Animal Drug User Fee Act (ADUFA) Reauthorization

FDA and Industry Group AHI (Animal Health Institute)

July 29, 2026 | 1:00 pm – 3:00 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 initial meeting. The overall purpose of the meeting was to discuss meeting ground rules and logistics, to develop a plan for the negotiation process, and to allow FDA and AHI to deliver their initial perspectives on ADUFA VI.

MEETING SUMMARY

Welcome and Introductions

FDA outlined the topics for the meeting and noted appreciation for AHI's in-person presence. The negotiating teams from FDA and Industry introduced themselves. Erik Mettler and Timothy Mueller were recognized as FDA lead negotiators, and Ellen Hart and Barrett Tenbarge were recognized as the AHI lead negotiators.

Negotiation Structure

FDA proposed a structure which included meetings consisting of priority-driven topics that will be chosen by Industry and FDA. Subject matter experts from the Center for Veterinary Medicine (CVM) and other FDA offices will be joining during pre-determined negotiation meetings to provide perspective on particular topics. FDA emphasized that presentations will be shared in advance and are intended to encourage dialogue. Industry noted they will mirror this approach by including the core negotiation team and bringing in other subject matter experts as needed.

FDA outlined a schedule with negotiation meetings occurring on a cycle every two weeks with outliers depending on schedules. FDA agreed to review calendars and send proposed dates via email as a follow-up to the meeting.

FDA stated that the ADUFA negotiations will run in parallel with the Animal Generic Drug User Fee Act (AGDUFA) reauthorization with AGDUFA meetings taking place during the alternate week. FDA is aware that AHI has some shared members and objectives with the AGDUFA industry representative, the Generic Animal Drug Alliance (GADA). FDA acknowledged that the

two groups may coordinate across both negotiations. This cross coordination will not change the official organizations, AHI and GADA, who are representing industry for the ADUFA and AGDUFA programs, respectively.

Ground Rules Discussion

The ground rules that will govern ADUFA VI negotiations were discussed.

Regarding the scope of negotiations, FDA emphasized that reauthorization of ADUFA focuses on process improvements and modernization first. Financial discussions would then be based on any variations to current practices. Policy and legislative matters outside the scope of negotiations could be identified as barriers, but resolution of such matters via statute or other regulatory actions should occur in a forum outside these negotiations.

FDA and Industry discussed and agreed on timeframes for providing agendas and meeting materials in advance of meetings and the review of meeting minutes. FDA emphasized the importance of maintaining forward progress and avoiding an extended focus on the details of the minutes. The parties agreed that the minutes would be consensus-based and the negotiating leads would work through any disagreement before posting.

Meeting minutes are important for transparency and will summarize any substantive proposals and significant controversies or differences of opinion in enough detail to ensure external stakeholders understand what was discussed.

FDA suggested that by November 2026, the group should have identified and agreed upon its focus areas and priorities. While discussions may continue beyond that point, the goal is to have those items captured by November. FDA further noted a goal for the group's efforts to be completed by March 2027 to allow sufficient time for internal review and to meet the statutory deadline for submitting the proposed legislative changes and goals letter to Congress. Industry generally agreed with these goals, noting that FDA and Industry should not use these goals as reasons to limit discussions.

As it relates to congressional engagement, each side agreed not to discuss specific negotiation topics with Congress when negotiations are ongoing but recognized that both FDA and Industry may continue to engage with Congress on other topics.

FDA and Industry both agreed to debriefing on future stakeholder meetings during negotiation meetings.

FDA agreed to make the updates discussed to the ground rules and share the updated document with Industry.

FDA Perspective and Goals on ADUFA VI

FDA broadly discussed the agency's perspective and goals. The Agency's first priority is maintaining top-tier reviewers.

Second, FDA discussed IT modernization and acknowledged modernization at the Agency requires system updates that need funding. Additional priority topics included conditional approval amendments (particularly in the antimicrobial space), harmonization with foreign regulatory authorities, and looking at opportunities to implement a "stop the clock" program.

The next topic was FDA's shared service model. FDA noted that most infrastructure support services are moving to FDA's Office of Operations (OO). Examples of functions moving to the shared services model include training, budget, hiring, and user fees. FDA shared that prior to simple reform, all centers had their own training staff and now that support has been centralized and the capacity is being built back up.

Finally, FDA noted that promoting domestic manufacturing is a priority for FDA and the Administration.

Industry asked if there would be discussions on artificial intelligence (AI) and how it is being used at FDA as part of the shared services discussion. FDA stated we are open to early discussions and noted that FDA policy is not to use AI to make reviewer decisions. FDA noted opportunities to modernize the intake of information, improve user interfaces, and make enhancements to eSubmitter.

Industry Perspective and Goals on ADUFA VI

Industry noted their charge is speed, innovation, and harmonization, with speed being an overarching priority. Industry expressed interest in exploring how to reduce development time while maintaining scientific rigor.

Industry referenced the information request they had submitted to obtain background information on the current program to support preparation for the upcoming ADUFA reauthorization negotiations. While they had not yet fully debriefed internally, they expressed disappointment with FDA's response. They noted openness to funding modernization efforts but noted that doing so requires more information. FDA requested that AHI provide additional context to clarify the purpose of the information request and ensure that the most appropriate information is provided. FDA noted that fulfilling such information requests often requires significant manual effort and staff resources, and that understanding the intended use and value of the data helps inform prioritization and resource allocation. FDA expressed openness to discussing specific questions of interest to Industry stemming from the information request.

Industry is in the process of identifying their priority topics and preferred order of discussion. One topic of interest is benefit-risk, and Industry noted it could serve as a lens for other topics.

Industry also noted IT modernization is a priority area for future meetings.

Next Steps

FDA will review and distribute updated ground rules. FDA will coordinate with OO to confirm readiness to deliver a presentation on shared services at the next meeting. Meeting minutes will be distributed to all parties within five days. FDA will also share a proposed upcoming meeting schedule.

PARTICIPANTS

Industry

Ellen Hart	AHI
Grace Gowda	AHI (Boehringer Ingelheim)
Beth Rigoni	AHI (Zoetis)
Gareth Harris	AHI (Merck)
Kathy Vannatta	AHI (Phibro)
John Mathai	AHI (Elanco)
Mary Hagler	AHI (Ceva)
Alan Taylor	AHI (Virbac)
Barrett Tenbarge	AHI (Faegre Drinker)
Ginny Siller	AHI

FDA

Erik Mettler	Human Foods Program, Office of Integrated Food Safety System Partnerships (HFP/OIFSSP)
Tim Mueller	OIFSSP
Angela Granum	Office of Finance, Budget, and Acquisitions (OFBA)
Madeline Faunce	OFBA
Edward Bonny	OFBA
Matthew Lucia	Office of New Animal Product Evaluation (ONAPE)
Petra Garosi	ONAPE
Elizabeth Cash	Office of Chief Counsel (OCC)
Andrew Becher	OCC