

MDUFA V Negotiation Meeting

October 20, 2021

Industry Presentation

User Fee Principles

- Timely patient access to safe and effective products
- Congressional appropriations remain primary source of CDRH's funding; user fees additive
- Use of fees for premarket review process; industry willing to partner with stakeholders on additional appropriations for appropriate post-market activities
- Industry has made significant and material investments under MDUFA I-IV
- User fees support mutual premarket goals and process improvements to achieve timely patient access

MDUFA V Industry Priorities

1. Maintain pre-COVID performance, including pre-submissions (FY18 and FY19 was 90% of presubs had written feedback within 70 days), and meet all MDUFA IV commitments
 2. 99% justifications in AI/Deficiency letters
 3. Reach agreement between FDA and industry to invest carryover balances
 4. Credit any remaining carry-over balances to MDUFA V
 5. Update the review process trigger from current year 2009 to FY20
 6. Update the appropriations trigger from \$320M to \$395M
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Hiring Accountability

- Hiring targets
 - Establish hiring targets on quarterly basis
 - By June 30, 2023 and every 12 months thereafter, assess progress on meeting quarterly hiring targets
 - Any unused hiring funds used to offset facility registration fees in the following year
- Vacancy Rates
 - By June 30, 2023 and every 12 months thereafter, assess the current vacancy rate for all MDUFA-funded FTEs (MI to MV)
 - If vacancy rate exceeds 5% (for MDUFA program), any unused funds used to offset facility registration fees in the following year

Opportunity: Add-on Payments & TAP Pilot

- By June 30, 2024 and every 12 months thereafter, evaluate FDA's performance for the following:
 - Average total time to decision for 510(k)s and PMAs (same goal as FY22 throughout MDUFA V)
 - 99% of deficiency letters include statement of justification
 - De Novo decision goals (same goal as FY22 throughout MDUFA V)
 - 90% pre-submission requests received written feedback within 70 days (same as FY18 and FY19 actual performance)
 - Substantive interactions and all FDA decision goals
- If all goals are met:
 - FDA will receive add-on payment of \$50M to be added to following fiscal year
 - 10% of add-on payment can be used to initiate a TAP pilot (for pre-market activities)

Opportunity: Add-on Payments & TAP Pilot

- If all goals are not met:
 - Add-on payment is not activated
 - TAP pilot cannot begin
 - Performance will be reassessed 12 months later

Industry Financial Counter Proposal

1. In an effort to reach a successful conclusion of the M5 negotiations quickly, the following proposal provides a significant increase in funding to FDA to meet ALL M4 goals as well as returning to pre-COVID performance for pre-submissions
2. The total cost of this industry counter-proposal is at the upper limit for the majority of trade associations representing industry
3. Proposal consists of two parts:
 - a. Use of MDUFA IV Carry-Over Balances
 - b. New/revised funding for MDUFA V

Industry Financial Counter Proposal (cont)

1. Industry is using “fully loaded” cost per FTE of \$299,329 (up from Aug. 10 proposal of 265k) despite average CDRH wide salary, benefits and bonus is \$184k under M4
2. This FTE cost allows for ample additional resources to cover any increase in salaries, benefits, etc. For example, FDA stated \$46.2 million of the “fully-loaded” FTE costs were used for “Digital Transformation” (14% of Digital Transformation came from FTE costs)
3. Industry also expects all FTE within this proposal to be actual people hired and that 100% of their time will be directly associated with the MDUFA review process

Use of MDUFA IV Carryover Balance

Proposal	\$ Amount in Millions
50 additional reviewers to begin hiring now and continue in MV (in addition to the MDUFA I-IV existing vacancies)	\$89.8M (FTE cost of \$299,329 for 6 years)
6 additional supervisors for oversight of additional reviewers to begin hiring now and continue in MV	\$8.9M (FTE cost of \$299,329 for 6 years)
Create “rainy day fund”	\$36M
HR Assessment	\$3M

Total : \$137.7 million

MDUFA V Financial Proposal: Base Package

1. MDUFA 4 Base = \$1,173,365 (does not include one-time costs)
2. MDUFA 5 Proposal: \$301.4M million
 - a. 56 FTEs from carryover balance to meet all M4 and pre-covid performance of pre-submissions (funded over 6 years) = \$100.575M
 - b. 75 new FTEs from to meet all M4 goals and pre-covid performance of pre-submissions = \$82.3M
 - c. One-Time Costs = \$44M
 - d. 17 new FTEs for Patient Engagement, Standards and International Harmonization = 38.6M
 - e. "Rainy Day Fund" (Requires Mutual Agreement by Industry and FDA to Invest) = \$36M
3. TOTAL Base Package of \$1.475B
 - a. With \$150M Add-On, Total Package = 1.625B