Federal Regulations prior to the effective date of this subchapter specified in section 825(a)(1)(A) of the VALID Act of 2022, such restrictions **described in paragraph (1)** shall be deemed to be restrictions under this ~~Act~~ **subchapter** as of such effective date.

"SEC. 587P. APPEALS.

"(a) Significant Decision.—

"(1) IN GENERAL.—The Secretary ~~shall~~ **shall—**

"(A) maintain a substantive summary of the scientific and regulatory rationale for any significant decision of the Food and Drug Administration pursuant to section 587F, regarding—

~~"(A)~~**"(i)** the submission of an application for, or a review of, an in vitro clinical test under section 587B or section 587D;

~~"(B)~~**"(ii)** an exemption under section 587C; or

~~"(C)~~**"(iii)** any requirements for mitigation measures to an in vitro clinical test or category of in vitro clinical tests**; and**~~.~~

~~Such~~**"(B) include in such** summaries ~~shall include~~ documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

"(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish a substantive summary described in paragraph (1) to the person who has made, or is seeking to make, a submission described in such paragraph.

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 587AA(c), as applicable.

"(b) Review of Significant Decisions.—

"(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—A developer may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the agency official who made the significant decision.

"(2) SUBMISSION OF REQUEST.—A developer requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after the decision for which the review is requested and shall indicate in the request whether such developer seeks an in-person meeting or a teleconference review.

"(3) TIMEFRAME.—The Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the developer requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a developer who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

"(c) Advisory Panels.—The process established under subsection (a) shall permit the appellant to request review by an advisory committee established under section 587G when there is a dispute involving substantial scientific fact. If an advisory panel meeting is held, the Secretary shall make a determination under this subsection not later than 45 days after the requested advisory committee meeting has concluded.

"(d) Least Burdensome Review.—Any developer who has submitted an application under section 587B or 587D may request a supervisory review of a request for additional information during an evaluation of such submission within 60 calendar days of receipt of the additional information request from the Secretary.

"(e) Availability of All Remedies.—The procedures set forth in this section shall be in addition to, and not in lieu of, other remedies available to the developer.

"SEC. 587Q. ACCREDITED PERSONS.

"(a) In General.—

"(1) AUTHORIZATION.—Beginning on the date of enactment of the VALID Act of 2022, the Secretary shall accredit persons for any of the following purposes:

"(A) Reviewing applications for premarket approval under section 587B and making findings with respect to such applications.

"(B) Reviewing applications for technology certification under section 587D and making recommendations to the Secretary with respect to such applications.

"(C) Conducting inspections as specified in subsection (c) of in vitro clinical test developers and other persons required to register pursuant to section ~~587I~~ **587J**.

"(2) PERSONS SUBMITTING APPLICATIONS.—A person submitting an application for premarket approval under section 587B or an application for technology certification under section 587D may submit such application to the Secretary or to a person accredited pursuant to subparagraph (A) or (B) of paragraph (1).

"(b) Accredited Persons Application Reviews, Findings and Recommendations.—

"(1) REQUIREMENTS FOR PREMARKET APPLICATION.—

"(A) REVIEW AND FINDING REQUIREMENTS.—An accredited person receiving an application for premarket approval under section 587B shall either—

"(i) provide to the Secretary, together with the application for premarket approval submitted by the applicant, a finding that the criteria for approval of the application under section ~~587B(g)(2)(A)~~ **587B(e)(2)(A)** are met and issue a copy of such finding to the applicant, which finding shall plainly state—

"(I) the basis for the accredited person's finding that the criteria under section ~~587B(g)(2)(A)~~ **587B(e)(2)(A)** are met; and

"(II) any proposed restrictions, mitigating measures, or conditions of approval under section ~~587B(g)(2)(B)~~ **587B(e)(2)(B)**, as applicable; or

"(ii) provide a notification to the applicant that the accredited person cannot find that the criteria for approval of the application under section ~~587B(g)(2)(A)~~ **587B(e)(2)(A)** are met and the reasons for such decision.

"(B) REQUESTING MISSING OR CLARIFYING INFORMATION.—After receipt of an application **from a developer** under this section, the Secretary may request missing or clarifying information from the applicant concerning the application, which the ~~applicant~~ **developer** shall promptly provide.

"(C) SECRETARY ACTION ON FINDING THAT APPROVAL CRITERIA ARE MET.—If the accredited person transmits a finding to the Secretary under ~~clause (i) of~~ subparagraph (A)**(i)**, then prior to the date that is 45 calendar days after the transmittal date**,** the Secretary shall—

"(i) approve the application for premarket approval under section ~~587B(g)(2)~~ **587B(e)(2)** with appropriate restrictions, mitigating measures, or conditions of approval, as applicable; or

"(ii) deny approval of the application by issuing a written notice that reflects appropriate management input and concurrence to the accredited person and the applicant detailing the scientific basis for the Secretary's determination that the criteria for issuance of an approval under section ~~587B(g)(2)(A)~~ **587B(e)(2)(A)** have not been met.

"(D) EFFECT OF INACTION ON FINDING.—If the Secretary fails to take an action under subparagraph (C) the Secretary shall—

"(i) within 45 calendar days after the transmittal date, provide written feedback to the applicant that—

"(I) includes all outstanding issues with the application preventing the Secretary from taking an action under subparagraph (B);

"(II) reflects appropriate management input and concurrence; and

"(III) includes action items for the Secretary, the applicant, or both, as appropriate, with an estimated date of completion for the Secretary and the applicant to complete their respective tasks, as applicable; and

"(ii) promptly schedule a meeting or teleconference to discuss the feedback provided under clause (i), unless the Secretary and applicant agree that the outstanding issues are adequately presented through written correspondence and a meeting or teleconference is not necessary.

"(2) REQUIREMENTS FOR TECHNOLOGY CERTIFICATION.—

"(A) REVIEW AND RECOMMENDATION REQUIREMENTS.—An accredited person receiving an application for technology certification under section 587D shall either—

"(i) provide to the Secretary, together with the application for technology certification submitted by the applicant, a recommendation that the criteria for issuance of a technology certification order under section ~~587D(f)(3)~~ **587D(d)(3)** are met and issue a copy of such recommendation to the applicant, which recommendation shall plainly state the basis for the accredited person's recommendation that the criteria under section ~~587D(f)(3)~~ **587D(d)(3)** are met; or

"(ii) provide a notification to the applicant that the accredited person cannot recommend that the criteria for issuance of a technology certification order under section ~~587D(f)(3)~~ **587D(d)(3)** are met and the reasons for such decision.

"(B) REQUESTING MISSING OR CLARIFYING INFORMATION.—After receipt of an application under this section, the ~~Secretary~~ **accredited person** may request missing or clarifying information from the applicant concerning the application, which the applicant shall promptly provide.

"(C) SECRETARY ACTION ON RECOMMENDATION FOR ISSUANCE OF A TECHNOLOGY CERTIFICATION ORDER.—If the accredited person transmits a recommendation to the Secretary under clause (i) of subparagraph (A), then prior to the date that is 60 calendar

days after the transmittal date the Secretary shall—

"(i) issue the technology certification order under section ~~587D(f)(3)~~ **587D(d)(3)**, consistent with such recommendation from the accredited person; or

"(ii) deny approval of the application by issuing a written notice to the accredited person and the applicant detailing the scientific basis for a determination by the Secretary that the criteria for issuance of a technology certification order under section ~~587D(f)(3)~~ **587D(d)(3)** have not been met.

"(c) Requirements for Inspections.—

"(1) IN GENERAL.—When conducting inspection, persons accredited under ~~subparagraph~~ **subsection** (a)(1)(B) shall record in writing their specific observations and shall present their observations to the designated representative of the inspected establishment.

"(2) INSPECTION REPORT REQUIREMENTS.—Each person accredited under ~~this subparagraph~~ **subsection** (a)(1)(C) shall prepare and submit to the Secretary an inspection report in a form and manner designated by the Secretary for conducting inspections. Any statement or representation made by an employee or agent of an establishment to a person accredited to conduct inspections under ~~subparagraph~~ **subsection** (a)(1)(C) shall be subject to section 1001 of title 18, United States Code.

"(3) SAVINGS CLAUSE.—Nothing in this section affects the authority of the Secretary to inspect any in vitro clinical test developer or other person registered under section ~~587I~~ **587J** or recognize inspections conducted by auditing organizations as described under section 704(g)(15).

"(4) INSPECTION LIMITATIONS.—The Secretary shall ensure that inspections carried out under this section are not duplicative of inspections carried out under section 353 of the Public Health Service Act. Inspections under this section shall be limited to the data and information necessary—

"(A) for routine surveillance activities of facilities associated with an approved application under section 587B or issuance of a technology certification order under section 587D; or

"(B) to meet the requirements for premarket approval under section 587B or issuance of a technology certification order under section 587D, as applicable.

"(d) Accreditation.—

"(1) ACCREDITATION PROGRAM.—The Secretary may provide for accreditation under this section through programs administered by the Food and Drug Administration, by other non-Federal government agencies, or by qualified nongovernmental organizations. A person may be accredited for the review of applications submitted under sections 587B as described in subsection (a)(1)(A), for the review of applications submitted under section 587D as described in subsection (a)(1)(B)**,** and to conduct inspection activities under subsection (a)(1)(C), or for a subset of such reviews or activities.

"(2) ELIGIBLE PERSONS.—

"(A) MINIMUM QUALIFICATIONS.—An accredited person, at a minimum, shall—

"(i) not be an employee of the Federal Government;

"(ii) not engage in the activities of a developer, as defined in section 587(7);

"(iii) not be a person required to register under section ~~587l~~ **587J**, unless such person has established sufficient processes and protocols to separate activities to develop in vitro clinical tests and the activities for which such person would be accredited under subsection (a) and discloses applicable information under this section;

"(iv) not be owned or controlled by, and shall have no organizational, material, or financial affiliation with, an in vitro clinical test developer or other person required to register under section ~~587l~~ **587J**;

"(v) be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

"(vi) ensure that the operations of such person are in accordance with generally accepted professional and ethical business practices; and

"(vii) include in its request for accreditation a commitment to, at the time of accreditation and at any time it is performing activities pursuant to this section—

"(I) certify that the information reported to the Secretary accurately reflects the data or protocol reviewed, and the documented inspection findings, as applicable;

"(II) limit work to that for which competence and capacity are available;

"(III) treat information received or learned, records, reports, and recommendations as proprietary information of the person submitting such information; and

"(IV) in conducting the activities for which the person is accredited in respect to a particular in vitro clinical test, protect against the use of any employee or consultant who has a financial conflict of interest regarding that in vitro clinical test.

"(B) WAIVER.—The Secretary may waive any requirements in clauses (i), (ii), (iii), or (iv) of subparagraph (A) upon making a determination that such person has implemented other appropriate controls sufficient to ensure a competent and impartial review.

"(3) ACCREDITATION PROCESS.—

"(A) ACCREDITATION PROCESS GUIDANCE AND REGULATIONS.—Not later than 180 days after the date of enactment of the VALID Act of 2022, the Secretary shall issue draft guidance specifying the process for submitting a request for accreditation and reaccreditation under this section, including the form and content of information to be submitted, including the criteria that the Secretary will consider to accredit or deny accreditation and, not later than 1 year after the close of the comment period for the draft guidance, issue final guidance.

"(B) RESPONSE TO REQUEST.—The Secretary shall respond to a request for

accreditation or reaccreditation within 60 calendar days of the receipt of the request. The Secretary's response may be to accredit or reaccredit the person, to deny accreditation, or to request additional information in support of the request. If the Secretary requests additional information, the Secretary shall respond within 60 calendar days of receipt of such additional information to accredit or deny the accreditation.

"(C) TYPE OF ACCREDITATION.—The accreditation or reaccreditation of a person shall specify the particular activity or activities under subsection (a) for which such person is accredited, and shall include any limitation to certain eligible in vitro clinical tests.

"(D) PUBLIC LIST.—The Secretary shall publish on the website of the Food and Drug Administration a list of persons who are accredited under this section. Such list shall be updated on at least a monthly basis. The list shall specify the particular activity or activities under this section for which the person is accredited.

"(E) AUDIT.—The Secretary may audit the performance of persons accredited under this section for purposes of ensuring that such persons continue to meet the published criteria for accreditation, and may modify the scope or particular activities for which a person is accredited if the Secretary determines that such person fails to meet one or more criteria for accreditation.

"(F) SUSPENSION OR WITHDRAWAL.—The Secretary may suspend or withdraw accreditation of any person accredited under this section, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or the published criteria for accreditation, or poses a threat to public health, or fails to act in a manner that is consistent with the purposes of this section.

"(G) REACCREDITATION.—Accredited persons may be initially accredited for up to 3 years. After expiration of such initial period, persons may be reaccredited for unlimited additional ~~35~~ **5**-year periods, as determined by the Secretary.

"(e) Compensation of Accredited Persons.—Compensation of an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

"(f) International Harmonization.—Notwithstanding any other provision of this section, to facilitate international harmonization the Secretary may recognize persons accredited or recognized by governments, who have also entered into information sharing agreements, including confidentiality commitments, with the Commissioner of Food and Drugs.

"(g) Information Sharing Agreements.—An accredited person may enter into an agreement with a test developer to provide information to the comprehensive test information system under section 587T, including any requirements under section ~~587I~~ **587J**.

"(h) Reports.—Not later than 2 years after the effective date of the VALID Act of 2022, and annually thereafter for the next 4 years, the Secretary shall post on the website of the Food and Drug Administration, a report describing the Secretary's performance in implementing this section, including the Secretary's progress in minimizing duplicative reviews of applications for which an accredited person finds the criteria for approval are met. Such reports shall include, for

each period—

"(1) with regard to premarket approval applications—

"(A) the total number of findings transmitted to the Secretary under subsection (b)(1)(A)(i);

"(B) the total number of determinations made by the Secretary under subsection (b)(1)(B)(i) within 30 calendar days of the transmittal date to approve an application;

"(C) the total number of determinations made by the Secretary under subsection (b)(1)(B)(ii) within 30 calendar days of the transmittal date to deny approval of an application; and

"(D) the total number of applications that were approved and the total number of applications that were denied approval, after the Secretary failed to make a determination within 30 calendar days of the transmittal date under subsection (b)(1)(B); and

"(2) with regard to applications for technology certification—

"(A) the total number of recommendations transmitted to the Secretary under subsection (b)(2)(A)(i);

"(B) the total number of determinations made by the Secretary under subsection (b)(2)(B)(i) to issue a technology certification order, including determinations made within 30 days of the transmittal date;

"(C) the total number of determinations made by the Secretary under subsection (b)(2)(B)(ii) to deny the application for technology certification, including determinations made within 30 calendar days of the transmittal date; and

"(D) the total number of technology certification orders issued, and the total number of applications for technology certification that were denied, including applications denied after the Secretary failed to make a determination within 30 calendar days of the transmittal date under subsection (b)(2)(B).

"SEC. 587R. RECOGNIZED STANDARDS.

"(a) In General.—The Secretary may recognize all or part of appropriate standards established by nationally or internationally recognized standards development organizations for which a person may submit a declaration of conformity in order to meet a requirement under this subchapter to which that standard is applicable. Standards for in vitro diagnostic devices previously recognized under section 514(c) shall be considered recognized standards under this section. Recognized and proposed standards shall be accessible to the public at no charge. The application of any such consensus standard shall only apply prospectively. The Secretary shall issue regulations establishing the criteria and process, for such recognition and adoption.

"(b) Amendment Process.—The procedures established in this section or in regulation or guidance issued under this section shall apply to amendment of an existing standard.

"SEC. 587S. INVESTIGATIONAL USE.

"(a) In General.—Subject to the conditions prescribed in subsections (c), (d), (e), (f), and (g)

~~of this section~~, an in vitro clinical test for investigational use shall be exempt from the requirements of this subchapter**,** other than sections 587A, 587P, 587T, and 587V. The Secretary may amend parts 50, 54, and 56 of title 21 of the Code of Federal Regulations~~, or any successor regulations,~~ to apply to in vitro clinical tests to permit the investigational use of such tests by experts qualified by scientific training and experience.

"(b) Regulations.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the VALID Act of 2022, the Secretary shall promulgate regulations, or amend existing regulations, to implement this section.

"(2) VARIATION.—The requirements in the regulations promulgated under this section shall take into account variations based on—

"(A) the scope and duration of clinical testing to be conducted under investigation that is the subject of such application;

"(B) the number of human subjects that are to be involved in such testing;

"(C) the need to permit changes to be made to the in vitro clinical test involved during testing conducted in accordance with a plan required under subsection ~~(c)(5);~~**(c)(6);** or

"(D) whether the clinical testing of such in vitro clinical test is for the purpose of developing data to obtain approval to offer such test.

"(c) Application for Investigational Use.—The following shall apply with respect to in vitro clinical tests for investigational use:

"(1) SIGNIFICANT RISK AND OTHER STUDIES.—In the case of an in vitro clinical test the investigational use of which poses a significant risk to the human subject **or involves an exception from informed consent for emergency research**, a sponsor of an investigation of such a test seeking an investigational use exemption shall submit to the Secretary an investigational use application with respect to the in vitro clinical test in accordance with paragraphs (3) and (4). ~~For purposes of this subparagraph, the term 'significant risk' means, with respect to an in vitro clinical test and that the use of such in vitro clinical test~~

~~* 9 "(A) is of substantial importance in performing an activity or activities described in section 201(ss)(1) for, a serious or life-threatening disease or condition without confirmation of the diagnosis by a medically established diagnostic product or procedure;~~

~~* 10 "(B) requires an invasive sampling procedure that presents a significant risk to the human subject, provided that routine venipuncture shall not be considered an invasive sampling procedure; or~~

~~* 11 "(C) otherwise presents a potential for serious risk to the health of a human subject.~~

"(2) NON-SIGNIFICANT RISK STUDIES.—In the case of an in vitro clinical test, the investigational use of which is not described in paragraph (1)—

"(A) the sponsor of such investigation shall—

"(i) ensure such investigation is conducted in compliance with an investigational plan approved by an institutional review committee and the labeling of the in vitro clinical test involved clearly and conspicuously states, 'For investigational use only', as specified in paragraph (4)(A)(ii);

"(ii) ensure each investigator obtains informed consent as required under part 50, 54, and 56 of title 21, Code of Federal Regulations (or any successor regulations), subject to the exceptions set forth in paragraph (6)(C);

"(iii) establish and maintain records with respect to all requirements in this subparagraph;

"(iv) maintain records and make reports as ~~established~~ **required** by the Secretary ~~in~~ **pursuant to** regulations issued under subsection (b); and

"(v) ensure that investigators monitor investigations, maintain records and make reports as ~~established~~ **required** by the Secretary ~~in~~ **pursuant to** regulations issued under subsection (b); and

"(B) the sponsor may rely on any exception or exemption described in paragraph ~~(5)(B)~~**(4)** or as established by the Secretary in regulations issued under subsection (b).

"(3) APPLICATION.—An investigational use application shall be submitted in such time and manner and contain such information as the Secretary may require in regulation, and shall include an investigational plan for proposed clinical testing and assurances that the sponsor submitting the application will—

"(A) establish and maintain records relevant to the investigation of such in vitro clinical test; and

"(B) submit to the Secretary annual reports of data obtained as a result of the investigational use of the in vitro clinical test during the period covered by the exemption that the Secretary reasonably determines will enable the Secretary—

"(i) to ensure compliance with the conditions for the exemption specified in paragraph (4);

"(ii) to review the progress of the investigation involved; and

"(iii) to evaluate the ability to meet the applicable standard.

"(4) CONDITIONS FOR EXEMPTION.—

"(A) IN GENERAL.—An application for an investigational use exemption with respect to a significant risk study shall be granted if each of the following conditions is met:

"(i) The risks to the subjects of the in vitro clinical test are outweighed by the anticipated benefits of the test to the subjects and the importance of the knowledge to be gained, and adequate assurance of informed consent is provided in accordance with paragraphs ~~(6)(A)(iii) and~~(6)(B) **and (6)(C)**.

"(ii) The proposed labeling for the in vitro clinical test involved clearly and conspicuously states 'For investigational use only'.

"(iii) Such other requirements the Secretary determines—

"(I) are necessary for the protection of the public health and safety; and

"(II) do not unduly delay investigation.

"(B) CERTAIN SIGNIFICANT RISK STUDIES OF IN VITRO CLINICAL TESTS FOR AN UNMET NEED.—The Secretary shall not impose a limit on the sample size for a significant risk study of an in vitro clinical test that has received breakthrough designation under section 587I.

"(5) COORDINATION WITH INVESTIGATIONAL NEW DRUG APPLICATIONS.—Any requirement for the submission of a report to the Secretary pursuant to an application for an investigational new drug exemption involving an in vitro clinical test shall supersede the reporting requirement ~~in~~ **under** paragraph (3)(B), but only to the extent the requirement with respect to the application for exemption with respect to the drug is duplicative of the reporting requirement under such paragraph.

"(6) INVESTIGATIONAL PLAN, PROCEDURES, AND CONDITIONS.—With respect to an investigational plan submitted under paragraph (3), the sponsor submitting such plan shall—

"(A) promptly notify the Secretary of the approval or the suspension or termination of the approval of such plan by an institutional review committee;

"(B) in the case of an in vitro clinical test made available to investigators for clinical testing, obtain agreements from each investigator that any testing of the in vitro clinical test involving human subjects will be under such investigator's supervision and in accordance with paragraph (C) and submit such agreements to the Secretary that ensure—

"(i) all investigators will comply with this section, regulations promulgated or revised under this section, and applicable human subjects regulations; and

"(ii) the investigator will ensure that—

"(I) informed consent is obtained as required under part 50 of title 21, Code of Federal Regulations (or any successor regulations), amended to apply to in vitro clinical tests; and

"(II) the requirements for institutional review board under part 56 of title 21 of the Code of Federal Regulations (or successor regulations), amended to apply to in vitro clinical tests, are met; and

"(C) ~~assure~~ **ensure** that informed consent will be obtained from each human subject (or the representative of such subject) of proposed clinical testing involving such in vitro clinical test, except where, subject to such other conditions as the Secretary may prescribe—

"(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

"(ii) the investigator conducting or supervising the clinical testing determines in

writing that there exists a life-threatening situation involving the human subject of such testing which necessitates the use of such in vitro clinical test and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from a representative of such subject.

"(7) CONCURRED BY LICENSED PHYSICIAN.—The determination required by paragraph (6)(C)(ii) shall be concurred in writing by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the ~~device~~ **in vitro clinical test** is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

"(8) SIGNIFICANT RISK.—For purposes of this subsection, the term 'significant risk' means, with respect to an in vitro clinical test, that the use of such in vitro clinical test—

**** 9** "(A) is of substantial importance in performing an activity or activities described in section 201(ss)(1) for, a serious or life-threatening disease or condition without confirmation of the diagnosis by a medically established diagnostic product or procedure;

**** 10** "(B) requires an invasive sampling procedure that presents a significant risk to the human subject, provided that routine venipuncture shall not be considered an invasive sampling procedure; or

**** 11** "(C) otherwise presents a potential for serious risk to the health of a human subject.

"(d) Review of Applications.—

"(1) IN GENERAL.—The Secretary may issue an order approving an investigation as proposed, approving it with conditions or modifications, or disapproving it.

"(2) FAILURE TO ACT.—Unless the Secretary, not later than ~~the date that is~~ 30 calendar days after the date of the submission of an application for an investigational use exemption that meets the requirements of subsection (c), issues an order under paragraph (1) and notifies the sponsor submitting the application, the application shall be treated as approved as of such date without further action by the Secretary.

"(3) DENIAL.—The Secretary may deny an investigational use application submitted under this subsection if the Secretary determines that the investigation with respect to which the application is submitted does not conform to the requirements of subsection (c). A notification of such denial submitted to the sponsor with respect to such a request shall contain the order of disapproval and a complete statement of the reasons for the Secretary's denial of the application.

"(e) Withdrawal of Exemption.—

"(1) IN GENERAL.—The Secretary may, by administrative order, withdraw an exemption approved under this section with respect to an in vitro clinical test, including an exemption treated as approved based on the Secretary's failure to act pursuant to subsection (d)(2), if the Secretary determines that an investigation conducted under such an exemption does not meet the applicable conditions under subsection (c)(3) for such exemption.

"(2) OPPORTUNITY TO BE HEARD.—

"(A) IN GENERAL.—Subject to subparagraph (B), an order withdrawing an investigational use exemption granted under this section may be issued only after the Secretary provides the sponsor of the in vitro clinical test with an opportunity for an informal hearing.

"(B) EXCEPTION.—An order referred to in subparagraph (A) with respect to an investigational use exemption granted under this section may be issued on a preliminary basis before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption will result in an unreasonable risk to the public health. The Secretary will provide an opportunity for an informal hearing promptly following any preliminary action under this subparagraph.

"(f) Changes.—

"(1) IN GENERAL.—The regulations promulgated under subsection (b) shall provide, with respect to an in vitro clinical test for which an exemption under this subsection is in effect, procedures and conditions under which changes are allowed without the additional approval of an application for an exemption or submission of a supplement to such an application. Such regulations shall provide that such a change may be made if—

"(A) the sponsor determines, on the basis of credible information (as defined in regulations) that the change meets the conditions specified in paragraph (2); and

"(B) the sponsor submits to the Secretary, not later than 5 calendar days after making the change, a notice of the change.

"(2) CONDITIONS.—The conditions specified in this paragraph are that—

"(A) in the case of developmental changes to an in vitro clinical test, including manufacturing changes, the changes—

"(i) do not constitute a significant change in design or in basic principles of operation;

"(ii) do not affect the rights, safety, or welfare of the human subjects involved in the investigation; and

"(iii) are made in response to information gathered during the course of an investigation; and

"(B) in the case of changes to clinical protocols applicable to the test, the changes do not affect—

"(i) the validity of data or information resulting from the completion of an approved clinical protocol, or the relationship of likely patient risk to benefit relied upon to approve a product;

"(ii) the scientific soundness of a plan submitted under subsection (c)(3); or

"(iii) the rights, safety, or welfare of the human subjects involved in the investigation.

"(g) Clinical Hold.—

"(1) IN GENERAL.—At any time, the Secretary may impose a clinical hold with respect to an investigation of an in vitro clinical test if the Secretary makes a written determination described in paragraph (2). The Secretary shall, in imposing such clinical hold, specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing. The applicant may immediately appeal any such determination pursuant to section 587P.

"(2) DETERMINATION.—

"(A) IN GENERAL.—For purposes of paragraph (1), a determination described in this subparagraph with respect to a clinical hold is a determination that, based on credible evidence, the in vitro clinical test involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the in vitro clinical test, the design of the clinical investigation, the condition for which the in vitro clinical test is to be investigated, and the health status of the subjects involved.

"(B) REMOVAL OF CLINICAL HOLD.—Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

"SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.

"(a) Establishment.—Not later than 2 years after the date of enactment of the VALID Act of 2022, the Secretary shall make available a comprehensive test information system for in vitro clinical tests that is designed to—

"(1) provide a transparent interface on the website of the Food and Drug Administration for stakeholders, to the extent permitted by applicable law, which may include access to the—

"(A) regulatory pathway designation information for each in vitro clinical test or tests with the same indications for use;

"(B) registration and listing information provided by developers under section 587J, including the use of a link for labels;

"(C) adverse event reports submitted under section 587M, as appropriate;

"(D) reports of corrections and removals submitted under section 587N; and

"(E) other information pertaining to an in vitro clinical test or tests with the same indications for use, as the Secretary determines appropriate; and

"(2) provide a secure portal for electronic submission, including applications and other in vitro clinical test submissions, registration and listing information, and adverse event reports, which provides protections from unauthorized disclosure of information, including of—

"(A) trade secret or ~~commercial~~ confidential **commercial or financial** information;

and

"(B) ~~national security, countermeasure, or other information restricted from disclosure pursuant to any provision of law.~~ **information that could compromise national security.**

"(b) Submission Function.—The comprehensive test information system shall serve as the electronic submission service for test developers submitting information for applications under sections 587B and 587D.

"SEC. 587U. PREEMPTION.

"(a) In General.—Except as provided in subsection (b), no State, Tribal, or local government (or political subdivision thereof) may establish or continue in effect any ~~requirement that~~ **requirement—**

"(1) **that** is different from, or in addition to, any requirement applicable to an in vitro clinical test under this Act; or

"(2) with respect to the analytical validity, clinical validity, or safety for individuals who come into contact with such an in vitro clinical test ~~under this Act~~.

"(b) Exceptions.—Subsection (a) shall not be construed to affect the authority of a State, Tribal, or local government to do any of the following:

"(1) To license laboratory personnel, health care practitioners, or health care facilities or to regulate any aspect of a health care practitioner-patient relationship.

"(2) To enforce laws of general applicability, such as zoning laws, environmental laws, labor laws, and general business laws.

"(3) To authorize laboratories to develop and perform an in vitro clinical test, pursuant to a law enacted by a State prior to January 1, 2022, as long as such law does not impose requirements that are different from any requirement applicable to an in vitro clinical test under this Act. If a State has enacted such a law, the Secretary may exempt such laboratories in that State from compliance with this subchapter.

"(c) Clarification.—Nothing in this section shall be construed to—

"(1) modify any action for damages or the liability of any person under the law of any State; or

"(2) shift liability to health care practitioners or other users.

"SEC. 587V. ADULTERATION.

"An in vitro clinical test shall be deemed to be adulterated:

"(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

"(2) If it has been developed, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

"(3) If its container or package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

"(4) If it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a).

"(5) If its analytical or clinical validity, as applicable, or with respect to a specimen receptacle, its safety, falls below that which it purports or is represented to possess.

"(6) If it is required to be, declared to be, purports to be, or is represented as being, in conformity with any performance standard established or recognized under section 587R and is not in conformity with such standard.

"(7) If it is required to be in compliance with mitigating measures established under section 587E and is not in conformity with such mitigating measures.

"(8) If it fails to have in effect an approved premarket application under section 587B**,** unless such in vitro clinical test is in compliance with the requirements for—

"(A) offering without an approved premarket application under section 587D**(b)(1)**;

"(B) an exemption from premarket approval under section 587C or 587G; or

"(C) investigational use pursuant to section 587S.

"(9) If it is not in conformity with any condition established under section 587B or 587D.

"(10) If it purports to be an in vitro clinical test subject to an exemption under section 587C and it fails to meet or maintain any criteria, condition, or requirement of such exemption.

"(11) If it has been granted an exemption under section 587S for investigational use, and the person granted such exemption or any investigator who uses such in vitro clinical test under such exemption fails to comply with a requirement prescribed by or under such section.

"(12) If it fails to meet the quality requirements prescribed in or established under section 587K (as applicable), or the methods used in, or facilities or controls used for, its development, packaging, storage, or installation are not in conformity with applicable requirements established under such section.

"(13) If it has been developed, processed, packaged, or held in any establishment, factory, or warehouse and the owner, operator or agent of such establishment, factory, or warehouse delays, denies, or limits an inspection, or refuses to permit entry or inspection.

"(14) If it is not in compliance with any restriction required under section 587O.

"SEC. 587W. MISBRANDING.

"An in vitro clinical test shall be deemed to be misbranded:

"(1) If its labeling is false or misleading in any particular.

"(2) If in a package form unless it bears a label containing—

"(A) the name and place of business of the test developer, packager, or distributor; and

"(B) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count with respect to small packages, unless an exemption is granted by

the Secretary by the issuance of guidance.

"(3) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling, including a test report, is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

"(4) Unless its labeling bears adequate directions for use and such adequate warnings as are necessary for the protection of users of the in vitro clinical test and recipients of the results of such in vitro clinical test, including patients, consumers, donors, and related health care professionals. Required labeling for in vitro clinical tests intended for use in health care facilities, blood establishments, or by a health care professional may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the test developer, or distributor affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

"(5) If there is a reasonable probability that it could cause serious or adverse health consequences or death, including through absence, delay, or discontinuation in diagnosis or treatment, when used in the manner prescribed, recommended, or suggested in the labeling thereof.

"(6) If it was developed, sterilized, packaged, repackaged, relabeled, installed, or imported in an establishment not duly registered under section 587J or it was not included in a listing under section 587J, in accordance with timely reporting requirements under this subchapter.

"(7) In the case of any in vitro clinical test subject to restrictions under section 587O, (1) if its advertising is false or misleading in any particular, (2) if it is offered for clinical use, sold, distributed, or used in violation of such restrictions, or (3) unless the test developer or distributor includes in all advertisements and other descriptive printed matter that such person issues or causes to be issued, a brief statement of the indications for use of the in vitro clinical test and relevant warnings, precautions, side effects, and contraindications. This ~~subsection~~ **paragraph** shall not be applicable to any printed matter that the Secretary determines to be labeling as defined in section 201(m).

"(8) If it is subject to a mitigating measure established under section 587E and does not bear such labeling as may be prescribed in such mitigating measure.

"(9) If it is subject to a standard established under section 587R and it does not bear such labeling as may be prescribed in such standard.

"(10) Unless it bears such labeling as may be required by or established under an applicable labeling requirement under this Act.

"(11) If there was a failure to comply with any requirement prescribed in or under section 587D, 587J, 587K, 587L, 587M, 587N, 587X, 587Y, 587Z, or to provide any report, material, or other information required with respect to in vitro clinical tests under this subchapter.

"SEC. 587X. POSTMARKET SURVEILLANCE.

"(a) In General.—

"(1) IN GENERAL.—In addition to other applicable requirements under this Act, the Secretary may issue an order requiring a developer of a high-risk or moderate-risk in vitro clinical test to conduct postmarket surveillance of such in vitro clinical test, if the failure of the in vitro clinical test is reasonably likely to result in serious adverse health consequences or death from use of such in vitro clinical test.

"(2) CONSIDERATION.—In determining whether to require a developer to conduct postmarket surveillance of an in vitro clinical test, the Secretary shall take into consideration the benefits and risks for the patient and the least burdensome ~~principles~~ **requirements** under section ~~587B(j)~~ **587AA(c)**.

"(b) Surveillance Approval.—

"(1) IN GENERAL.—Each developer required to conduct surveillance of an in vitro clinical test shall submit, within 30 days of receiving an order from the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has the appropriate qualifications and experience to undertake such surveillance and if the plan will result in useful data that can reveal unforeseen adverse events or other information necessary to protect the health of patients or the public.

"(2) TIMELINE.—The developer shall commence surveillance under this section not later than 15 months after the day on which the Secretary orders such postmarket surveillance, unless the Secretary determines more time is needed to commence surveillance.

"(3) PROSPECTIVE SURVEILLANCE.—The Secretary may order a prospective surveillance period of up to 3 years. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the developer or, if no agreement can be reached, upon the completion of a dispute resolution process pursuant to section 562.

"SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.

"(a) In General.—All submissions to the Food and Drug Administration with respect to an in vitro clinical test, unless otherwise agreed to by the Secretary, shall—

"(1) be made electronically; and

"(2) with respect to the information required under sections 587B and 587D, utilize the system described in section ~~587U~~ **587T**.

"(b) Electronic Format.—Beginning on such date as the Secretary specifies in final guidance issued under subsection (c), submissions for in vitro clinical tests, including recommendations submitted by accredited and recognized persons under section 587Q, and any appeals of action taken by the Secretary with respect to such submissions, shall be submitted in such electronic format as specified by the Secretary in such guidance.

"(c) Guidance.—The Secretary shall issue guidance implementing this section. Such guidance may—

"(1) provide standards for the electronic submission required under subsection (a) or the

submission in electronic format required under subsection (b);

"(2) set forth criteria for waivers of, or exemptions from, the requirements of subsection (a) or (b); and

"(3) provide any other information for the efficient implementation and enforcement of this section.

"SEC. 587Z. POSTMARKET REMEDIES.

"(a) Safety Notice.—

"(1) IN GENERAL.—If the Secretary determines that an in vitro clinical test presents an unreasonable risk of substantial harm to the public health, and notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate the risk, the Secretary may issue such order as may be necessary to ensure that adequate safety notice is provided in an appropriate form, by the persons and means best suited under the circumstances, to all health care professionals who prescribe, order, or use the in vitro clinical test and to any other person (including developers, importers, distributors, retailers, and users) who should properly receive such notice.

"(2) NOTICE TO INDIVIDUALS.—An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notice. If the Secretary makes such a determination with respect to such individuals, the order shall require the health care professionals who prescribed, ordered, or used the in vitro clinical test provide notification to the individuals for whom the health professionals prescribed, ordered, or used such test, of the risk presented by such in vitro clinical test and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons required to give notice under the order.

"(b) Repair, Replacement, or Refund.—

"(1) DETERMINATION AFTER AN INFORMAL HEARING.—

"(A) IN GENERAL.—If, after affording opportunity for an informal hearing, the Secretary determines that—

"(i) an in vitro clinical test presents an unreasonable risk of substantial harm to the public health;

"(ii) there are reasonable grounds to believe that the in vitro clinical test was not properly developed or manufactured considering the state of the art as it existed at the time of its development;

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a developer, importer, distributor, or retailer of the in vitro clinical test to exercise due care in the installation, maintenance, repair, or use of the in vitro clinical test; and

"(iv) the notice authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the developer, importer, or any distributor of such in vitro clinical test, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a health professional or user of the in vitro clinical test) other than the person the Secretary determines bears such responsibility.

"(B) SECRETARY APPROVAL OF PLAN.—The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless the Secretary determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, the Secretary shall order a revised plan to be submitted within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary ~~shall (i)~~ **shall—**

"(i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed~~,~~**;** or

~~(ii)~~**"(ii)** after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a developer, importer, distributor, or retailer of the in vitro clinical test with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

"(2) ACTIONS ON A PLAN.—The actions ~~which~~ **that** may be taken under a plan submitted under an order issued under paragraph (1)(A) are as follows:

"(A) To repair the in vitro clinical test so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1)(A) was issued.

"(B) To replace the in vitro clinical test with a like or equivalent test which is in conformity with all applicable requirements of this Act.

"(C) To refund the purchase price of the in vitro clinical test (less a reasonable allowance for use if such in vitro clinical test has been in the possession of the user for one year or more at the time of notice ordered under subsection (a), or at the time the user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1)(A), whichever occurs first).

"(3) NO CHARGE.—No charge shall be made to any person (other than a developer,

importer, distributor, or retailer) for using a remedy described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a developer, manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in using such remedy.

"(c) Reimbursement.—An order issued under subsection (b)(1)(A) with respect to an in vitro clinical test may require any person who is a developer, importer, distributor, or retailer of the in vitro clinical test to reimburse any other person who is a developer, importer, distributor, or retailer of such in vitro clinical test for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

"(d) Recall Authority.—

"(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that an in vitro clinical test approved under section 587B or offered under a technology certification order under section 587D would cause serious, adverse health consequences or death, including by the absence, significant delay, or discontinuation of appropriate medical treatment, the Secretary shall issue an order requiring the appropriate person (including the developers, importers, distributors, or retailers of the in vitro clinical test)—

"(A) to immediately cease distribution of such in vitro clinical test; and

"(B) to immediately notify health professionals and applicable in vitro clinical test user facilities of the order and to instruct such professionals and facilities to cease use of such in vitro clinical test.

"(2) INFORMAL HEARING.—The order issued under paragraph (1)(A), shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 calendar days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such in vitro clinical test. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(3) AMENDED ORDER.—

"(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that the order should be amended to include a recall of the in vitro clinical test with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the recall will occur and shall require periodic reports describing the progress of the recall.

"(B) REQUIREMENTS.—An amended order under subparagraph (A)—

"(i) shall not include recall of the in vitro clinical test from individuals;

"(ii) shall not include recall of an in vitro clinical test from test user facilities if the Secretary determines that the risk of recalling such in vitro clinical test from

the facilities presents a greater health risk than the health risk of not recalling the in vitro clinical test from use; and

"(iii) shall provide for notice to individuals subject to the risks associated with the use of such in vitro clinical test. In providing the notice required by this clause, the Secretary may use the assistance of health professionals who prescribed, ordered, or used such an in vitro clinical test for individuals.

"(4) CLARIFICATION.—The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

"SEC. 587AA. APPLICABILITY.

"(a) In General.—An in vitro clinical test shall be subject to the requirements of this subchapter, except as otherwise provided in this subchapter. **Laboratory operations shall not be subject to the requirements of this subchapter.**

"(b) Interstate Commerce.—Any in vitro clinical test that is offered, including by making available for clinical use in the United States is deemed to be an act that constitutes introduction into interstate commerce for purposes of enforcing the requirements of this Act.

"(c) Least Burdensome Requirements.—

"(1) IN GENERAL.—In carrying out this subchapter, the Secretary shall consider the least burdensome means necessary to meet the applicable standard, and other regulatory requirements, as determined by the Secretary.

"(2) NECESSARY DEFINED.—For purposes of paragraph (1) ~~and paragraph (3)~~, the term 'necessary' means the minimum required information that would support a determination by the Secretary that the application meet the applicable standard or regulatory requirement, as determined by the Secretary.

"(d) Service of Orders.—Orders of the Secretary under this section with respect to applications under subsection (a) or (b) of section 587B or supplements under subsection (f) of such section shall be served—

"(1) in person by any officer or employee of the Department of Health and Human Services designated by the Secretary; or

"(2) by mailing the order by registered mail or certified mail or electronic equivalent addressed to the applicant at the last known address in the records of the Secretary.

"(e) Laboratories and Blood and Tissue Establishments.—

"(1) RELATION TO LABORATORY CERTIFICATION PURSUANT TO SECTION 353 OF THE PUBLIC HEALTH SERVICE ACT.—Nothing in this subchapter shall be construed to modify the authority of the Secretary with respect to laboratories or clinical laboratories under section 353 of the Public Health Service Act.

"(2) AVOIDING DUPLICATION.—In implementing this subchapter, the Secretary shall avoid issuing or enforcing regulations or guidance that are duplicative of regulations or guidance under section 353 of the Public Health Service Act.

"(3) BLOOD AND TISSUE.—Nothing in this subchapter shall be construed to modify the

authority of the Secretary with respect to laboratories, establishments, or other facilities to the extent they are engaged in the propagation, manufacture, or preparation, including filling, labeling, packaging, and storage, of blood, blood components, human cells, tissues, or tissue products pursuant to any requirements under this Act or section 351 or 361 of the Public Health Service Act.

"(f) Not Combination Product.—A product constituted of a device and an in vitro clinical test is not a combination product and shall be regulated as a device.

"(g) Practice of Medicine.—Nothing in this subchapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any lawfully offered in vitro clinical test for any condition or disease within a legitimate health care practitioner-patient relationship pursuant to applicable Federal or State law.

"(h) **Sale, Distribution, Labeling.—Nothing in this section** ~~Rules of Construction.—~~

~~"(1) Sale, distribution, labeling.—Nothing in this paragraph~~ shall be construed to limit the authority of the Secretary to establish or enforce restrictions on the sale, distribution, or labeling of an in vitro clinical test under this Act.

~~"(2)~~**"(i)** Promotion of ~~unapproved uses.—Nothing~~ **Unapproved Uses.—Nothing** in this ~~paragraph~~ **section** shall be construed to alter any prohibition on the promotion of unapproved uses of legally marketed in vitro clinical tests.

"SEC. 587BB. JUDICIAL REVIEW.

"(a) In General.—Not later than 30 days after an order issued pursuant to sections 587B or 587D, any person adversely affected by such order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has a principal place of business for judicial review of such order, in accordance with the procedure set forth in section 517(a).

"(b) Application of Provisions.—Subsections (a) through (e) of section 517 shall apply with respect to a petition under subsection (a) of this section in the same manner such subsections apply to a petition under section 517. Subsection (f) of section 517 shall apply to an order issued under section 587B or 587D.".

SEC. 824. ENFORCEMENT AND OTHER PROVISIONS.

(a) Prohibited Acts.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 811, is further amended—

(1) in paragraphs (a), (b), (c), (g), (h), (k), (q), (r), and (y), by inserting "in vitro clinical test," after "device," each place it appears;

(2) in paragraph (g), by inserting after "misbranded", ", and the development within any Territory of any in vitro clinical test that is adulterated or misbranded";

(3) in paragraph (y), by inserting "or 587Q" after "section 523" each place it appears;

(4) in paragraph (ff), by striking "or device" and inserting ", device, or in vitro clinical test"; and

(5) by adding at the end, the following:

~~"(jjj)(1)~~**"(kkk)(1)** Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification upon any in vitro clinical test or container, packaging, or labeling thereof so as to render such in vitro clinical test a counterfeit in vitro clinical test.

"(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing upon any in vitro clinical test or container, packaging, or labeling thereof so as to render such in vitro clinical test a counterfeit in vitro clinical test.

"(3) The doing of any act which causes an in vitro clinical test to be a counterfeit in vitro clinical test, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit in vitro clinical test.

~~"(kkk)(1)~~**"(lll)(1)** The introduction or delivery for introduction into interstate commerce of an in vitro clinical test in violation of section ~~587B(a)~~ **587A(a)**.

"(2) The making of a false, fraudulent, or deceptive statement about an in vitro clinical test that is exempt from premarket review under section 587C.

"(3) The failure to maintain complete and accurate documentation for an exemption as required under section 587C or the failure to provide labeling required under section 587L.

"(4) With respect to an in vitro clinical test, the submission of any report or listing under this Act that is false or misleading in any material respect.

"(5) The failure to comply with a condition of approval, or restriction required under an approved application under section 587B; the failure to perform a risk analysis required by section 587B; the failure to submit an annual update required under section 587J(c)(2)(B); or the failure to complete postmarket surveillance as required under section 587X.

"(6) The failure to comply with applicable requirements to submit an application or report under section 587D(e).

"(7) The failure to comply with applicable mitigating measures established under section 587E or to submit, maintain, or make available the documentation required under section 587E(b); or the failure to comply with applicable performance standards established under section 587R.

"(8) The failure to register in accordance with section 587J, the failure to provide information required under section 587J(b), or the failure to maintain or submit information required under section 587J(c).

"(9) The failure to comply with requirements under section 587M or 587N, the failure to comply with a restriction required under section 587O, or the failure to comply with labeling and advertising requirements under section 587O(b).

"(10) The failure to comply with the requirements of section 587Q.

"(11) The failure to comply with any requirement of section 587S; the failure to furnish any notification, information, material, or report required under section 587S; or the failure to comply with an order issued under section 587S.

"(12) The failure to furnish information requested by the Secretary under 587G(d)(2).".

(b) Penalties.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) in subsection (b)(8), by inserting "or counterfeit in vitro clinical test" after "counterfeit drug";

(2) in subsection (c)—

(A) by striking "; or (5)" and inserting "; (5)"; and

(B) by inserting before the period at the end the following: "; or (6) for having violated section ~~301(fff)(2)~~ **301(kkk)(2)** if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in an in vitro clinical test being a counterfeit in vitro clinical test, or for having violated section ~~301(fff)(3)~~ **301(kkk)(3)** if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the in vitro clinical test was a counterfeit in vitro clinical test"; and

(3) in subsection (f)(1)—

(A) in subparagraph (A)—

(i) by inserting "or in vitro clinical tests" after "which relates to devices";

(ii) by inserting "or section ~~587Q(a)(2)"~~ **587Q(a)(1)"** after "section 704(g)"; and

(iii) by inserting "or in vitro clinical tests, as applicable" before the period at the end of the second sentence; and

(B) in subparagraph (B)(i), by striking "or 520(f)" and inserting ", 520(f), 587K, or 587M,".

(c) Seizure.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ", and (E)" and inserting ", (E)"; and

(B) by inserting before the period at the end the following: ", and (F) Any in vitro clinical test that is a counterfeit in vitro clinical test, (G) Any container, packaging, or labeling of a counterfeit in vitro clinical test, and (H) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit in vitro clinical test";

(2) in subsection (d)(1), by inserting "in vitro clinical test," after "device,"; and

(3) in subsection (g)—

(A) in paragraph (1), by inserting ", in vitro clinical test," after "device" each place it appears; and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ", in vitro clinical test," after "device"; and

(ii) in subparagraph (B), by inserting "or in vitro clinical test" after "device"

each place it appears.

(d) Debarment, Temporary Denial of Approval, and Suspension.—Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended by adding at the end the following:

"(n) In Vitro Clinical Tests; Mandatory Debarment Regarding Third-Party Inspections and Reviews.—

"(1) IN GENERAL.—If the Secretary finds that a person has been convicted of a felony for a violation of section 301(gg) or ~~301(jjj)(1)~~ **301(kkk)(1)**, the Secretary shall debar such person from being accredited under section 587Q and from carrying out activities under an agreement described in section 803(b).

"(2) DEBARMENT PERIOD.—The Secretary shall debar a person under paragraph (1) for the following periods:

"(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

"(B) The debarment of an individual shall be permanent.

"(3) TERMINATION OF DEBARMENT; JUDICIAL REVIEW; OTHER MATTERS.—Subsections (c)(3), (d), (e), (i), (j), and (l)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.".

(e) Expanded Access to Unapproved Therapies and Diagnostics.—Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended—

(1) in subsections (a) through (d)—

(A) by striking "or investigational devices" each place it appears and inserting ", investigational devices, or investigational in vitro clinical tests"; and

(B) by striking "or investigational device" each place it appears (other than the second such place in paragraph (3)(A)) of subsection (c)) and inserting ", investigational device, or investigational in vitro clinical test";

(2) in subsection (b)(4) by striking "or 520(g)" **each place it appears** and inserting ", 520(g), or 587S" ~~each place it appears~~;

(3) in subsection (c)—

(A) by amending the subsection heading to read: "Treatment Investigational New Drug Applications, Treatment Investigational Device Exemptions, and Treatment Investigational in Vitro Clinical Test ~~Exemptions.—"~~ **Exemptions."**;

(B) in paragraph (3)(A), by striking "or investigational device exemption in effect under section 520(g)" and inserting ", investigational device exemption in effect under section 520(g), or investigational in vitro clinical test exemption under section 587S";

(C) by striking "or treatment investigational device exemption" each place it appears and inserting ", treatment investigational device exemption, or treatment

investigational in vitro clinical test exemption";

(D) in paragraph (5), by striking "or 520(g)" and inserting ", 520(g), or 587S"; and

(E) in the matter following paragraph (7) by striking "or 520(g)" each place it appears and inserting ", 520(g)**,** or 587S"; and

(4) by amending subsection (e) to read as follows:

"(e) Definitions.—In this section, the terms 'investigational drug', 'investigational device', 'investigational in vitro clinical test', 'treatment investigational new drug application', 'treatment investigational device exemption', and 'treatment investigational in vitro clinical test exemption' shall have the meanings given the terms in regulations prescribed by the Secretary.".

(f) Optimizing Global Clinical Trials.—Section 569A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8a(b)) is ~~amended~~ **amended—**

(1) by striking "subsection" each place it appears and inserting "paragraph"; and

(2) by inserting "an in vitro clinical test, as defined in ~~subsection~~ **paragraph** (ss) of such section," before "or a biological product".

(g) Patient Participation in Medical Product Discussion.—The heading of subsection (a) of section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended by striking "Drugs and Devices" and inserting "Drugs, Devices, and ~~In~~ **in** Vitro Clinical Tests".

(h) Regulations and ~~Hearings.—Section 701(h)(1)(C)(ii)~~ **Hearings.—Clause (ii) of section 701(h)(1)(C)** of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)~~(ii)) is amended~~**) is amended—**

(1) by inserting "and in vitro clinical tests" after "devices"**; and**

(2) by moving the margin of such clause 2 ems to the left.

(i) Records.—Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

(1) by inserting "in vitro clinical ~~tests"~~ **tests,"** after ~~"devices"~~**"devices,"** each place such term appears; and

(2) by inserting "in vitro clinical ~~test"~~ **test,"** after ~~"device"~~**"device,"** each place such term appears.

(j) Factory Inspection.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other than subsection (g)) is amended—

(1) by striking "drugs or devices" each place it appears and inserting "drugs, devices, or in vitro clinical tests";

(2) in subsection (a)(1), in the fourth sentence, by striking "or chapter IX" and inserting "section 587S, section 587M, section 587N, or chapter IX";

(3) after making the amendments in paragraphs (1) and (2), by inserting "in vitro clinical tests," after "devices," each place it appears;

(4) in subsection (a)(2)(B)—

(A) by inserting "or in vitro clinical tests" after "prescribe or use devices"; and

(B) by inserting "or in vitro clinical tests" after "process devices";

(5) by inserting "in vitro clinical test," after "device," each place it appears;

(6) in subsection (e), by inserting ", or section 587M, 587N, or 587S," after "section 519 or 520(g)";

(7) in subsection (f)(3)—

(A) in subparagraph (A), by striking "or" at the end;

(B) in subparagraph (B), by striking the period at the end and inserting "; or"; and

(C) after subparagraph (B), by inserting the following:

"(C) is accredited under section 587Q."; and

(8) by adding at the end the following:

"(i) For purposes of this section, the term 'establishment' includes a laboratory performing an in vitro clinical test.".

(k) Publicity.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended by inserting "in vitro clinical tests," after "devices,".

(l) Presumption.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by inserting "in vitro clinical test," after "device,".

(m) Listing and Certification of Color Additives for Foods, Drugs, and Cosmetics.—Section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(a)) is amended—

(1) in the matter preceding paragraph (1), by inserting "or in vitro clinical tests" after "or devices"; and

(2) in the flush text following paragraph (2)—

(A) by inserting "or an in vitro clinical test" after "a device"; and

(B) by inserting "or in vitro clinical tests" after "devices".

(n) Imports and Exports.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting "in vitro clinical tests," after "devices," each place it appears; and

(B) by inserting "in the case of an in vitro clinical test, the test does not conform to the applicable requirements of section 587K, or" after "requirements of section 520(f), or";

(2) in subsection (d)(3)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by inserting "and no component of an in vitro clinical test or other article of in vitro clinical test that requires further processing," after "health-related purposes";

(ii) in clause (i), by striking "drug or device" and inserting "drug, device, or in

vitro clinical test"; and

(iii) in clause (i)(I), by inserting "in vitro clinical test," after "device,"; and

(B) in subparagraph (B), by inserting "in vitro clinical test," after "device,";

(3) in subsection (e)(1), by inserting "in vitro clinical test," after "device,"; and

(4) in subsection (o)—

(A) by inserting "or in vitro clinical test" after "device"; and

(B) by inserting ~~"section~~**", or under section** 587J of each foreign ~~establishment"~~ **establishment,"** after "section 510(i) of each establishment".

(o) Office of International Relations.—Section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383) is amended—

(1) in subsection (b)—

(A) in the matter preceding paragraph (1), by inserting "and in vitro clinical tests" after "devices"; and

(B) in paragraph (1), by **striking ", and" and** inserting ~~"quality~~**"and quality** requirements established under section 587K; and" ~~at the end~~; and

(2) in subsection (c)—

(A) in paragraph (2), by inserting "in vitro clinical tests," after "devices,"; and

(B) in paragraph (4), by inserting "or in vitro clinical tests" after "devices".

(p) Recognition of Foreign Government Inspections.—Section 809(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by inserting ", or of foreign establishments registered under section 587J" after "510(h)".

(q) Food and Drug Administration.—Section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)) is amended—

(1) in subparagraph (D), by striking "and" at the end;

(2) in subparagraph (E), by striking the semicolon at the end and inserting "; and"; and

(3) by adding at the end the following:

"(F) in vitro clinical tests are analytically and clinically valid;".

(r) Office of Women's Health.—Section 1011(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399b(b)) is amended—

(1) in paragraph (1), by inserting "in vitro clinical tests," after "devices,"; and

(2) in paragraph (4), by striking "and device manufacturers" and inserting "device manufacturers, and in vitro clinical test ~~developers,"~~ **developers"**.

(s) Countermeasure Provisions of the Public Health Service Act.—Title III of the Public Health Service Act is amended—

(1) in section 319F–1(a)(2)(A) (42 U.S.C. 247d–6a(a)(2)(A))—

(A) in the matter preceding clause (i)—

(i) by striking "or device" and inserting "device"; and

(ii) by inserting "or an in vitro clinical tests (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss))," after "Act (21 U.S.C. 321(h))),"; and

(B) in each of clauses (ii) and (iii), by striking "or device" and inserting "device, or in vitro clinical test";

(2) in section 319F–2(c)(1)(B) (42 U.S.C. 247d–6b(c)(1)(B))—

(A) by striking "or device" and inserting "device"; and

(B) by inserting ", or an in vitro clinical test (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss)))" after "Act (21 U.S.C. 321(h))),"; and

(3) in section 319F–3(i)(7) (42 U.S.C. 247d–6d(i)(7))—

(A) in the matter preceding subparagraph (A)—

(i) by striking "or device" and inserting "device"; and

(ii) by inserting "or an in vitro clinical tests (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss))," after "Act (21 U.S.C. 321(h))";

(B) in subparagraph (A)—

(i) by moving the margin of clause (iii) 2 ems to the left; and

(ii) in clause (iii), by striking "or device" and inserting "device, or in vitro clinical test"; and

(C) in subparagraph (B)—

(i) in clause (i), by inserting "or ~~the subject of~~ **offered under** a technology certification order" after "approved or cleared"; and

(ii) in clause (ii), by striking "or 520(g)" and inserting ", 520(g), or 587S".

SEC. 825. TRANSITION.

(a) Implementation.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this Act shall take effect on October 1, 2027 (in this section and in subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, referred to in this section as the "effective date of this Act").

(B) EXCEPTIONS.—

(i) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") may take the actions described in paragraph ~~(3)~~**(2)**, and may expend such funds as the Secretary determines necessary to ensure an orderly transition, including prior to the effect date of this Act.

(ii) IMPLEMENTATION OF CERTAIN PROVISIONS.—The Secretary may implement sections 587J and 587U of the Federal Food, Drug, and Cosmetic Act (as added by section ~~3)~~ **823)** beginning on October 1, 2024, and such sections may take effect not earlier than October 1, 2027, to the extent and for the purposes indicated in such sections. In the case of a developer who, between October 1, 2024, and the effective date of this Act ~~specified in subparagraph (A)~~, registers under such section ~~587K~~ **587J** with respect to an article that is an in vitro clinical test, such developer shall not be required to register with respect to such article under section 510 of ~~such~~ **the Federal Food, Drug, and Cosmetic** Act (21 U.S.C. 360).

(2) ACTIONS.—The Secretary—

(A) shall—

(i) within 1 year of the date of enactment of this Act, hold the public meetings described in section ~~587D(c)~~ **587D(i)** of the Federal Food, Drug, and Cosmetic Act (as added by section ~~3)~~ **823)**;

(ii) within 3 years of the date of enactment of this Act, promulgate final regulations required under the amendments made by this Act; and

(iii) within 30 months of the date of enactment of this Act, issue final guidance on applicability requirements under amendments made by this Act; and

(B) may take additional actions after the date of enactment that the Secretary determines necessary to ensure an orderly transition, ~~which may not take effect until after the effective date,~~ including—

(i) establishment of mitigating measures for an in vitro clinical test or category of in vitro clinical tests**, which may not take effect until after the effective date described in paragraph (1)(A)**; and

(ii) establishment of the comprehensive test information system under section 587T **of the Federal Food, Drug, and Cosmetic Act, as added by section 823**.

(3) APPLICABILITY OF GUIDANCE AND REGULATIONS.—Notwithstanding the date on which guidance or regulations are issued under paragraph ~~(3)~~**(2)** and section 587K **of the Federal Food, Drug, and Cosmetic Act, as added by section 823**, no guidance or regulations issued pursuant to the amendments made by this Act shall be implemented or take effect until the effective date of this Act, ~~as described in paragraph (1),~~ except as otherwise specified in this Act (including the amendments made by this Act).

(b) Application of Authorities to in Vitro Clinical Tests Under Review on the Effective Date of This Act.—For any in vitro clinical test~~, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 822,~~ for which a submission for approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e), clearance under section 510(k) of such Act (21 U.S.C. 360(k)), authorization under section 513(f)(2) of such Act (21 U.S.C. 360c(f)(2)), or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) is pending on the effective date of this Act, including transitional in vitro clinical tests as described in subsection (c), the Secretary may review and take action on such submission after the effective date of this Act according to the statutory provision under which such

submission was submitted.

(c) Application of Authorities to Transitional In Vitro Clinical Tests.—

(1) DEFINITION.—For purposes of this section, the term "transitional in vitro clinical test" means an in vitro clinical test~~, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act,~~ that—

(A) is first offered for clinical use during the period beginning on the date of enactment of this Act and ending on the effective date of this Act;

(B) is developed by a clinical laboratory certified by the Secretary under section 353 of the Public Health Service Act (42 U.S.C. 263a) that meets the requirements for performing high-complexity testing and performed—

(i) in the same clinical laboratory in which the test was developed and for which a certification is still in effect under such section 353 that meets the requirements to perform tests of high complexity;

(ii) by another laboratory for which a certificate is in effect under such section 353 that meets the requirements to perform tests of high complexity, is within the same corporate organization, and has common ownership by the same parent corporation as the laboratory in which the test was developed; or

(iii) in the case of a test that was developed by the Centers for Disease Control and Prevention or another laboratory **in** a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, by a clinical laboratory for which a certificate is in effect under **such** section 353 ~~of such Act~~ that meets the requirements to perform tests of high complexity, and that is within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention; and

(C) when first offered, is not approved under section 515 of the Federal Food, Drug, and Cosmetic Act, cleared under section 510(k) of such Act, authorized under section 513(f)(2) of such Act, subject to a humanitarian device exemption under section 520(m) of such Act (21 U.S.C. 360j(m)), subject to an exemption for investigation use under section 520(g) of such Act (21 U.S.C. 360j(g)), authorized under section 564 of such Act (21 U.S.C. 360bbb–3), or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) PREMARKET REVIEW OR TECHNOLOGY CERTIFICATION.—A transitional in vitro clinical test that is the subject of an application for premarket review under section 587B of the Federal Food, Drug, and Cosmetic Act or technology certification application under section 587D of such Act, as added by this Act, may continue to be offered, sold, or distributed **without marketing authorization** until completion of the Secretary's review of the premarket application or technology certification application, if such application is submitted no later than 90 days after the effective date of this Act.

(3) TESTS APPROVED BY NEW YORK STATE.—Notwithstanding paragraph (2), a transitional in vitro clinical test that has been approved by the New York State Department of Health may continue to be offered, sold, or distributed after the effective date if—

(A) starting on the effective date of this Act, the in vitro clinical test complies with

the requirements of subchapter J of the Federal Food, Drug, and Cosmetic Act, as added by this Act, except for ~~sections 587B~~ **section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 823,** and design control provisions of section 587K **of such Act**;

(B) each test report template for the test bears a statement of adequate prominence that reads as follows: "This in vitro clinical test was developed and first introduced prior to the effective date of the VALID Act of 2022. This test was approved by the New York State Department of Health, but the test has not been reviewed by the Food and Drug Administration.";

(C) a premarket application under section 587B **of the Federal Food, Drug, and Cosmetic Act, as added by section 823,** or technology certification application under section 587D **of such Act, as added by section 823,** is submitted no later than—

(i) 5 years after the effective date of this Act, if the in vitro clinical test is approved by the New York State Department of Health as a genetic testing molecular test, a microbiology molecular test, an oncology molecular test, or any other type of molecular test; or

(ii) 2 years after the effective date of this Act, if the in vitro clinical test is approved by the New York State Department of Health as a type of test not described in clause (i); and

(D) a test in compliance with this paragraph ~~(3)~~ may continue to be offered, sold, or distributed until the completion of the Secretary's review of the premarket application or technology certification application ~~referenced~~ **described** in subparagraph (C).

(d) Conversion.—

(1) DEEMED PREMARKET APPROVAL.—Beginning on the effective date of this Act—

(A) any in vitro clinical test ~~(as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 822)~~ with a premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) or a licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) is deemed to be approved pursuant to an application under section ~~587B(c)~~ **587B(a)** of the Federal Food, Drug, and Cosmetic Act, as added by this Act; and

(B) any in vitro clinical test (as so defined) that was cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) or authorized under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)) is deemed to be approved pursuant to an application under section ~~587B(d)~~ **587B(b)** of the Federal Food, Drug, and Cosmetic Act, as added by this Act.

(2) DEEMED INVESTIGATIONAL USE EXEMPTION.—Any in vitro clinical test ~~(as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 822)~~ that has an investigational device exemption in effect under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is deemed to have an investigational use exemption in effect under section 587S of such Act, as added by this Act, beginning on the effective date of this Act.

(3) DEEMED HUMANITARIAN DEVICE EXEMPTION.—Any in vitro clinical test ~~(as defined in~~

~~section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 822)~~ that has an approved humanitarian device exemption under section 520(m) of such Act is deemed to have a humanitarian test exemption under section 587A(g) of such Act, as added by this Act, beginning on the effective date of this Act.

(4) DEEMED DESIGNATED BREAKTHROUGH.—Any in vitro clinical test ~~(as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act, as added by section 822)~~ that has received a breakthrough device designation under section 515B(e)(1)(D) of such Act (21 U.S.C. 360e–3(e)(1)(D)) is deemed to have a breakthrough in vitro clinical test designation under section 587C of such Act, as added by this Act, beginning on the effective date of this Act.

(5) DEEMED REQUEST FOR INFORMAL FEEDBACK.—With regard to any in vitro clinical test that is the subject of a pre-submission request described in the guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program", issued by the Food and Drug Administration on January 6, 2021, such request is deemed to constitute a request for informal feedback under section 587F of the Federal Food, Drug, and Cosmetic Act, as added by section 823, beginning on the effective date of this Act.

(e) Previously Classified Devices.—Notwithstanding section 587 of the Federal Food, Drug, and Cosmetic Act, as added by section 823, for purposes of subchapter J of chapter V of such Act, as added by section 823, the following apply:

(1) In the case of an in vitro clinical test type that has been classified by the Secretary as a class I device pursuant to section 513 of such Act (21 U.S.C. 360c), such in vitro clinical test shall be low-risk, unless the in vitro clinical test is a test described in section 510(l) **of such Act** or the test is redesignated by the Secretary pursuant to section 587F of such Act.

(2) In the case of an in vitro clinical test type that has been classified by the Secretary as a class II device pursuant to section 513 of such Act (21 U.S.C. 360c), such in vitro clinical test shall be moderate-risk, unless inaccurate results from the test would be immediately life threatening or the test is redesignated by the Secretary pursuant to section 587F of such Act.

(3) In the case of an in vitro clinical test type that ~~is~~ **has been classified by the Secretary as** a class III device pursuant to section 513 of such Act (21 U.S.C. 360c) **or an in vitro clinical test licensed pursuant to section 351 of the Public Health Service Act (42 U.S.C. 262)**, such in vitro clinical test shall be high-risk, unless redesignated by the Secretary pursuant to section 587F of ~~such~~ **the Federal Food, Drug, and Cosmetic** Act.

SEC. 826. EMERGENCY USE AUTHORIZATION.

(a) In General.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) **by inserting "or developer" after "manufacturer", each place such term appears;**

(2) in subsection (a)—

(A) in paragraphs (1) and (4)(C), by inserting "in vitro clinical test," before "or biological product" each place such term appears;~~ and~~

(B) in paragraph (2)(A), by striking "or 515" and inserting "515, or 587B"; **and**

(C) by adding at the end the following:

"(F) The terms 'develop' and 'developer', with respect to an in vitro clinical test, have the meanings given such terms in section 587.";

(3) in subsection (b), by inserting "or developer" after "manufacturer" each place such term appears;

(4)~~(2)~~ in subsection (e)—

(A) ~~in paragraph (3)—~~ **by inserting "or developers" after "manufacturers" each place such term appears;**

~~(i)~~**(B) in paragraph (2)(B)(ii), by inserting "or develop" after "not manufacture";**

(C) in paragraph (3)—

(i) in subparagraph (A), by striking "or 520(f)(1)" and inserting ", 520(f)(1), or 587V";

(ii) in subparagraph (B), by striking "and" at the end;

~~(ii)~~**(iii)** in subparagraph (C), by striking the period and inserting " **or 587O**; and"; and

~~(iii)~~**(iv)** by adding at the end the following:

"(D) quality requirements (with respect to in vitro clinical tests) under section 587K."; and

~~(B)~~**(D)** in paragraph (4)—

(i) in subparagraph (A), by striking "; or" and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting "; or"; and

(iii) by adding at the end the following:

"(C) with respect to in vitro clinical tests, requirements applicable to restricted in vitro clinical tests pursuant to section 587O.";

(5) in subsection (k), by striking "or 520(g)" and inserting "520(g), or 587S"; and

(6)~~(3)~~ in subsection (m)—

(A) in the subsection heading, by striking "Laboratory Tests Associated With Devices" inserting "in Vitro Clinical Tests" after "Devices"; and

(B) in paragraph (1)—

(i) by striking "to a device" and inserting "to an in vitro clinical test"; and

(ii) by striking "such device" and inserting "such in vitro clinical test".

(b) Emergency Use of Medical Products.—Section 564A~~(a)(2)~~ of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a~~(a)(2)) is amended~~**) is amended—**

(1) in subsection (a)—

(A) in paragraph (2), by inserting "in vitro clinical test," after "device,"**; and**

(B) by adding at the end the following:

"(3) DEVELOPER.—The term 'developer', with respect to an in vitro clinical test, has the meaning given such term in section 587.";

(2) by inserting "or developer" after "manufacturer" each place it appears; and

(3) in subsection (c)(1)—

(A) by inserting "or quality requirements" after "good manufacturing practice requirements"; and

(B) by striking "or 520(f)(1)" and inserting ", 520(f)(1), or 587K".

(c) Products Held for Emergency Use.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b(2)) is amended—

(1) in subparagraph (A), by striking "or 515" and inserting "515, or 587B"; and

(2) in subparagraph (B), by striking "or 520" and inserting 520, or 587S.

SEC. 827. ANTIMICROBIAL SUSCEPTIBILITY TESTS.

Section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a–2) is amended—

(1) in subsection (a)(1)(C)—

(A) by striking "clear under section 510(k), classify under section 513(f)(2), or approve under section 515" and inserting "approve under section 587B, exempt from premarket review under section 587C, or grant a technology certification order under section 587D"; and

(B) by striking "testing devices" and inserting "in vitro clinical tests";

(2) in subsection ~~(c)(5),~~**(c)(5)—**

(A) by striking "drug or device" ~~each place it appears~~ and inserting "drug, **device, or in vitro clinical test"; and**

(B) by striking "the drug or the device" and inserting "the drug, device, or in vitro clinical test";

(3) in subsection (e)—

(A) in the heading, by striking "Testing Devices" and inserting "In Vitro Clinical Tests";

(B) in paragraph (1)—

(i) by striking "510, 513, and 515," and inserting "587B, and 587D";

(ii) by striking "antimicrobial susceptibility testing device" and inserting "antimicrobial susceptibility in vitro clinical test"; and

(iii) by striking "such device" and inserting "such in vitro clinical test"; and

(C) in paragraph (2)—

(i) in the heading, by striking "TESTING DEVICES" and inserting "IN VITRO CLINICAL TESTS";

(ii) in subparagraphs (A) and (B) (other than clause (iii) of such subparagraph (B)), by striking "device" each place it appears and inserting "in vitro clinical test";

(iii) in subparagraph (B)(iii), by striking "a device" and inserting "an in vitro clinical test"; and

(iv) by amending subparagraph (C) to read as follows:

"(C) The antimicrobial susceptibility in vitro clinical test meets all other requirements to be approved under section 587B, **to be** exempted from premarket review under section 587C, or **to be** offered under a technology certification order under section 587D.";

(4) in subsection (f), by amending paragraph (1) to read as follows:

"(1) The term 'antimicrobial susceptibility in vitro clinical test' means an in vitro clinical test that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).''; and

(5) in subsection (g)(2)—

(A) by amending the matter preceding subparagraph (A) to read as follows:

"(2) with respect to approving an application under section 587B or granting a technology certification order under section 587D—"; and

(B) in subparagraph (A)—

(i) by striking "device" and inserting "in vitro clinical test"; and

(ii) by striking "antimicrobial susceptibility testing device" and inserting "antimicrobial susceptibility in vitro clinical test".

SEC. 828. COMBINATION PRODUCTS.

(a) In General.—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by striking "or biological product" and inserting "in vitro clinical test, or biological product (except for a product constituted of a device and an in vitro clinical test)";

(B) in subparagraph (B), by adding at the end the following: "For purposes of this Act, a product that constitutes a combination of a ~~drug~~ **device** and an in vitro clinical test is not a combination product within the meaning of this subsection."; and

(C) in subparagraph (D)(ii)—

(i) by inserting "or in vitro clinical test" after "device"; and

(ii) by inserting "and in vitro clinical tests" before "shall";

(2) in paragraph (3), by striking "safety and effectiveness or substantial equivalence" and inserting "safety and effectiveness, substantial equivalence, or analytical validity and clinical validity" before "for the approved constituent part";

(3) in paragraph (4)—

(A) in subparagraph (A), by striking "or 513(f)(2) (submitted in accordance with paragraph (5))" and inserting "513(f)(2) (submitted in accordance with paragraph (5)), 587B, or 587D, or an exempt test under section 587C, as applicable"; and

(B) in subparagraph (B), by inserting ", 587B, or 587D" after "section 515";

(4) in paragraph (5)(A), by striking "or 510(k)" and inserting ", 510(k), 587B, or 587D";

(5) in paragraph (7), by striking "or substantial equivalence" and inserting ", substantial equivalence, or analytical validity and clinical validity";

(6) in paragraph (8), by adding at the end the following:

"(I) This paragraph shall not apply to a product constituted of a device and an in vitro clinical test."; and

(7) in paragraph (9)—

(A) in subparagraph (C)(i), by striking "or 520(g)" and inserting "520(g), 587B, or 587D"; and

(B) in subparagraph (D), by striking "or 520" and inserting "520, 587B, or 587D".

(b) Classification of Products.—Section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–2) is amended by adding at the end the following:

"(d) Exemption.—This section shall not apply to a product constituted of a device and an in vitro clinical test.".

SEC. 829. RESOURCES.

(a) Findings.—Congress finds that the fees authorized by this section will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

(b) ~~Authorization of Appropriations.—For purposes of funding implementation of subchapter J of title V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, including undertaking activities for the development of regulations and guidances, hiring of necessary staff, and the development of technology systems to implement this subchapter in a timely, effective, and efficient manner there is authorized to be appropriated $480,000,000.~~

~~(c)~~ Establishment of User Fee Program.—

(1) DEVELOPMENT OF USER FEES FOR IN VITRO CLINICAL TESTS.—

(A) IN GENERAL.—Beginning not later than October 1, ~~2021~~ **2025**, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of in vitro clinical test submissions

and applications under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, for the first 5 fiscal years after fiscal year ~~2022~~ **2027 and for the authorization of the In Vitro Clinical Test User Fee Program, as described in this section, for such fiscal years**. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the authorization of ~~such subchapter J~~ **the In Vitro Clinical Test User Fee Program, as described in this section**, the Secretary shall—

(i) publish a notice in the Federal Register requesting public input on the authorization of user fees;

(ii) hold a public meeting at which the public may present its views on the authorization, including specific suggestions for the recommendations submitted under subparagraph (E);

(iii) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to ~~such subchapter J;~~ **the authorization of the In Vitro Clinical Test User Fee Program, as described in this section;** and

(iv) publish any comments received under clause (iii) on the website of the Food and Drug Administration.

(C) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of the authorization ~~under such subchapter J~~ **of the In Vitro Clinical Test User Fee Program** and to solicit suggestions to be included in the recommendations transmitted to Congress under subparagraph (E).

(D) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(E) TRANSMITTAL OF RECOMMENDATIONS.—

(i) IN GENERAL.—Not later than January 15, 2027, the Secretary shall transmit to Congress the revised recommendations under subparagraph (A), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(ii) RECOMMENDATION REQUIREMENTS.—The recommendations transmitted under this subparagraph shall—

(I) include the number of full-time equivalent employees per fiscal year that are agreed to be hired to carry out the goals included in such recommendations for each year of the 5-year period;

(II) provide that the amount of operating reserve balance in the user fee program established under this section is not more than the equivalent of 10 weeks of operating reserve;

(III) require the development of a strategic plan for any surplus within the operating reserve account above the 10-week operating reserve within 2 years of the establishment of the program;

(IV) include an operating reserve adjustment such that, if the Secretary has an operating reserve balance in excess of 10 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 10 weeks of such operating reserves;

(V) if an adjustment is made as described in subclause (IV), provide the rationale for the amount of the decrease in fee revenue and fees shall be contained in the Federal Register; and

(VI) provide that the fees assessed and collected for the full-time equivalent employees at the Center for Devices and Radiological Health, with respect to which the majority of time reporting data indicates are dedicated to the process for the review of in vitro clinical test submissions and applications under paragraph (5), are not supported by the funds authorized to be collected and assessed under section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j).

(F) PUBLICATION OF RECOMMENDATIONS.—The Secretary shall publish on the website of the Food and Drug Administration the revised recommendations under subparagraph (A), a summary of the views and comments received under subparagraphs (B) through (D), and any changes made to the recommendations originally proposed by the Secretary in response to such views and comments.

(G) MINUTES OF NEGOTIATION MEETINGS.—

(i) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the

website of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry not later than 30 days after such meeting.

(ii) CONTENT.—The minutes described under clause (i) shall summarize any substantive proposal made by any party to the negotiations, any significant controversies or differences of opinion during the negotiations, and the resolution of any such controversy or difference of opinion.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—Effective on October 1, 2027, provided that the Secretary transmits the recommendations under paragraph (1)(E), the Secretary is authorized to collect user fees relating to the review of in vitro clinical test submissions and applications **submitted** under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act. Fees under such program shall be assessed and collected only if the requirements under paragraph (4) are met.

(3) AUDIT.—

(A) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to submission of an in vitro clinical test application submitted under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and on a biennial basis thereafter, the Secretary shall perform an audit of the costs of reviewing such applications under such subchapter J. Such an audit shall compare the costs of reviewing such applications under such subchapter J to the amount of the user fee applicable to such applications.

(B) ALTERATION OF USER FEE.—If the audit performed under subparagraph (A) indicates that the user fees applicable to applications submitted under such subchapter J exceed 49 percent of the costs of reviewing such applications, the Secretary shall alter the user fees applicable to applications submitted under such subchapter J such that the user fees do not exceed such percentage.

(C) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under subparagraph (A) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United States Code, to ensure the validity of any potential variability.

(4) CONDITIONS.—The user fee program described in this subsection shall take effect only if the Food and Drug Administration issues draft guidance related to the review requirements for in vitro diagnostic tests that would be subject to premarket review under section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 823, the review requirements for test categories eligible for technology certification under section 587D of such Act, as added by section 823, and the parameters for the test categories that would be exempt from any review under subchapter J of chapter V of such Act.

(5) USER FEE PROGRAM DEFINITIONS AND RESOURCE REQUIREMENTS.—

(A) IN GENERAL.—The term "process for the review of in vitro clinical test submissions and applications" means the following activities of the Secretary with respect to the review of in vitro clinical test premarket and technology certification applications including supplements for such applications:

(i) The activities necessary for the review of premarket applications, premarket reports, technology certification applications, and supplements to such applications.

(ii) Actions related to submissions in connection with in vitro clinical test development, the issuance of action letters that allow the marketing of in vitro clinical tests or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to support the development of in vitro clinical tests.

(iii) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, technology certifications, and supplements.

(iv) Monitoring of research conducted in connection with the review of such applications, supplements, and submissions.

(v) Review of in vitro clinical test applications subject to section 351 of the Public Health Service Act (42 U.S.C. 262) and activities conducted in anticipation of the submission of such applications for investigational use under section 587S of the Federal Food, Drug, and Cosmetic Act (as added by section 823).

(vi) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, technology certification applications, and supplements.

(vii) The development of voluntary test methods, consensus standards, or mandatory performance standards in connection with the review of such applications, supplements, or submissions and related activities.

(viii) The provision of technical assistance to in vitro clinical test developers in connection with the submission of such applications, reports, supplements, or submissions.

(ix) Any activity undertaken in connection with the initial classification or reclassification of an in vitro clinical test in connection with any requirement for approval or eligibility for an exemption from premarket review of an in vitro clinical test.

(x) Any activity undertaken in connection with making a pathway determination of an in vitro clinical test, including the identification, establishment, and implementation of mitigation measures.

(xi) Evaluation of postmarket studies required as a condition of an approval of a premarket application of an in vitro clinical test and ensuring such studies are conducted as required.

(xii) Any activity undertaken in connection with ensuring in vitro clinical tests marketed under an exemption from premarket review pursuant to section 587C or 587G meet the criteria for such exemption and the applicable standard.

(xiii) Compiling, developing, and reviewing information on in vitro clinical tests necessary to identify issues with the ability of in vitro clinical tests to meet

the applicable standard, as applicable.

(B) RESOURCE REQUIREMENTS.—Fees collected and assessed under this section shall be used for the process for the review of in vitro clinical test applications, as described in subparagraph (A), and shall—

(i) be subject to the limitation under section 738(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)(3)), in the same manner that fees collected and assessed under section 737(9)(C) of such Act (21 U.S.C. 379i(9)(C)) are subject to such limitation;

(ii) include travel expenses for officers and employees of the Food and Drug Administration only if the Secretary determines that such travel is directly related to an activity described in subparagraph (A); and

(iii) not be allocated to purposes described under section 722(a) of the Consolidated Appropriations Act, 2018 (Public Law 115–141).

~~(d)~~**(c)** Reports.—

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—

(i) GENERAL REQUIREMENTS.—Beginning with fiscal year ~~2027~~ **2028**, for each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(ii) ADDITIONAL INFORMATION.—Beginning with fiscal year ~~2021~~ **2028**, the annual report under this subparagraph shall include the progress of the Food and Drug Administration in achieving the goals, and future plans for meeting the goals, including—

(I) the number of premarket applications filed under section 587B of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year;

(II) the number of technology certification applications submitted under section 587D of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year for each review division;

(III) the number of breakthrough designations under section 587I of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year; and

(IV) the number of information requests requested by the Secretary pursuant to section 587G(d) of such Act.

(iii) REAL-TIME REPORTING.—

(I) IN GENERAL.—Not later than 30 calendar days after the end of the

second quarter of fiscal year ~~2027~~ **2028**, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

(II) DATA.—The Secretary shall post the following data in accordance with subclause (I):

(aa) The number and titles of draft and final regulations on topics related to the process for the review of in vitro clinical test submissions and applications, and whether such ~~guidances~~ **regulations** were required by statute or pursuant to the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(bb) The number and titles of draft and final guidance on topics related to the process for the review of in vitro clinical test submissions and applications, and whether such guidances were issued as required by statute or pursuant to the recommendations transmitted to Congress by the Secretary pursuant to subsection ~~(c)(1)(E)~~**(b)(1)(E)**.

(cc) The number and titles of public meetings held on topics related to the process for the review of in vitro clinical tests, and if such meetings were required by statute or pursuant to the recommendations transmitted to Congress by the Secretary pursuant to subsection ~~(c)(1)(E)~~**(b)(1)(E)**.

(iv) RATIONALE FOR IVCT USER FEE PROGRAM CHANGES.—Beginning with fiscal year ~~2027~~ **2028**, the Secretary shall include in the annual performance report under paragraph (1)—

(I) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) and the number of full-time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of in vitro clinical test submissions and applications, including identifying drivers of such changes; and

(III) for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

(v) ANALYSIS.—For each fiscal year, the Secretary shall include in the report

under clause (i) an analysis of the following:

(I) The difference between the aggregate number of premarket applications filed under section 587B or section 587D of the Federal Food, Drug, and Cosmetic Act and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

(aa) the number of applications filed under each of sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications under each of sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act for each fiscal year that did not meet the goals as identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(III) The most common causes and trends for external or other circumstances affecting the ability of the Food and Drug Administration to meet review time and performance enhancement goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E), the Secretary shall make such information publicly available on the website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies.

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all in vitro clinical test premarket applications and technology certification orders and supplements, premarket, and technology certification notifications in the cohort.

(2) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2022, for each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit a corrective action report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives. The report shall include the following information, as applicable:

(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the

analysis under paragraph (1)(A)(v), that each of the goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the in vitro clinical test premarket application and technology certification review process.

(B) GOALS MISSED.—For each of the goals identified by the letters described in recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(i) a justification for such determination;

(ii) a description of the types of circumstances, in the aggregate, under which applications or reports submitted under sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act missed the review goal times but were approved during the first cycle review, as applicable;

(iii) a summary and any trends with regard to the circumstances for which a review goal was missed; and

(iv) the performance enhancement goals that were not achieved during the previous fiscal year and a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

(3) FISCAL ~~REPORT.—FOR~~ **REPORT.—**

(A) IN GENERAL.—For fiscal years ~~2027~~ **2028** and annually thereafter, not later than 120 days after the end of each fiscal year during which fees are collected under this ~~subpart~~ **section**, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

~~(A)~~**(B)** CONTENTS.—Such report shall include expenditures delineated by budget authority and user fee dollars related to administrative expenses and information technology infrastructure contracts and expenditures.

~~(B)~~**(C)** OPERATING RESERVE.—Such report shall provide the amount of operating ~~reserve balance~~ **reserves of carryover user fees** available each year, and any planned allocations or obligations of such balance ~~that is above 10 weeks~~ of operating ~~reserve~~ **reserves** for the program.

(4) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) through (3) available to the public on the website of the Food and Drug Administration.

(5) ENHANCED COMMUNICATION.—

(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of in vitro clinical tests shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives from the Food and Drug Administration shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this section.

SEC. 830. AUTHORIZATION OF APPROPRIATIONS.

For purposes of funding implementation of this subtitle (including the amendments made by this subtitle), including undertaking activities for the development of regulations and guidances, hiring of necessary staff, and the development of technology systems to implement this subtitle (including the amendments made by this subtitle) in a timely, effective, and efficient manner, there is authorized to be appropriated ~~not more than~~ $480,000,000, to remain available through the end of fiscal year ~~2027.~~

2028.

SEC. 831. GUIDANCE ON DIAGNOSTIC INNOVATION.

Not later than January 1, 2025, the Secretary shall issue guidance to assist developers of in vitro clinical tests intended to identify or diagnose rare diseases and in vitro clinical tests intended to address an unmet medical need. Such guidance shall include considerations for addressing barriers to developing sufficient data to demonstrate clinical validity for such tests, such as challenges associated with data collection and obstacles to the timely generation of evidence.

TITLE IX—OTHER PROVISIONS

SEC. 901. FACILITIES MANAGEMENT.

(a) PDUFA Authority.—Section 736(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. ~~379h(g)(2))~~ **379h(g)(2)) is amended—**

(1) in subparagraph (A)(ii)—

(A) by striking "shall be available to defray" and inserting the following: "shall be available—

"(I) for fiscal year 2023, to defray";

(B) by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of the resources allocated for the process for the review of human drug applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with the process for the review of human drug applications, is no less than the amount allocated for such costs, excluding any such costs paid from fees collected under this section, for fiscal year 1997, multiplied by the adjustment factor."; and

(2) in subparagraph (B), by striking "for the process for the review of human drug applications" and inserting "as described in subclause (I) or (II) of such subparagraph, as applicable".

(b) BsUFA Authority.—Section 744H(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(f)(2)) is amended—

(1) in subparagraph (B)(i)—

(A) by striking "available for a fiscal year beginning after fiscal year 2012" and inserting the following: "available—

"(I) for fiscal year 2023";

(B) by striking "the fiscal year involved." and inserting "such fiscal year; and"; and

(C) by adding at the end the following:

"(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with the process for the review of biosimilar biological product applications, is no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved."; and

(2) in subparagraph (C), by striking "subparagraph (B) in any fiscal year if the costs described in such subparagraph" and inserting "subparagraph (B)(i) in any fiscal year if the costs allocated as described in subclause (I) or (II) of such subparagraph, as applicable,".

(c) GDUFA Authority.—Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42) is amended—

(1) in subsection (e)(2), by striking "744A(11)(C)" and inserting "744A(12)(C)"; and

(2) in subsection (i)(2)—

(A) in subparagraph (A)(ii)—

(i) by striking "available for a fiscal year beginning after fiscal year 2012" and inserting the following: "available—

"(I) for fiscal year ~~2023; and"~~ **2023"**;

(ii) by striking "the fiscal year involved." and inserting "such fiscal year; and"; and

(iii) by adding at the end the following:

"(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with human generic drug activities, is no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved."; and

(B) in subparagraph (B), by striking "for human generic activities" and inserting "as described in subclause (I) or (II) of such subparagraph, as ~~applicable"~~ **applicable,"**.

(d) MDUFA Authority.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in subsection (h)(2)—

(A) in subparagraph (A)(ii)—

(i) by striking "shall be available to defray" and inserting the following: "shall be available—

"(I) for fiscal year 2023, to defray";

(ii) by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of the resources allocated for the process for the review of device applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture and other necessary materials and supplies in connection with the process for the review of device applications, is no less than the amount allocated for such

costs, excluding any such costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor."; and

(B) in subparagraph (B)(i), in the matter preceding subclause (I), by striking "for the process for the review of device applications" and inserting "as described in subclause (I) or (II) of such subparagraph, as applicable"; and

(2) in subsection (g)(3), by striking "737(9)(C)" and inserting "737(10)(C)".

(e) Technical Correction.—

(1) IN GENERAL.—Section 905(b)(2) of the FDA Reauthorization Act of 2017 (Public Law 115–52) is amended by striking "Section 738(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)) is amended" and inserting "Subsection (g) of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as so redesignated by section 203(f)(2)(B)(i), is amended".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as though included in the enactment of section 905 of the FDA Reauthorization Act of 2017 (Public Law 115–52).

SEC. 902~~. ANNUAL REPORT ON INSPECTIONS.~~

~~Section 902 of the FDA Reauthorization Act of 2017 (Public Law 11552) is amended, in the matter preceding paragraph (1)—~~

~~(1) by striking "March 1 of each year" and inserting "120 days after the end of each fiscal year"; and~~

~~(2) by striking "previous calendar year" and inserting "previous fiscal year".~~

~~SEC. 903~~. USER FEE PROGRAM TRANSPARENCY AND ACCOUNTABILITY.

(a) PDUFA.—

(1) REAUTHORIZATION; REPORTING **REQUIREMENTS.—Section** ~~requirements.—~~

~~(A) Performance report.—Section~~ 736B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is amended—

~~(i)~~**(A)** in paragraph (1)—

~~(I)~~**(i)** in subparagraph (B)—

~~(aa)~~**(I)** in clause (vii), by striking "; and" and inserting a semicolon;

~~(bb)~~**(II)** in clause (viii), by striking the period and inserting "; and"; and

~~(cc)~~**(III)** by adding at the end the following:

"(ix) the number of investigational new drug applications submitted per fiscal year, including for each review division."; and

~~(II)~~**(ii)** by adding at the end the following flush text:

"Nothing in subparagraph (B) shall be construed to authorize the disclosure of ~~confidential commercial information or other information considered proprietary or trade secret, as prohibited~~ **information that is prohibited from disclosure** under section 301(j) of this Act ~~of~~ **or** section 1905 of title 18, **United States Code, or that is subject to withholding under section 552(b)(4) of title 5,** United States Code."; and

~~(ii)~~**(B)** in paragraph (4)—

~~(I)~~**(i)** by amending subparagraph (A) to read as follows:

"(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 736, and the number of full-time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;";

~~(II)~~**(ii)** by amending subparagraph (B) to read as follows:

"(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of human drug applications, including identifying—

"(i) drivers of such changes; and

"(ii) changes in the average total cost per full-time equivalent in the prescription drug review program;";

~~(III)~~**(iii)** in subparagraph (C), by striking the period and inserting "; and"; and

~~(IV)~~**(iv)** by adding at the end the following:

"(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of human drug application.".

(2) REAUTHORIZATION.—Section 736B(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(f)) is amended—

(A) by redesignating paragraphs (4) through (6) as paragraphs (5) through (7), respectively;

(B) by inserting after paragraph (3) the following:

"(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives."; and

(C) in paragraph (7), as so redesignated—

(i) in subparagraph (A)—

(I) by striking "Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the" and inserting "The"; and

(II) by inserting ", not later than 30 days after each such negotiation meeting" before the period at the end; and

(ii) in subparagraph (B), by inserting ", in sufficient detail," after "shall summarize".

(b) MDUFA.—

(1) REAUTHORIZATION; REPORTING **REQUIREMENTS.—Section** ~~requirements.—~~

~~(A) Reports.—Section~~ 738A(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)(1)(A)) ~~is~~**, as amended by section 204, is further** amended—

~~(i)~~**(A)** in clause (ii)—

~~(I)~~**(i)** in subclause (II), by striking "; and" and inserting a semicolon;

~~(II)~~**(ii)** in subclause (III), by striking the period and inserting a semicolon; **and**

(iii)~~(III)~~ by adding at the end the following:

"(IV) the number of investigational device exemption applications submitted under section 520(g) per fiscal year, including for each review division; and

"(V) the number of expedited development and priority review requests and designations under section 515B per fiscal year, including for each review ~~division."; and~~ **division.**

~~(IV) by adding at the end the following flush text:~~

~~"Nothing~~ **Nothing** in this clause shall be construed to authorize the disclosure of ~~confidential commercial information or other information considered proprietary or trade secret, as prohibited~~ **information that is prohibited from disclosure** under section 301(j) of this Act or section 1905 of title 18, **United States Code, or that is subject to withholding under section 552(b)(4) of title 5,** United States Code."; **and**

(B)~~(ii)~~ in ~~the first~~ clause (iv) (relating to rationale for MDUFA program changes)—

~~(I)~~**(i)** by amending subclause (I) to read as follows:

"(I) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 738, and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;";

~~(II)~~**(ii)** by amending subclause (II) to read as follows:

"(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of device applications, including identifying—

"(aa) drivers of such changes; and

"(bb) changes in the average total cost per full-time equivalent in the medical device review program;";

~~(III)~~**(iii)** in subclause (III), by striking the period and inserting "; and"; and

~~(IV)~~**(iv)** by adding at the end the following:

"(IV) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of medical device application types."~~; and~~**.**

~~(iii) by redesignating the second clause (iv) (relating to analysis) as clause (v).~~**(2) REAUTHORIZATION.—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b)), as amended by section 204, is further amended—**

~~* 1 (2) Reauthorization.—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j1(b)) is amended—~~

(A) by redesignating paragraphs (4) through (6) as paragraphs (5) through (7), respectively;

(B) by inserting after paragraph (3) the following:

"(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives."; and

(C) in paragraph (7), as so redesignated—

(i) in subparagraph (A)—

(I) by striking "Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the" and inserting "The"; and

(II) by inserting ", not later than 30 days after each such negotiation meeting" before the period at the end; and

(ii) in subparagraph (B), by inserting ", in sufficient detail," after "shall summarize".

(c) GDUFA.—

(1) REAUTHORIZATION; REPORTING **REQUIREMENTS.—Section** ~~requirements.—~~

~~(A) Performance report.—Section~~ 744C(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)(3)) is amended—

(A) in the matter preceding subparagraph (A), by striking "fiscal year 2020" and inserting "fiscal year 2023";

(B)~~(i)~~ by amending subparagraph (A) to read as follows:

"(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 744B, and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;";

~~(ii)~~**(C)** by amending subparagraph (B) to read as follows:

"(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including—

"(i) identifying drivers of such changes; and

"(ii) changes in the total average cost per full-time equivalent in the generic drug review program;";

~~(iii)~~**(D)** in subparagraph (C), by striking the period at the end and inserting "; and"; and

~~(iv)~~**(E)** by adding at the end the following:

"(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of abbreviated new drug application.".

(2) REAUTHORIZATION.—Section 744C(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43(f)) is amended—

(A) by redesignating paragraphs (4) through (6) as paragraphs (5) through (7), respectively;

(B) by inserting after paragraph (3) the following:

"(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives."; and

(C) in paragraph (7), as so redesignated—

(i) in subparagraph (A)—

(I) by striking "Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the" and inserting "The"; and

(II) by inserting ", not later than 30 days after each such negotiation meeting" before the period at the end; and

(ii) in subparagraph (B), by inserting ", in sufficient detail," after "shall summarize".

(d) ~~BSUFA.—~~ **BsUFA.—**

(1) REAUTHORIZATION; REPORTING REQUIREMENTS.—Section 744I(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)(4)) is amended—

(A) by amending subparagraph (A) to read as follows:

"(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 744H, and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;";

(B) by amending subparagraph (B) to read as follows:

"(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of biosimilar biological product applications, including identifying—

"(i) drivers of such changes; and

"(ii) changes in the average total cost per full-time equivalent in the biosimilar biological product review program;";

(C) in subparagraph (C), by striking the period at the end and inserting "; and"; and

(D) by adding at the end the following:

"(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of biosimilar biological product application.".

(2) REAUTHORIZATION.—Section 744I(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(f)) is amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (5) and (6), respectively;

(B) by inserting after paragraph (1) the following:

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization;

"(B) hold a public meeting at which the public may present its views on the reauthorization;

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's website.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during

negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives."; and

(C) by adding at the end the following:

"(7) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the public website of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry, not later than 30 days after each such negotiation meeting.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize, in sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. ~~904~~ **903**. OTC HEARING AIDS FINAL RULE.

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final rule to establish a category of over-the-counter hearing aids, as defined in subsection (q) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as described in section 709(b) of the FDA Reauthorization Act of 2017 (Public Law 115–52).

SEC. ~~905. ENHANCE INTRA-AGENCY~~ **904. ENHANCING** COORDINATION AND ~~PUBLIC HEALTH ASSESSMENT WITH REGARD TO COMPLIANCE ACTIVITIES.~~ **TRANSPARENCY ON INSPECTIONS.**

(a) Coordination.—Section 506D of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is amended—

(1) by adding at the end the following:

"(g) Coordination.—The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding the reviews of reports shared pursuant to section 704(b)(2), and any feedback or corrective or preventive actions in response to such reports."; and

(2) by amending subsection (f) to read as follows:

"(f) Temporary Sunset.—Subsection (a) shall cease to be effective on the date that is 5 years

after the date of enactment of the Food and Drug Administration Safety and Innovation Act. Subsections (b), (c), and (e) shall not be in effect during the period beginning 5 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act and ending on the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022. Subsections (b), (c), and (e) shall be in effect beginning on the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022.".

(b) Reporting.—Section 506C–1(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1(a)) is amended—

(1) by redesignating paragraphs (3) through (7) as paragraphs (4) through (8), respectively;

(2) by inserting after paragraph (2) the following:

"(3) provides the number of reports that were required under section 704(b)(2) to be sent to the appropriate offices of the Food and Drug Administration with expertise regarding drug shortages, and the number of such reports that were sent;"; and

(3) in paragraph ~~(3)(A)~~**(4)(A), as so redesignated**, by striking "paragraph (7)" and inserting "paragraph (8)".

(c) Applicability.—

(1) SUBSECTION (A).—The amendments made by subsection (a) shall apply beginning on the date of enactment of this Act.

(2) SUBSECTION (B).—The amendments made by subsection (b) shall apply beginning on the date that is 1 year after the date of enactment of this Act.

(d) Reporting of Mutual Recognition Agreements for Inspections and Review Activities.—Section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A), by striking ~~clause~~ **clauses (i) and** (ii) and inserting the following:

"(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year;

"(ii) the number of such registered establishments in each region of interest;

"(iii) the number of such domestic establishments and the number of such foreign establishments, including the number of establishments in each region of interest, that the Secretary inspected in the previous ~~calendar~~ **fiscal** year;

"(iv) the number of inspections to support actions by the Secretary on applications under section 505 of this Act or section 351 of the Public Health Service Act, including the number of inspections to support actions by the Secretary on supplemental applications, including changes to manufacturing processes, the Secretary conducted in the previous fiscal year;

"(v) the number of routine surveillance inspections the Secretary conducted in the previous fiscal year**, including in each region of interest**;

"(vi) the number of for-cause inspections the Secretary conducted in the previous fiscal year, not including inspections described in clause (iv)**, including in each region of interest**; and

"(vii) the number of inspections the Secretary has recognized pursuant to an agreement entered into pursuant to section 809, or otherwise recognized, for each of the types of inspections described in clauses (v) and (vi)~~;"~~**, including for inspections of establishments in each region of interest.";**

(B) in subparagraph (B), by striking "; and" and inserting a semicolon;

(C) in subparagraph (C), by striking the period and inserting "; and"; and

(D) by adding at the end the following:

"(D) the status of the efforts of the Food and Drug Administration to expand its recognition of inspections conducted or recognized by foreign regulatory authorities under section 809, including any obstacles to expanding the use of such recognition."; and

(2) by adding at the end the following:

"(7) REGION OF INTEREST.—For purposes of paragraph (6)(A), the term 'region of interest' means a foreign geographic region or country, including the People's Republic of China, India, the European Union, the United Kingdom, and any other country or geographic region, as the Secretary determines appropriate.".

(e) Enhancing Transparency of Drug Facility Inspection Timelines.—Section 902 of the FDA Reauthorization Act of 2017 (21 U.S.C. 355 note) is amended to read as follows:

"SEC. 902. ANNUAL REPORT ON INSPECTIONS.

"Not later than ~~March 1~~ **120 days after the end** of each **fiscal** year, the Secretary of Health and Human Services shall post on the website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)~~,~~ **or** approval of a device under section 515 of such Act (21 U.S.C. 360e)~~, or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k))~~ that were conducted during the previous ~~calendar~~ **fiscal** year. Such information shall include the following:

"(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, including—

"(A) the median time for drugs described in 505(j)(11)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

"(B) the median time for drugs ~~described in~~ **for which a notification has been submitted in accordance with** section 506C(a) of such Act (21 U.S.C. 356c(a)) ~~only;~~ **during the previous fiscal year;** and

"(C) the median time for drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C. ~~356f)~~ **356e) at the time of such request**.

"(2) The median time from the issuance of a report pursuant to section 704(b) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

"(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting related to conditions observed by the Secretary during an inspection, to the time at which the Secretary concludes that corrective actions to resolve such conditions have been taken.

"(4) The median time spent by staff of the Food and Drug Administration at a facility during an inspection, including—

"(A) the median time when records were provided remotely in accordance with a request under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)) in advance of the inspection; and

"(B) the median time when a request for records pursuant to such section 704(a)(4) was not issued, or complied with, in advance of the inspection.

"(5) The number and type of violations identified during inspections when a request for records pursuant to such section 704(a)(4) was issued and complied with in advance of the inspection, versus when a request for records pursuant to such section 704(a)(4) was not issued or complied with.

"(6) The number of facilities that did not implement ~~requested~~ **adequate** corrective or preventive actions following a report issued pursuant to such section 704(b), resulting in a withhold recommendation **for an application under review**, including the number of such ~~times for~~ **facilities manufacturing** each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).".

SEC. 905. CERTIFICATES TO FOREIGN GOVERNMENTS.

Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) in subparagraph (E), by striking clause (iii); and

(2) by adding at the end the following:

"(F)(i) This paragraph applies to requests for certification under this subparagraph of a device manufactured by a device establishment located outside of the United States that is registered under section 510, if the device is listed pursuant to section 510(j), the device has been cleared, approved, or is not required to submit a premarket report pursuant to subsection (l) or (m) of section 510, and the device is imported or offered for import into the United States.

"(ii) The Secretary shall issue the certification as described in clause (iii) if the device or devices for which certification is requested under this subparagraph meet the applicable requirements of this Act.

"(iii)(I) A certification for a device described in clause (i) shall be subject to the fee described in subparagraph (B).

"(II) Notwithstanding subparagraph (C), a certification for a device described in clause (i) shall address and include the same material information as a 'Certificate to Foreign Government' and shall have a document title including the words 'Certificate to Foreign Government'.

"(iv) The requirements and procedures of subparagraph (E) shall apply to a denial of a certification under this subparagraph.".

SEC. 906. IMPORTATION OF DRUGS.

(a) In General.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended to read as follows:

"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

"(a) Definitions.—In this section:

"(1) FOREIGN SELLER.—The term 'foreign seller' means an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States, that—

"(A) has an active Drug Establishment License to wholesale drugs by the appropriate Canadian regulatory authority;

"(B) is registered with the applicable regulatory authorities to distribute drugs approved by the appropriate Canadian regulatory authority;

"(C) is not licensed by a regulatory authority with an international pharmacy license that allows it to distribute drugs that are approved by countries other than Canada and that are not approved by the appropriate Canadian regulatory authority for distribution in Canada; and

"(D) is registered with the Secretary under this section.

"(2) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

"(3) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

"(4) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

"(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(C) an infused drug (including a peritoneal dialysis solution);

"(D) an intravenously injected drug;

"(E) a drug that is inhaled during surgery;

"(F) an intrathecally or intraocularly injected drug;

"(G) a drug that is subject to a risk evaluation and mitigation strategy under section 505-1;

"(H) a drug that is not a 'product' for purposes of section 582 as defined in section 581(13);

"(I) a compounded drug; or

"(J) a drug the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health.

"(5) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that complies with the applicable current good manufacturing practice requirements and has been approved by the Secretary for the purposes of this section.

"(6) SECTION 804 IMPORTATION PROGRAM SPONSOR.—The term 'section 804 importation program sponsor' means a State or Indian Tribe that regulates wholesale drug distribution and the practice of pharmacy, or a pharmacist or wholesaler that is not the importer, as the Secretary may determine, that submits a proposal to the Secretary that describes a program to facilitate the importation of prescription drugs from Canada under this section and is responsible for oversight of the implementation of the program.

"(7) WHOLESALER.—The term 'wholesaler'—

"(A) means a person licensed (as defined in section 581(9)(A)) as a wholesale distributor (as defined in section 581(29)); and

"(B) excludes a person authorized to import drugs under section 801(d)(1).

"(b) Regulations.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting time-limited section 804 importation programs, which shall be authorized by the Secretary and managed by States or Indian Tribes, or in certain circumstances by pharmacists and wholesalers, to import prescription drugs from Canada into the United States. The time limit for a section 804 importation program authorized by the Secretary may be extended for a period not to exceed the initial time limit authorized by the Secretary.

"(c) Limitation.—The regulations under subsection (b) shall—

"(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

"(2) require that a section 804 importation program sponsor and an importer of a prescription drug under the regulations comply with subsections (d)(1), (d)(2), (d)(3), and (e);

"(3) require that the section 804 importation program sponsor demonstrates that the importation program meets the certification requirements under subsection (l)(1);

and

"(4) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

"(d) Information and Records.—

"(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

"(A) The name and quantity of the active ingredient of the prescription drug.

"(B) A description of the dosage form of the prescription drug.

"(C) The date on which the prescription drug is shipped.

"(D) The quantity of the prescription drug that is shipped.

"(E) The point of origin and destination of the prescription drug.

"(F) The price paid by the importer for the prescription drug.

"(G) Documentation from the foreign seller specifying—

"(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

"(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

"(I) The name, address, telephone number, and professional license number (if any) of the importer.

"(J) Documentation demonstrating that the prescription drug was received by the foreign seller from the manufacturer and subsequently shipped by the foreign seller to the importer.

"(K) Documentation of the quantity of each lot of the prescription drug received by the foreign seller demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the foreign seller.

"(L)(i) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

"(ii) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

"(M) Documentation that each supply chain under a section 804 importation program proposal is limited to one manufacturer, one foreign seller, and one importer.

"(N) For each prescription drug imported under a section 804 importation program, documentation that the prescription drug was purchased directly from the manufacturer by the foreign seller and that the foreign seller sold the prescription drug directly to the importer.

"(O) Certification from the importer that the prescription drug—

"(i) is approved for marketing in the United States and is not adulterated or misbranded; and

"(ii) is relabeled after the Secretary has accepted the results of testing required by subparagraphs (J) through (P)) and meets all labeling requirements under this Act.

"(P) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

"(Q) Documentation demonstrating that the testing required by subparagraphs (J) through (P) was conducted at a qualifying laboratory in the United States.

"(R) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

"(2) SECTION 804 IMPORTATION PROGRAM PROPOSAL.—The regulations under subsection (b) shall require a sponsor of a time-limited section 804 importation program authorized under such subsection to submit to the Secretary the following information and documentation in its proposal to the Secretary:

"(A) The names of all participants in the supply chain, including—

"(i) the foreign seller;

"(ii) the importer;

"(iii) the repackager or relabeler, if different from the importer, that will relabel the eligible prescription drugs; and

"(iv) the qualifying laboratory that will conduct testing for the importer.

"(B) Information about how the section 804 importation program sponsor will ensure that—

"(i) the prescription drug meets the testing requirements in subparagraphs (J) through (P) of paragraph (1);

"(ii) the supply chain is secure;

"(iii) the prescription drug will meet the labeling requirements of this Act;

"(iv) the adverse event-related requirements of this Act are met; and

"(v) the section 804 importation program will result in a significant reduction in the cost to the American consumer of the prescription drug.

"(C) A compliance plan.

"(D) Information about how the section 804 importation sponsor will ensure

that any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies are kept in strict confidence and used only for the purposes of testing or otherwise complying with Federal law.

"(3) PRE -IMPORT REQUEST.—The regulations under subsection (b) shall require an importer under a program authorized under such subsection to submit a pre-import request to the Secretary at least 30 calendar days before the scheduled date of arrival or entry for consumption of a shipment containing a prescription drug covered by the section 804 importation program, whichever is earlier.

"(4) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraphs (1), (2), and (3) for such period of time as the Secretary determines to be necessary.

"(e) Testing.—The regulations under subsection (b) shall require—

"(1) that testing described in subparagraphs (J) through (P) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

"(2) if the tests are conducted by the importer—

"(A) that information needed to—

"(i) authenticate the prescription drug being tested; and

"(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act,

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

"(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

"(3) such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

"(f) Registration of Foreign Sellers.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

"(g) Suspension of Importation.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

"(h) Approved Labeling.—The manufacturer of a prescription drug shall provide an

importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

"(i) Charitable Contributions.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

"(j) Importation for Personal Use.—

"(1) DECLARATIONS.—Congress declares that, in implementing the provisions under this section, the Secretary may—

"(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

"(B) exercise discretion to permit individuals to make such importations in circumstances in which—

"(i) the importation is clearly for personal use; and

"(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

"(2) REGULATIONS.—

"(A) IN GENERAL.—The Secretary may, by regulation, permit importation of a prescription drug, or class of prescription drugs, for personal use, provided that such importation—

"(i) does not increase the public's exposure to counterfeit prescription drug products;

"(ii) does not pose a risk of creating, exacerbating, or prolonging an opioid epidemic, including by increasing the public's exposure to counterfeit prescription opioid drug products, such as counterfeit fentanyl, or increasing the public's misuse of prescription opioid drug products;

"(iii) meets the certification requirements under subsection (l)(1); and

"(iv) meets such other conditions as the Secretary determines to be appropriate.

"(B) REQUIREMENTS.—Regulations described in subparagraph (A) may permit importation into the United States of a prescription drug that—

"(i) is imported in a quantity that does not exceed a 90-day supply;

"(ii) is for personal use by an individual, not for resale;

"(iii) is accompanied by a copy of a valid prescription issued by a health care practitioner licensed by a State to practice in the United States to administer the drug, and is not distributed to anyone other than the individual for whom such prescription is written;

"(iv) is imported from Canada, from a licensed pharmacy physically

located in Canada and registered with the Secretary;

"(v) is a prescription drug that complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

"(vi) is accompanied by an electronic import entry for such prescription drug regardless of its values, submitted using an authorized electronic data interchange system;

"(vii) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

"(viii) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

"(C) PROCEDURE.—The Secretary shall—

"(i) proceed in accordance with section 553 of title 5 (without regard to any reference in such section to sections 556 and 557 of such title) when promulgating a regulation under subparagraph (A), and shall—

"(I) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;

"(II) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

"(III) hold a public meeting; and

"(IV) promulgate a final rule based on the matter in the rulemaking record;

"(ii) consult with the United States Trade Representative, the Commissioner of the U.S. Customs and Border Protection, and the Administrator of the Drug Enforcement Administration prior to proposing and finalizing a rule under subparagraph (A);

"(iii) include in the preamble to the proposed rule under subparagraph (A) a clear and complete description of how the Secretary made each of the determinations in subparagraph (A), including associated analyses, assumptions, and information sources used to make each such determination, and a description of any key limitations or uncertainties that could affect each determination; and

"(iv) publish the proposed rule and final rule under subparagraph (A) in the Federal Register and concurrently publish the record of the consultations described in clause (ii) and the descriptions described in clause (iii).

"(k) Construction.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, including the Secretary's authority to refuse admission of a drug under section 801(a), other than with respect to section 801(d)(1) as provided in this section.

"(l) Effectiveness of Section.—

"(1) COMMENCEMENT OF PROGRAM.—This section shall become effective only if the Secretary certifies to Congress that the implementation of this section will—

"(A) pose no additional risk to the public's health and safety;

"(B) result in a significant reduction in the cost of covered products to the American consumer; and

"(C) be subject to adequate and consistent oversight by the Secretary.

"(m) Termination of Program.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) or (j), the Secretary submits to Congress a certification that, in the option of the Secretary, the benefits of implementation of either or both such subsections do not outweigh any detriment of implementation of such subsection or subsections and any regulations promulgated thereunder, such subsection or subsections shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

"(n) Authorization of Appropriations.—There are authorized to be appropriated such sums as are necessary to carry out this section.".

(b) Requirement.—The Secretary of Health and Human Services shall reissue, or amend, as appropriate, the regulations published at part 251 of title 21 of the Code of Federal Regulations pursuant to section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)), as in effect on the day before the date of enactment of this Act.

SEC. 907. IMPROVING INFORMATION TECHNOLOGY SYSTEMS OF THE FOOD AND DRUG ADMINISTRATION.

(a) FDA Strategic Information Technology Plan.—

(1) IN GENERAL.—Not later than September 30, 2023, and at least every 4 years thereafter, the Secretary of Health and Human Services shall develop and submit to the appropriate committees of Congress and post on the website of the Food and Drug Administration, a coordinated information technology strategic plan to modernize the information technology systems of the Food and Drug Administration. Each such report shall be known as the "Food and Drug Administration Strategic Information Technology Plan.". The first such report may include the Data and Technology Modernization Strategy, as set forth in the letters described in section 101(b) of the Food and Drug Administration Safety and Landmark Advancements Act of 2022.

(2) CONTENT OF STRATEGIC PLAN.—The Food and Drug Administration Strategic Information Technology Plan under paragraph (1) shall include—

(A) agency-wide strategic goals and priorities for modernizing the information technology systems of the Food and Drug Administration to maximize the efficiency and effectiveness of such systems for enabling the Food and Drug Administration to fulfill its public health mission;

(B) specific activities and strategies for achieving the goals and priorities identified under subparagraph (A), and specific milestones, metrics, and performance measures for assessing progress against the strategic goals and priorities in subparagraph (A);

(C) specific activities and strategies for improving and streamlining internal coordination and communication within the Food and Drug Administration, including for activities and communications related to signals of potential public health concerns;

(D) challenges and risks the Food and Drug Administration will face in meeting its strategic goals and priorities, and the activities the Food and Drug Administration will undertake to overcome those challenges and mitigate those risks;

(E) the ways in which the Food and Drug Administration will use the plan to guide and coordinate the projects and activities of the Food and Drug Administration across its offices and centers; and

(F) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

(3) EVALUATION OF PROGRESS.—Each Food and Drug Administration Strategic Information Technology Plan issued pursuant to this subsection, with the exception of the first such Food and Drug Administration Strategic Information Technology Plan, shall include an evaluation of—

(A) the progress the Secretary has made, based on the metrics, benchmarks, and other milestones that measure successful development and implementation of information technology systems; and

(B) whether such actions improved the capacity of the Food and Drug Administration to achieve the strategic goals and priorities set forth in the previous Food and Drug Administration Strategic Information Technology Plan.

(b) GAO Report.—

(1) IN GENERAL.—Not later than September 30, 2026, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report assessing the implementation of the Food and Drug Administration Strategic Information Technology Plan adopted pursuant to subsection (a).

(2) CONTENT OF REPORT.—The report required under paragraph (1) shall include an assessment of—

(A) the development and implementation of the Food and Drug Administration Strategic Information Technology Plan, including the sufficiency of the plan, progress of the Food and Drug Administration in meeting the results-oriented goals, milestones, and performance measures identified in such plan and any gaps in such implementation;

(B) the efficiency and effectiveness of the Food and Drug Administration's expenditures on information technology systems over the preceding 10 fiscal years, including the implementation by the Food and Drug Administration of the Technology Modernization Action Plan and Data Modernization Action Plan;

(C) challenges posed by the information technology systems of the Food and Drug Administration for carrying out the Food and Drug Administration's public health mission, including on meeting user fee agreement performance goals, conducting inspections, responding to identified safety concerns, and keeping pace with new scientific and medical advances; and

(D) recommendations for the Food and Drug Administration to address the identified challenges, improve its implementation of the Food and Drug Administration Strategic Information Technology Plan, and to otherwise improve the Food and Drug Administration's information technology systems.

SEC. 908. REGULATION OF CERTAIN PRODUCTS AS DRUGS.

Section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) is amended by adding at the end the following:

"(h) Deeming Certain Products as Drugs.—

"(1) IN GENERAL.—Any contrast agent, radioactive drug, OTC monograph drug, or ophthalmic drug article shall be deemed to be a drug under section 201(g) and not a device under section 201(h).

"(2) DEFINITIONS.—For purposes of this subsection—

"(A) the term 'contrast agent' means an article that is intended for use in conjunction with a medical imaging device, and that—

"(i) is a diagnostic radiopharmaceutical, as defined in section 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations), including PET drugs, as defined in section 212.1 of title 21, Code of Federal Regulations (or any successor regulations) and positron emission tomography radiotracers; or

"(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid;

"(B) the term 'ophthalmic drug article' means any eye cup, eye dropper, or other similar dispenser intended for ophthalmic use if packaged with the drug with which such article is intended to be used;

"(C) the term 'OTC monograph drug' has the meaning given such term in section 744L; and

"(D) the term 'radioactive drug' has the meaning given such term in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations), except that such term does not include—

"(i) implants or articles similar to an implant;

"(ii) articles that apply radiation from outside of the body; or

"(iii) the radiation source of an article described in clause (i) or (ii).

"(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as allowing for the classification of a product as a drug (as defined in section 201(g)) if such product—

"(A) is not described in paragraph (1); and

"(B) meets the definition of a device under section 201(h), unless another provision of this Act otherwise indicates a different classification.

"(4) FEES.—The Secretary shall waive the application fee under sections 736 and 744B for applications for products that are, on the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, legally marketed as medical devices and that are deemed drugs pursuant to paragraph (1).".

SEC. 909. REPORTING ON MAILROOM AND OFFICE OF THE EXECUTIVE SECRETARIAT OF THE FOOD AND DRUG ADMINISTRATION.

(a) Report.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) information related to policies, procedures, and activities of the mailroom and the Office of the Executive Secretariat of the Food and Drug Administration, including—

(A) taking receipt, tracking, managing, and prioritizing confidential informant complaints;

(B) taking receipt of common carrier packages to the Food and Drug Administration;

(C) the organizational structure and management of the mailroom;

(D) the organizational structure and management of the Office of the Executive Secretariat;

(E) the total number of employees and contractors in the mailroom including those working remotely and those working in person;

(F) the total number of employees and contractors in the Office of the Executive Secretariat;

(G) the number of vacant positions in the mailroom;

(H) the number of vacant positions in the Office of the Executive Secretariat;

(I) the average number of days for response to correspondence received by the

Office of the Secretariat;

(J) the extent to which there is a backlog of common carrier packages received by the mailroom and the number of common carrier packages in any backlog;

(K) the extent to which there is a backlog of correspondence in the Office of the Executive Secretariat that has not been appropriately responded to by the Food and Drug Administration and the number of correspondence or common carrier packages in any backlog;

(L) a rationale for the failure of the Office of the Executive Secretariat to respond to correspondence in any backlog and the position of the decision-making official who determined not to respond to such correspondence;

(M) the number of whistleblower correspondence received, including within each agency center;

(N) the amount of resources expended for the mailroom, including a breakdown of budget authority and user fee dollars;

(O) the amount of resources expended for the Office of the Executive Secretariat and correspondence-related activities, including a breakdown of budget authority and user fee dollars; and

(P) the performance of third-party contractors responsible for correspondence-related activities with respect to the receipt and tracking of correspondence, and efforts by the Food and Drug Administration to improve performance by such contractors; and

(2) the development and implementation of new or revised policies and procedures of the Food and Drug Administration to monitor and ensure—

(A) the effective receipt, tracking, managing, and prioritization of such complaints; and

(B) the effective receipt of common carrier packages to the Food and Drug Administration.

(b) Quarterly Reporting.— Beginning on the date of enactment of this Act, the Secretary shall issue a report each quarter through September 30, 2024, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the implementation of the new or revised policies of the Food and Drug Administration reported under subsection (a)(2), and since such implementation—

(1) the volume of incoming common carrier packages to the mailroom;

(2) the volume of incoming correspondence to the Office of the Executive Secretariat;

(3) the extent to which new backlogs occur in the processing of common carrier packages received by the mailroom;

(4) the extent to which new backlogs occur in the processing of correspondence received by the Office of the Executive Secretariat;

(5) the length of time required to resolve each such backlog;

(6) any known issues of unreasonable delays in correspondence being provided to the intended recipient, or in correspondence being lost, and the measures taken to remedy such delays or lost items;

(7) the average number of days it takes to respond to correspondence received by the Office of the Executive Secretariat;

(8) the resources expended by the mailroom, including a breakdown of budget authority and user fee dollars; and

(9) the resources expended by the Office of the Executive Secretariat on correspondence-related activities, including a breakdown of budget authority and user fee dollars.

(c) GAO Report.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report assessing the policies and practices of the Division of Executive Operations of the Office of the Executive Secretariat of the Food and Drug Administration with respect to the receipt, tracking, managing, and prioritization of correspondence.

SEC. 910. PROTECTING INFANTS AND IMPROVING FORMULA SUPPLY.

(a) Definitions.—

(1) IN GENERAL.—In this section—

(A) the term "infant formula" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); and

(B) the term "Secretary" means the Secretary of Health and Human Services.

**** 12** ~~(c) Enforcement.—Section 301~~**(2) CRITICAL FOOD.—Section 201** of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. ~~331)~~ **321)**, as amended by section ~~824~~ **822**, is further amended by adding at the end the following:

"(tt) The term 'critical food' means a food that—

"(1) is an infant formula;

"(2) is a medical food, as defined in section 5(b)(3) of the Orphan Drug Act; or

"(3) is intended for use by individuals with certain inborn errors of metabolism or other conditions requiring a medical food.".

(b) Office of Critical Foods.—

(1) IN GENERAL.—The Secretary shall establish within the Center for Food Safety and Applied Nutrition an office to be known as the Office of Critical Foods. The Secretary shall appoint a Director to lead such Office.

(2) DUTIES.—The Office of Critical Foods shall be responsible for oversight,

coordination, and facilitation of activities related to critical foods, as defined in section 201(tt) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)(2), and any other food determined by the Secretary to be critical.

(c) Premarket Submissions of Infant Formula to Address Shortages.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended by adding at the end the following:

"(j) Premarket Submissions to Address Shortages.—

"(1) IN GENERAL.—The Secretary shall waive the 90 day premarket submission requirement under section 412(c) and apply a 30-day premarket submission requirement, for any person who intends to introduce or deliver for introduction into interstate commerce any new infant formula.

"(2) EFFECTIVE PERIOD.—The waiver authority under this subsection shall remain in effect for 90 days beginning on the date that the Secretary distributes information under section 424(a)(2), or such longer period as the Secretary determines appropriate to prevent or mitigate a shortage of infant formula.

"(3) REPORT.—Not later than one year after the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

"(A) the number of premarket submissions for new infant formula the Secretary has received under subsection (d) each year since 2012;

"(B) how many of such submissions received requests from the Secretary for additional information;

"(C) how long after receiving such submissions the Secretary sent such requests for additional information;

"(D) what additional information the Secretary requested of the persons submitting such submissions; and

"(E) the date each new infant formula product described in subparagraph (A) was first marketed, if available.".

(d) Infant Formula Flexibilities.—The Secretary shall publish a list on the website of the Food and Drug Administration detailing which infant formula products may be appropriate substitutes for infant formula products in shortage that are relied upon by infants and other individuals with amino-acid and metabolic conditions.

(e) International Harmonization of Infant Formula Requirements.—

(1) IN GENERAL.—The Secretary—

(A) shall participate in meetings with representatives from other countries to discuss methods and approaches to harmonizing regulatory requirements for infant formula, including with respect to inspections, labeling, and nutritional requirements; and

(B) may enter into agreements regarding such requirements with other countries, as appropriate.

(2) STUDY ON INFANT FORMULA.—

(A) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this paragraph as the "National Academies") to examine and report on challenges in supply, market competition, and regulation of infant formula in the United States.

(B) REQUIREMENTS OF FOREIGN COUNTRIES.—The report developed pursuant to the agreement under subparagraph (A) shall assess and evaluate infant formula marketed in the United States, any challenges in supply, market competition, and any differences in infant formula marketed in the European Union, including with respect to nutritional content and applicable labeling and other regulatory requirements.

(C) FINAL REPORT.—The agreement under subparagraph (A) shall specify that the National Academies shall, not later than 1 year after the date of enactment of this Act, complete such study and submit a report on the results of such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(f) Transparency and Accountability to Support Infant Formula Innovation.—

(1) ANNUAL REPORT TO CONGRESS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by subsection (c), is further amended by adding at the end the following:

"(k) Annual Report to Congress.—

"(1) IN GENERAL.—Not later than March 30 of each year, the Secretary shall submit a report to Congress containing, with respect to the preceding calendar year, the following information:

"(A) The number of submissions received by the Secretary under subsection (d).

"(B) The number of submissions that included any new ingredients that were not included in any infant formula already on the market.

"(C) The number of inspections conducted by the Food and Drug Administration or any agent thereof to evaluate compliance with the requirements for infant formulas under subsection (b)(2).

"(D) The time between any inspection referred to in paragraph (3) and any necessary reinspection to evaluate compliance with the requirements for infant formulas under subsection (b)(2).

"(E) A breakdown of the information described in subparagraphs (A) through (D) between foreign and domestic manufacturers and facilities.

"(2) CONFIDENTIALITY.—The Secretary shall ensure that the reports under

paragraph (1) do not include any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.".

(2) MARKETING SUBMISSIONS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by paragraph (1), is further amended by adding at the end the following:

"(l) Marketing Submissions.—

"(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall respond to a submission under subsection (d) for infant formula not later than 65 days after receiving such submission.

"(2) EXPEDITED RESPONSE.—The Secretary shall respond to a submission under subsection (d) for infant formula not later than 45 days after receiving such notification if it—

"(A) is submitted by a manufacturer that is not already marketing infant formula in the United States; or

"(B) is a new infant formula, as defined in subsection (c)(2).".

(3) LIST OF NUTRIENTS.—Section 412(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)) is amended by striking "or, if revised by the Secretary under paragraph (2), as so revised" and inserting the following: ", which shall be reviewed by the Secretary every 4 years as appropriate. In reviewing such table, the Secretary shall consider any new scientific data or information related to infant formula nutrients, including international infant formula standards. The Secretary may revise the list of nutrients and the required level for any nutrient required by the table".

(4) TECHNICAL CORRECTION.—Section 412(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(c)(1)(B)) is amended by striking "subsection (c)(1)" and inserting "subsection (d)(1)".

(g) Response to Recall.—

(1) MANUFACTURER SUBMISSION.—

(A) IN GENERAL.—Promptly after the initiation of a recall of infant formula, the manufacturer of the recalled infant formula shall submit information to the Secretary regarding such recall.

(B) CONTENTS.—A submission under subparagraph (A) shall include the following:

(i) A plan (including an estimated timeline, as applicable) of actions the manufacturer will take, suited to the individual circumstances of the particular recall, including—

(I) to identify and address any cause of adulteration or misbranding; and

(II) if appropriate, to restore operation of the impacted facilities.

(ii) In the case that a recall of the manufacturer's infant formula products,

and subsequent actions to respond to such recall, impacts over 10 percent of the production of the infant formula intended for sale in the United States, a plan to backfill the supply of the manufacturer's infant formula supply if the current domestic supply of such infant formula has fallen, or is expected to fall, below the expected demand for the formula.

(2) REPORT TO CONGRESS.—

(A) IN GENERAL.—Promptly after a submission under paragraph (1) is received, the Secretary shall provide such submission, together with the information specified in subparagraph (B), in a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(B) CONTENTS.—A submission under subparagraph (A) shall include the following:

(i) Information concerning the current domestic supply of infant formula, including—

(I) a breakdown of the specific types of formula involved; and

(II) an estimate of how long current supplies will last.

(ii) In the case that a submission or submissions under paragraph (1) show that the recall and subsequent actions to respond to the recall impact over 10 percent of the domestic production of infant formula intended for sale in the United States—

(I) actions to work with the impacted manufacturer or other manufacturers to increase production; and

(II) specification of—

(aa) any additional authorities needed regarding production or importation to fill a supply gap; and

(bb) any supplemental funding necessary to address the shortage.

(3) SUNSET.—This subsection shall cease to have force or effect on of September 30, 2026.

(h) Coordination With Manufacturer.—

(1) INSPECTIONS.—The Secretary shall ensure timely communication with a manufacturer of infant formula following an inspection of a facility engaged in the manufacturing of infant formula for consumption in the United States. If a reinspection of a manufacturer of an infant formula is required to ensure that such manufacturer completed any remediation actions or addressed any deficiencies, the Secretary shall reinspect such facility in a timely manner. The Secretary shall prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent a shortage of an infant formula.

(2) ANNUAL INSPECTIONS.—Not later than 6 months after the date of enactment of this Act, and not less than once per calendar year thereafter, the Secretary shall

conduct inspections, including unannounced inspections, of the facilities (including foreign facilities) of each manufacturer of an infant formula required to be registered under section 412(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(c)(1)(A)), in accordance with a risk based approach and ensure timely and effective internal coordination and alignment among the investigators and the Center for Food Safety and Applied Nutrition.

(i) National Strategy on Infant Formula.—

(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture and other heads of relevant departments and agencies, shall develop and issue, not later than 90 days after the date of enactment of this Act, a national strategy on infant formula to increase the resiliency of the infant formula supply chain, protect against future contamination and other potential causes of shortages, and ensure parents and caregivers have access to formula and information they need.

(2) NATIONAL STRATEGY.—The national strategy under paragraph (1) shall—

(A) increase the resiliency of the infant formula supply chain in the short-term by—

(i) assessing causes of the current shortage and potential causes of future shortages,

(ii) assessing and addressing immediate infant formula needs associated with the shortage, and

(iii) developing a plan to increase infant formula supply, including through increased competition;

(B) improve preparedness against infant formula shortages in the long-term by—

(i) outlining methods to improve information-sharing between the Federal Government and State and local governments, and other entities as appropriate, regarding shortages;

(ii) recommending measures for protecting the integrity of infant formula supply and preventing contamination;

(iii) outlining methods to incentivize new infant formula manufacturers to increase supply and mitigate future shortages; and

(iv) recommending other necessary authorities to gain insight into the supply chain and risk for shortages, and to incentivize new infant formula manufacturers; and

(C) ensure the development and updating of education and communication materials for parents and caregivers that cover—

(i) where and how to find infant formula;

(ii) comparable infant formulas on the market,

(iii) what to do if a medical or specialty infant formula is unavailable;

(iv) safe practices for handling infant formula; and

(v) other topics, as appropriate.

(j) Meaningful Disruption in the Production of Critical Food.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 424. REQUIREMENTS FOR CRITICAL FOOD.

"(a) Notification of Meaningful Disruption for Critical Food.—

"(1) IN GENERAL.—A manufacturer of a critical food (as defined in section 201(tt)) shall notify the Secretary of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption.

"(2) DISTRIBUTION OF INFORMATION.—Not later than 5 calendar days after receiving a notification under paragraph (1), the Secretary shall distribute, to the Secretary of Agriculture and to the maximum extent practicable to the appropriate entities, as determined by the Secretary through such means as the Secretary determines appropriate, information on the meaningful disruption of a critical food reported under this subsection.

"(3) CONFIDENTIALITY.—Nothing in this subsection authorizes the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(4) MEANINGFUL DISRUPTION.—In this subsection, the term 'meaningful disruption'—

"(A) means a change in production that is reasonably likely to lead to a significant reduction in the supply of a critical food by a manufacturer that affects the ability of the manufacturer to meet expected demand for its product; and

"(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

"(b) Risk Management Plans.—Each manufacturer of a critical food shall develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which such food is manufactured. A risk management plan under this subsection—

"(1) may identify and evaluate risks to the supply of more than one critical food, or critical food category, manufactured at the same establishment; and

"(2) shall be subject to inspection and copying by the Secretary pursuant to an inspection under section 704.

"(c) Failure to Meet Requirements.—

"(1) IN GENERAL.—If a person fails to submit information required under, and in accordance with, subsection (a)—

"(A) the Secretary shall issue a letter to such person informing such person of such failure; and

"(B) not later than 45 calendar days after the issuance of a letter under subparagraph (A), subject to paragraph (2), the Secretary shall make available to the public on the website of the Food and Drug Administration, with appropriate redactions made to protect the information described in subsection (a)(3)—

"(i) the letter issued under subparagraph (A); and

"(ii) at the request of such person, any response to such letter such person submitted to the Secretary.

"(2) EXCEPTION.—If the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not submitting a notification as required under subsection (m), the requirements of paragraph (1)(B) shall not apply.".