Animal Drug User Fee Act (ADUFA) Reauthorization

FDA and Industry Group AHI (Animal Health Institute)

August 19, 2026 | 3:00 pm – 5:00 pm

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

MEETING PURPOSE

Section 740A(d)(1)(F) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with representatives of the regulated Industry to negotiate recommendations for reauthorization of the Animal Drug User Fee Act (ADUFA) program, ADUFA VI. For the ADUFA VI negotiations, regulated Industry is represented by the Animal Health Institute (AHI). FDA's meetings with AHI will satisfy the requirement in section 740A(d)(1)(F) of the FD&C Act. This was the second meeting. The overall purpose of the meeting was to discuss negotiation priorities, calendar planning, and AHI's information request.

MEETING SUMMARY

Old Business

FDA and Industry had no old business to mention.

Calendar Planning

FDA and Industry discussed the overall schedule for negotiations. They agreed to have initial presentations on all topics early in the process, with the goal of ensuring sufficient time for meaningful discussion and shared understanding of issues in the session with the initial presentation before circling back to solutions and potential goals letter language in the later negotiating sessions. Several days will have both a half-day Steering Committee meeting and a half-day full group meeting.

Information Request

FDA discussed the Agency's responses to Industry's first information request on the following topics: CVM Staffing; Shared Services; IT Services; Workload and Performance; Raw Data; Conditional Approval; Harmonization with Peer Foreign Regulators; Stop the Clock; and the Chemistry, Manufacturing, and Controls (CMC) Technical Section.

Where there is any additional information to share, FDA agreed to provide updated responses to the information request two weeks before relevant topics of discussion.

General Discussion of Priorities

While the meeting generally focused on logistics of the calendar and the information request, some key points were made regarding FDA's and Industry's priorities throughout those discussions.

FDA noted it would present on Shared Services, FDA's user fee standardization priorities, and the Administration's America First priorities (concerning the promotion of domestic manufacturing) in the next meeting.

Industry noted they are interested in discussing a process for creating a structured benefit-risk assessment framework, building on the approach adopted in the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures on the human drug side. On harmonization with foreign regulatory authorities, Industry noted that there is a broad range of options that could fit under this umbrella. Recognizing that some options would likely be more difficult to implement than others, Industry is interested in exploring the processes and understanding what CVM sees as useful. Industry also noted they see an opportunity to learn lessons from the New World screwworm response in terms of best practices that could be adopted for submission and review processes more broadly. Across the topics in the negotiations, they are interested in understanding the relative resource intensity of different options for reform.

FDA noted that the group can build on the work already completed by the exploratory working groups and review their reports as a starting point, rather than beginning from ground zero. Industry noted that while that work is informative, they are also encouraging their members to build from that foundation, while continuing to think creatively and bring forward new ideas.

Next Steps

Future negotiation meetings will continue to be scheduled for Wednesdays, with next month's scheduled meetings to be on September 2nd, September 16th, and September 30th. FDA is currently considering additional meetings for the calendar in November and December and updating the previously circulated meeting schedule.

PARTICIPANTS

AHI Stakeholders

Ellen Hart	AHI
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
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