



Animal Generic Drug User Fee Act (AGDUFA) Reauthorization

FDA and Industry Group GADA (Generic Animal Drug Alliance)

September 9, 2026 | 10:00 am – 12:00 pm / 1:00 pm – 3:00 pm

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

MEETING PURPOSE

Section 742(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 Generic Drug User Fee Act (AGDUFA) program, AGDUFA V. For the AGDUFA V negotiations, regulated Industry is represented by the Generic Animal Drug Alliance (GADA). This was the fourth meeting. The overall purpose of the meeting was to discuss old business from the prior meeting, discuss FDA financial standardization proposals, review FDA's response to Industry's information request, and identify priority topics for future meetings.

MEETING SUMMARY

Old Business

- SharePoint Site: FDA stated that the agency was working on granting Industry access to the site.
- Information Request from Prior Meeting: Instead of providing follow-up to Industry questions in isolation as each question is posed, FDA is gathering and incorporating answers into upcoming presentations.
- Industry Minute Review and Calendar Approval: Industry will provide feedback on the previous AGDUFA meeting minutes and respond to the remainder of the meeting calendar.

OFBA Presentation on Financial Standardization Proposals

The Office of Finance, Budget and Acquisitions presented additional details on several financial agency standardization proposals for AGDUFA V that were discussed at the August 5th negotiation meeting.

- Inflation Adjustment:
 - FDA proposed adopting a consistent inflation approach that would eliminate the compound inflation adjustment methodology and move to updating base revenue each year, standardize the Consumer Price Index (CPI) used, and standardize the methodology to calculate the proportion attributed to Personnel and Compensation Benefits (PC&B). FDA noted that the changes are intended to simplify inflation calculations and improve transparency, and are not intended to have major impacts on total funding levels.

- FDA noted that AGDUFA has higher payroll costs than the FDA-wide percentage because CVM programs are generally payroll heavy. FDA confirmed that the payroll proportion could change annually and that carryover spent on contracted research could also affect that percentage. FDA added that keeping a 3-year average is intended to smooth out potential swings.
- In response to Industry's questions on what drives payroll increases, FDA noted that payroll increases are primarily driven by the Congressional cost of living adjustment each year. The mix of staffing can also have an impact, and in recent years implementation of the CURES Act pay authority has also contributed. Industry requested that FDA provide historical data comparing pay growth to the CPI.
- Industry questioned whether including Food and Energy in the CPI would bring more volatility to inflation calculations. FDA will bring a comparison of the two measures to a future meeting.
- Industry asked whether increasing the base by inflation each year would also increase the Capacity Planning Adjustment (CPA) or Workload Adjustment. FDA noted that CPA would be a fixed-dollar amount rather than a percentage and would replace the workload adjustment. FDA noted that a CPA subject matter expert will participate in a future meeting to discuss calculations for the workload adjuster as compared to a CPA approach. FDA will also model what impact the inflation changes would have on the workload adjuster if that method is retained.
- Operating Reserve Adjustment
 - FDA proposed an Operating Reserve Adjustment (ORA) with a defined floor and ceiling for carryover balances to replace the final year offset, the excess collections offset within the workload adjustment (or successor capacity planning adjustment, if agreed to), and the recovery of collections shortfall adjustments.
 - FDA noted that a shift to ORA would bring consistency across the agency and proposed a floor of 12 weeks and a ceiling of 24 weeks.
 - FDA provided modeling of the impact to submission-based fees if the ORA were implemented in year one with an incremental phase in of the ceiling. Because significantly lower fees could drive submission activity, FDA proposed a transition in which product and sponsor fees are reduced in years 1-4 of AGDUFA V, and the ORA is implemented in year 5. Industry noted being aligned with FDA on reducing the product and sponsor fees.
 - FDA and industry discussed the 24-week ceiling and agreed to discuss the optimal ceiling further in future meetings. FDA noted that one consideration for the floor and ceiling is the timing of fee collections. Animal drug fee due dates occur in December/January, compared with October 1 for human drugs. FDA noted that sufficient carryover must be maintained to support program operations until fees are collected.
 - Industry recognized that reducing below a 24-week ceiling may not be possible for the upcoming user fee cycle, however, they would like to discuss what the optimal ceiling would be and potentially capture it as a future goal. FDA noted that we do not want to bind future negotiations to historical goals, but we could potentially provide language capturing the aspirational ceiling based on current understanding from this cycle.
 - Industry expressed concern that the existing carryover was continuing to increase

and that fees might be over collected during the next 5 years. FDA responded that the ceiling would help keep carryover smaller in future and that drafting the statute to provide FDA flexibility in the product and sponsor fee reductions could help manage this during the transition.

- America First Proposals: FDA outlined several options for American First proposals.
 - One-time ANADA waiver for domestic manufacturing.
 - Support for CVM Pilot Program to Support Animal Generic Drug Manufacturing and Testing in the US. This program prioritizes review of generic animal drug applications where both finished drug products and the active ingredients are manufactured in the U.S. FDA explained that prioritization of an application involves moving the application out of the queue and viewing it ahead of other submissions. This proposal is expected to have a small number of qualified submissions which would have a neutral effect on staffing.

Information Request Update

FDA discussed the Agency's responses to Industry's information request on the following topics: shared services, staffing, inflation adjustment, capacity planning, general metrics, and other AGDUFA program information.

Priorities Discussion

Industry stated that they are preparing a list of priority topics for discussion which will be shared with FDA. The initial list includes: carryover spend down, review times for sentinel submissions, shortened reactivations, and stop the clock or end review amendment process. Industry noted they are interested in understanding the costs of new proposals and how those would impact the carryover drawdown.

Next Steps

The next meeting will be scheduled for September 23, 2026. Industry plans to provide initial feedback on the FDA priorities presented on August 26th. FDA will provide Industry with CVM's insight and feedback on Industry's proposed topics after they are received. FDA also noted that the priorities Industry has specified will be added to the schedule.

PARTICIPANTS

Industry

Stephanie Batliner	GADA (Bimeda Inc.)
Ben Moses	GADA (Dechra Veterinary Products LLC)
Kim Huls	GADA (Cronus Pharma LLC)
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FDA

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