UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE GOOD FOOD INSTITUTE, **1380 Monroe St. NW, #229** **Washington, DC 20010,** **Plaintiff,** **v.** **FOOD AND DRUG ADMINISTRATION,** **5600 Fishers Lane** **Rockville, MD 20854** **Defendant.**	)	**Civil Action No. 1:16-cv-1052**

COMPLAINT FOR INJUNCTIVE RELIEF

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 (2012), for injunctive and other relief, seeking the release of agency records requested by The Good Food Institute ("GFI") from the U.S. Food and Drug Administration ("FDA").

2. This lawsuit challenges the failure of FDA to disclose agency records in response to two April 7, 2016, FOIA requests submitted by GFI. GFI requested documents related to FDA's regulatory treatment of the common and usual name "soy milk" or "soymilk" to refer to a liquid food derived from the cooking and processing of whole soybeans with water. FDA has failed to comply with statutory deadlines and largely failed to disclose responsive records. GFI asks the Court to order disclosure of all responsive records.

Jurisdiction and Venue

3. The Court has subject matter jurisdiction over this action and personal jurisdiction over the parties under FOIA. *See* 5 U.S.C. §§ 552(a)(4)(B), 552(a)(6)(C)(i) (2012). The Court also has subject matter jurisdiction over this action under 28 U.S.C. § 1331 (2012).

4. Venue is proper in this district under FOIA. *See* 5 U.S.C. § 552(a)(4)(B) (2012).

Parties

5. Plaintiff GFI is a public interest organization incorporated as a non-profit corporation in Washington, D.C. GFI is working toward a healthy, humane, and sustainable food supply. Among other activities, GFI widely shares information throughout the country by various means, including through its website, social media outlets, publications (including opinion pieces in major media outlets), and media interviews. Consumers of the information GFI disseminates include scientists, students, governmental entities, the regulated communities, media outlets, and the general public.

6. Defendant FDA is an agency of the U.S. Department of Health and Human Services, a cabinet-level department of the executive branch of the United States government. FDA is an agency within the meaning of FOIA, 5 U.S.C. § 552(f)(1) (2012).

FACTS

Background

7. For decades, consumers in the United States have been consuming a beverage commonly called "soy milk" (or "soymilk"). This beverage also exists (often with similar names in other languages) around the world, with a long history dating back centuries.

8. Consumption of soy milk and other plant-based milks (including, for example, almond milk) has increased rapidly in recent years in the United States.

9. In 1997, a trade association called the Soyfoods Association of America petitioned FDA to formally recognize "soy milk" as the common and usual name for soy beverages, and to establish standards of identity for this product.

10. To date, FDA has not responded to the 1997 petition.

11. In government literature, different agencies of the federal government, including FDA, USDA, and HHS have at various times referred to soy milk or soymilk by such names.

12. However, the government's (and FDA's) position on the propriety of such names has not always been consistent.

13. On August 8, 2008, FDA included language in a warning letter to Lifesoy, Inc., stating that the name "soy milk" is improper because such products do not contain (dairy) "milk," and such beverages should instead be labeled "soy beverage" or "soy drink."

14. On March 7, 2012, FDA issued a warning letter to Fong Kee Tofu Company that included similar language stating FDA's preference for the names "soy beverage" or "soy drink."

15. Notwithstanding FDA's varying positions on the matter, many major brands of soy milk continue to label their products as "soy milk" or "soymilk." This has resulted in consumer confusion and an uneven competitive landscape.

16. On May 25, 2012, United States Senators from dairy-producing states wrote to FDA Commissioner Margaret Hamburg urging FDA to take stronger action to enforce the dairy-related standards of identity against plant-based alternatives such as soy milk, similar to the positions outlined in FDA's warning letters.

17. A similar letter was sent to FDA by the National Milk Producers Federation on April 28, 2010, among other similar requests from this group.

18. Compounding the problem of the government's varying positions on the matter, these calls for regulation (originating from the producers of competitive products) have created significant regulatory uncertainty regarding these products.

GFI's FOIA Requests

19. On April 7, 2016, GFI submitted three FOIA requests to FDA, two of which are the subject of this lawsuit. FDA acknowledged receipt of these requests the next day, April 8, 2016, and assigned the control numbers used as references below.

20. FOIA Request 2016-3010 sought information relating to FDA's communications with third parties, and the decision-making process by which the above-described warning letters were issued. The exact scope of the request was the following:

a. All communications, memoranda, or other documents in the possession of, created by, or directed to or coming from the San Francisco District Office in 2011 and 2012 which include the terms "soy milk," "soymilk," "soy beverage," or "soy drink." More particularly, responsive documents are likely be found in agency records relating to the warning letter issued by that Office to Fong Kee Tofu Company, Inc. on March 7, 2012 (CMS case 268776).

b. All communications, memoranda, or other documents in the possession of, created by, or directed to or coming from the Los Angeles District Office in 2008 which include the terms "soy milk," "soymilk," "soy beverage," or "soy drink." More particularly, responsive documents are likely be found in agency records relating to the warning letter issued by that Office to Lifesoy, Inc. on August 8, 2008 (W/L 20-08).

c. All communications, including emails or letters, issued to any third party from February 1997 to present, that discuss the propriety of the terms "soy milk" or "soymilk" as a common or usual product name.

21. GFI also included the names of FDA employees whose electronic records should be searched due to their role in the preparation of the warning letters, and the names of major producers of soy milk who may have been in communication with FDA.

22. On May 3, 2016, the San Francisco District Office issued what it termed a "final response" by that Office to GFI's FOIA request. The documents disclosed with this response consisted entirely of inspection reports of the Fong Kee Tofu Company facility.

23. The response letter did not identify any documents being withheld or explain the scope of the search conducted, and did not explain FDA's decision not to search the electronic records identified.

24. Although this Court now has jurisdiction over this matter, GFI also filed an administrative appeal with the agency regarding this response on June 3, 2016.

25. No other component of FDA, including the Los Angeles District Office or the Center for Food Safety and Applied Nutrition ("CFSAN"), has communicated with GFI regarding its request since the agency's initial acknowledgement of receipt on April 8, 2016.

26. On information and belief, the above request was not even forwarded to CFSAN or any other component at FDA besides the two field offices.

27. FOIA Request 2016-3006 sought information related to the letters sent to FDA by the Senators and the National Milk Producers Federation. The exact scope of the request was the following:

a. All documents relating to the May 25, 2012, letter sent to Commissioner Hamburg by Senators Dan Coats, Richard Lugar, and Kirsten Gillibrand, related to standards of identity and dairy products, including all attachments and enclosures to the letter itself, all responses issued by the Commissioner or other employees of FDA, and all agency documents generated in reference to or response to this letter (including, but not limited to, emails and presentations discussing the letter, notes related to meetings, presentations prepared in response).

b. All documents relating to the April 28, 2010, letter sent to Commissioner Hamburg by the National Milk Producers Federation, related to standards of identity and dairy products, including all responses issued by the Commissioner or other employees of FDA, and all agency documents generated in reference to or response to this letter (including, but not limited to, emails and presentations discussing the letter, notes related to meetings, and presentations prepared in response.)

28. On May 12, 2016, FDA sent GFI three pages in response to this request, comprising of the letter from the Senators (without attachments or enclosures) and a two-page letter of reply sent to Senator Dan Coats by the FDA Associate Commissioner for Legislation.

29. After further inquiry from GFI, FDA indicated that it would conduct a further search, and on May 23, informed GFI by email that GFI's request was "still pending" with CFSAN.

COUNT I
Violation of FOIA: Failure to Comply with Statutory Deadlines

30. Paragraphs 1–29 are incorporated by reference as if set forth fully herein.

31. FDA's failure to respond to GFI's above FOIA requests within 20 working days violated the statutory deadline imposed by FOIA. *See* 5 U.S.C. § 552(a)(6)(A)(i).

32. FDA failed to meet the statutory deadline even assuming the agency took the full ten days allowed to send the requests to the appropriate components. 5 U.S.C. § 552(a)(6)(A).

33. As a result of FDA's failure to comply with the statutory deadlines, GFI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

34. GFI is entitled to an order "to enjoin the agency from withholding agency records and to order the production of any agency record improperly withheld" from GFI. 5 U.S.C. § 552(a)(4)(B).

COUNT II
Violation of FOIA: Failure to Make Reasonable Efforts to Search for Responsive Records

35. Paragraphs 1–34 are incorporated by reference as if set forth fully herein.

36. FDA's failure to make reasonable efforts to search for responsive documents, including records in electronic form or format, violates FOIA. 5 U.S.C. § 552(a)(3)(B)–(C).

37. As a result of FDA's failure to comply with the statutory deadlines, GFI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

38. GFI is entitled to an order "to enjoin the agency from withholding agency records and to order the production of any agency record improperly withheld" from GFI. 5 U.S.C. § 552(a)(4)(B).

COUNT III
Violation of FOIA: Failure to Make Compliance Determination and Notification

39. Paragraphs 1–38 are incorporated by reference as if set forth fully herein.

40. As described above, FDA has failed to comply with statutory deadlines.

41. Additionally, any non-final responses from FDA have failed to notify GFI whether FDA will comply with GFI's request, along with the reasons for such determination and the right to appeal such determination. 5 U.S.C. § 552(a)(6)(A)(i).

42. In particular, FDA has not notified GFI of any records it would not search, or any exemptions justifying such failure to search.

43. As a result of FDA's failure to comply with the statutory deadlines, GFI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

44. GFI is entitled to an order "to enjoin the agency from withholding agency records and to order the production of any agency record improperly withheld" from GFI. 5 U.S.C. § 552(a)(4)(B).

COUNT IV
Violation of FOIA: Unlawful Withholding of Agency Records

45. Paragraphs 1–44 are incorporated by reference as if set forth fully herein.

46. As described above, FDA failed to comply with statutory deadlines, failed to make reasonable efforts to search for responsive records, and failed to make a compliance determination regarding GFI's request.

47. As a result of FDA's unlawful delay and failures, the agency has withheld responsive records in violation of FOIA, 5 U.S.C. § 552(a)(3)(A).

48. As a result of FDA's failure to comply with the statutory deadlines, GFI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

49. GFI is entitled to an order "to enjoin the agency from withholding agency records and to order the production of any agency record improperly withheld" from GFI. 5 U.S.C. § 552(a)(4)(B).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

A. order Defendant to conduct a reasonable search for all responsive records;

B. order Defendant to promptly disclose to Plaintiff all responsive records;

C. award Plaintiff its costs and reasonable attorneys' fees incurred in this action, under 5 U.S.C. § 552(a)(4)(E); and

D. grant any other relief that the Court deems just and proper.

Dated: June 6, 2016

Respectfully submitted,

/s/ Nigel Barrella
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