Animal Drug User Fee Act (ADUFA) Reauthorization

FDA and Industry Group AHI (Animal Health Institute)

September 30, 2026 | 9:00 am – 12:00 pm & 2:30 pm – 4:00 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 fifth meeting. The overall purpose of the meeting was for FDA and Industry to discuss opportunities to improve the review process.

MEETING SUMMARY

Old Business

There was no old business to discuss.

Industry and FDA Presentations

Six presentations were made, four by Industry and two by FDA.

Presentation #1: FDA – ADUFA VI; Clock Stop Background and Working Group Outcomes
FDA presented an overview of the ADUFA V goals letter commitment on clock stop. FDA summarized the work of the joint FDA-Industry Clock Stop Working Groups, including the July 2024–September 2025 Exploratory Working Group and the October 2025–May 2026 Tactical Working Group. FDA reviewed the proposed clock stop process for non-administrative NADAs, including eligibility and pre-filing requirements, the opt-in/opt-out approach, review timelines, and the use of up to two clock stops to address minor deficiencies. FDA also reviewed performance goals, metrics, and annual reporting for the process.

Presentation #2: Industry – Stop-the-Clock / Mid-Cycle Resolution
Industry presented on a stop clock approach to begin with the scope discussed in the Exploratory Working Group for non-administrative NADAs, and then adapt and expand to phased INAD P submissions. Industry also discussed time lost during the review cycle and establishing baseline performance metrics. FDA asked clarifying questions. Industry acknowledged the alignment with FDA on a stop clock approach for non-administrative NADAs, and conveyed that expanding the stop clock approach to P submissions is needed to achieve meaningful efficiency gains and reductions in total time to approval, and that the driver of such improvements is the ability to get FDA feedback earlier in the process (i.e., at day 120) and to address outstanding issues in one cycle. FDA discussed the importance of consistency across Industry submissions, noting that greater consistency could help reviewers manage and transition between

multiple concurrent reviews. Industry conveyed interest in further discussing the topic of inter-sponsor consistency, including receiving more specific information from FDA on areas where the agency notes a lack of consistency and where improvements could improve review efficiency. FDA noted that variations in submission size, quality, number, and type can add complexity to balancing reviewer workload and review timelines.

Presentation #3: Industry – Modernizing and Streamlining the Path to Pre-Pivotal Alignment

Industry presented on modernizing and streamlining the path to pre-pivotal alignment, including the impact of pre-pivotal interactions on development timelines, the value of and opportunity to improve H submissions, targeted resolution mechanisms, and the use of the Veterinary Innovation Program as a precedent for efficient communication to reduce time spent in pre-pivotal alignment. With the overarching goal of reaching faster regulatory decisions, Industry proposed applying a proportionate, critical-element standard to protocol evaluation and raised the concept of making protocol concurrence optional in practice without weakening scientific standards. FDA asked clarifying questions. FDA and Industry discussed how to operationalize this at the reviewer level through distinguishing “need to know” for a regulatory decision versus “like to know.” FDA discussed the range of existing tools available to sponsors — including pre-INAD meetings, A-0000 submissions, and shortened review times (SRT) — noting that several are underutilized. Industry shared that it is open to a better understanding of existing options, but that current tools may not be fit-for-purpose for efficiently resolving regulatory questions that arise during review. FDA acknowledged the value of earlier engagement and expressed openness to examining existing practices, while noting that submission inconsistency and unshared assumptions add complexity for reviewers.

Presentation #4: Industry – Field Study Modernization

Industry presented on field study modernization and the need for greater clarity and predictability regarding the use of alternative field study approaches. Industry discussed challenges with study feasibility and enrollment, including placebo-controlled studies, as well as study design considerations and international precedents, including differences between U.S. and EU approaches to control strategies. Industry emphasized the importance of identifying scientifically appropriate alternatives that are defined and predictable, support animal welfare, and are understood early enough to inform development planning. FDA asked clarifying questions, particularly regarding Industry’s use of the term "fit-for-purpose.” FDA noted that it would consider existing mechanisms and how FDA could clarify sponsors’ options for different approaches.

Presentation #5: Industry – Using Global Evidence

Industry presented on the use of global evidence to support U.S. animal drug approvals and the opportunity to build on FDA’s existing policies and practices. Industry discussed FDA’s current use of foreign and multinational evidence and challenges associated with using global evidence when studies were conducted without FDA protocol concurrence. Industry acknowledged that while the use of global evidence is acceptable in theory, Industry is interested in making the use of such evidence more normalized and easier to operationalize. Industry proposed making scientifically applicable and reliable global evidence more readily usable for U.S. regulatory decisions, with the goal of reducing duplicative studies and supporting more timely U.S. approvals. FDA asked clarifying questions, indicated areas where they have successfully used global data to make regulatory decisions and expressed general support for

investigating additional ways to use global data in the approval process.

Presentation #6: FDA – Global Harmonization Activities

FDA presented on its statutory authority and current activities to support global harmonization, including bilateral relationships with foreign regulatory counterparts, collaborative review pathways, mutual recognition agreements, and participation in international fora. FDA discussed existing collaborative review efforts and opportunities to further align animal drug applications across countries and regions. FDA also discussed its participation in international harmonization efforts. Industry expressed general support of FDA's prioritization of harmonization-related activities, and interest in considering opportunities to go further.

Clarifying Questions and Action Items

FDA stated that it hoped to finalize discussion on open topics (such as benefit-risk, stop the clock, metrics, etc.) in the next few meetings. FDA also stated that work on these topics will bring these negotiations closer to the point of being able to draft language for the goals letter. Additionally, FDA said the current meeting format with morning presentations and afternoon discussions has been effective and should continue in future meetings.

Next Steps

FDA will send out an updated schedule with revised topics and presentations covering the next few months. The next meeting is scheduled for October 14th with planned discussions on IT modernization; raw data; and Chemistry, Manufacturing, and Controls (CMC).

PARTICIPANTS

AHI Stakeholders

Ellen Hart	AHI
Grace Gowda	AHI (Boehringer Ingelheim)
Beth Rigoni	AHI (Zoetis)
Gareth Harris	AHI (Merck)
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FDA

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