Animal Drug User Fee Act (ADUFA) Reauthorization

FDA and Industry Group AHI (Animal Health Institute)

September 2, 2026 | 11:00 am – 12:40 pm

FDA Harvey W. Wiley Federal Building, College Park, MD and Virtual Format

MEETING PURPOSE

Pursuant to section 740A(d)(1)(F) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is meeting with representatives of the regulated industry, represented by the Animal Health Institute (AHI) to negotiate recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA) program, ADUFA VI. This was the third meeting. The overall purpose of the meeting was to discuss financial proposals.

MEETING SUMMARY

Old Business

Industry previously asked for an org chart to understand FDA's new structure. FDA referred industry to the July 29th Federal Register Notice and informed industry that the agency would provide more on the Shared Services restructure after October 1, 2026.

OFBA Presentation on Financial Proposals

The Office of Finance, Budget and Acquisitions presented several financial proposals for ADUFA VI.

- Shared Services Transition Proposal
    - The Shared Services reorganization is intended to centralize numerous operational and administrative support functions which used to be performed in FDA centers but will be performed in the Office of Operations. FDA noted that shared services performed outside of the centers are not new, and a list of current shared services can be found in the financial report. FDA stated Shared Services was not creating new support functions, but rather a reorganization of how and where certain existing services (e.g., HR functions, timekeeping, travel, communications) are provided. Industry asked how the new model would work for something like training, where there are program-specific needs. FDA noted it would require support from both CVM subject matter experts (SMEs) and the training group.
    - Industry raised concerns that CVM, as FDA's smallest center, will likely be adversely affected regarding resources and support once FDA completes the transition as part of the Shared Services reorganization. Industry also sought clarity on the key performance indicators that will be used to track changes in performance due to the reorganization (e.g., to ensure that there is no degradation in performance), the magnitude and nature of potential efficiencies gained from this reorganization, and how the ADUFA program might benefit from such efficiencies.
    - FDA responded that Shared Services is intended to provide consistency of services and resources across all FDA centers by ensuring that needs are reported to Shared Services so appropriate and responsive support can be provided and is consistent with anticipated resource consumption.

- FDA also explained that its aim is for Shared Services funding to continue to align proportionally with the scope of the program the funding was originally intended to support.
- FDA, responding to Industry's question on how resource consumption will be calculated, noted that each of the services was evaluated differently and where possible, FDA used transaction data to estimate consumption costs.
    - FDA informed Industry that the agency would provide more information on the calculation of funding for Shared Services at a future meeting.

- Financial Standardization Proposals
    - Inflation: FDA proposed to eliminate the compound inflation adjustment, standardize Consumer Price Index (CPI) used, and standardize the methodology to calculate proportion of the Personnel and Compensation Benefit (PC&B). FDA noted that the changes are intended to simplify inflation calculations, improve transparency, and not to have major changes on total funding levels. Industry raised questions about how the proposals compare to prior ADUFA authorizations, noting that the contemplated proposal does not seem to eliminate compounding of inflation, and that the calculations in previous cycles have driven rapid growth and/or volatility in base revenue and fee collections. FDA responded that more detail regarding how the inflation calculation has evolved over each reauthorization period will be developed for a future meeting to provide further context and clarification.
    - Capacity Planning Adjustment: FDA proposed transitioning to a Capacity Planning Adjustment (CPA) to address limitations in the current Workload Adjuster model. This transition would involve using modern analytics to incorporate leading workload indicators, utilizing time reporting data to convert submission volume into staffing requirements, and adjusting only for submission-driven staffing needs. Industry conveyed that additional information is needed regarding the specific models and analytics that FDA would propose to use for a CPA. Industry also raised questions regarding how a proposed CPA would reflect changes in CVM's workload, especially as workload has generally declined over recent years. FDA responded that it would provide more detail regarding a proposed CPA at a future meeting.
    - Target Revenue Setting Process: FDA provided a summary of how the target revenue would be set in such a way that would incorporate the proposed inflation and CPA changes.

- America First Proposals: FDA outlined several options for American First proposals.
    - Waivers:
        - Limit existing small business waivers to domestic entities (U.S. domiciled).
        - One-time NADA waiver per company for products that are domestically manufactured.
    - Add a Foreign Differential to the Establishment Fee: Establishments outside the U.S. would have a higher fee to support the additional cost of regulating those entities
    - Support for CVM Pilot Program to Support Animal Drug Manufacturing and Testing in the US: Prioritizes review of animal drug applications where both finished drug products and the active ingredients are manufactured in the U.S.
    - Industry expressed openness to considering certain of these proposals and asked for further information regarding the nature and scope of the proposals, including how certain terms would be defined and the proposed differential in fees.

Next Steps

Industry said that it would provide FDA with follow-up questions in writing regarding the proposals and topics discussed at today's meeting. The next meeting is scheduled for September 16, 2026, tentatively from 9am to 12pm, with a focus on the overall animal drug development and approval timeline and benefit-risk assessment. Planned discussions on post-market have been delayed to a later meeting.

PARTICIPANTS

AHI Stakeholders

Ellen Hart	AHI
Grace Gowda	AHI (Boehringer Ingelheim)
Beth Rigoni	AHI (Zoetis)
Gareth Harris	AHI (Merck)
Kathy Vannatta	AHI (Phibro)
Mary Hagler	AHI (Ceva)
Barrett Tenbarge	AHI (Faegre Drinker)
Siobhan DeLancey	AHI (DeLancey Strategies)

FDA

Erik Mettler	Human Foods Program, Office of Integrated Food Safety System Partnerships (HFP/OIFSSP)
Tim Mueller	OIFSSP
Olufunmilayo Ariyo	Office of Finance, Budget and Acquisitions (OFBA)
Angela Granum	OFBA
Madeline Faunce	OFBA
Edward Bonny	OFBA
Elizabeth Cash	Office of Chief Counsel (OCC)
Andrew Becher	OCC