



Animal Drug User Fee Act (ADUFA) Reauthorization

FDA and Industry Group AHI (Animal Health Institute)

September 16, 2026 | 09:00 am – 12:00 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 fourth meeting. The overall purpose of the meeting was for Industry and FDA to present on product development times, metrics, and benefit-risk analyses.

MEETING SUMMARY

Old Business

FDA confirmed that Capacity Planning Adjustment and other financial standardization follow-up items would be incorporated into a future meeting.

Industry and FDA Presentations

Four presentations were made, two by Industry and two by FDA.

Presentation #1: Industry – Reducing Total Animal Drug Development Time

Industry presented considerations on reducing total animal drug development time and establishing a shared baseline for measuring progress. Industry expressed support for public statements made by CVM Director Dr. Tim Schell, highlighting an aspirational vision to significantly cut development times, explained using the hypothetical example of reducing the total development time from 10 years to 5 years. Industry also reinforced interest in considering reforms that could achieve such significant reductions and metrics to track the impact of any reforms against that ultimate goal. Industry emphasized that total time to approval is an important public health consideration that reflects both sponsor and FDA activities and that improvement will require attention to the full development process (and not just those elements that are currently tracked in ADUFA metrics). Industry discussed building on the ADUFA V foundation through greater timeline visibility, expanded metrics, and a common measurement approach to evaluate whether interventions are reducing development and review time (including increasing favorable single-cycle reviews), improving predictability, and reducing activities that are unnecessary to reaching sound regulatory decisions. Industry also noted that greater visibility into timeline data could help identify where delays or variability occur and support further examination of their underlying drivers, as well as enable measurement of reforms adopted during negotiations to assess progress over time. Industry provided initial considerations for potential timeline anchors. FDA asked clarifying questions.

Presentation #2; FDA - ADUFA Metrics

FDA presented on metrics introduced in ADUFA V and expounded upon recent FDA/Industry working group recommendations to enhance animal drug approval reporting. FDA's presentation included information from the ADUFA V third-party assessment that included information on a submission's Time in Agency vs. Time in Industry. FDA noted that collecting and reporting on the metrics without a structured system is a labor-intensive, highly manual process that requires resources and can take time away from review. FDA and Industry discussed whether "Time in Agency" vs. "Time in Industry" is a helpful metric for assessing the ADUFA program, and that this information requires an assessment of root causes to understand the implications of this data. FDA emphasized that, regardless of the metrics ultimately agreed upon, an appropriate system would need to be in place to support efficient data collection, tracking, and reporting. Industry asked clarifying questions.

Presentation #3: Industry - Structured Benefit-Risk Assessment for Animal Drug Review

Industry presented its perspective on benefit-risk assessment, noting that CVM has processes in place for benefit-risk assessment in animal drug review and that Industry sees opportunities for increased communication and coordination by connecting these elements through a common, transparent analytic structure across review contexts. Industry discussed how a more structured approach could make explicit how benefits, risks, uncertainty, risk-management options, and the totality of available evidence are considered in regulatory decision-making, supporting greater consistency and transparency and enabling fit-for-purpose approaches across review contexts. Industry also presented on the benefit-risk assessment framework created through the Prescription Drug User Fee Act reauthorization (PDUFA V) and discussed how elements of that framework could be instructive, and potentially adapted, to support the creation of a benefit-risk assessment framework in animal drug review. FDA asked clarifying questions.

Presentation #4: FDA -Risk Assessment of Animal Drugs

FDA presented on the risk assessment of animal drugs, highlighting the March 2026 GAO Report, *Animal Drugs, Strengthening Federal Incentives Could Help Address Unmet Animal Health Needs*, and noting FDA's use of alternative study designs and approaches to risk assessment. FDA acknowledged that information related to benefit-risk assessment is available in various places online but can be difficult to identify and consolidate. FDA also emphasized the importance of using consistent terminology.

FDA noted that it had committed to developing guidance on benefit-risk assessment in response to the GAO report. The group further discussed the benefit-risk framework developed under PDUFA. FDA noted that additional discussion would be needed to determine whether aspects of the PDUFA framework should be leveraged for animal drugs. Industry asked clarifying questions, and noted that the discussion should be a "benefit-risk" discussion that does not lose sight of the "benefit" element of the framework to overly focus on the "risk" element.

No agreements were reached at this time.

Next Steps

The next meeting will be scheduled for September 30, 2026. It was noted that the schedule has been set until mid-November.

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)
John Mathai	AHI (Elanco Animal Health)
Alan Taylor	AHI (Virbac)
Ginny Siller	AHI

FDA

Erik Mettler	Human Foods Program, Office of Integrated Food Safety System Partnerships (HFP/OIFSSP)
Tim Mueller	OIFSSP
Petra Garosi	Center for Veterinary Medicine (CVM)
Matthew Lucia	CVM
Barbara Leotta	CVM
Holly Zahner	CVM
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