Animal Generic Drug User Fee Act (AGDUFA) Reauthorization

FDA and Industry Group GADA (Generic Animal Drug Alliance)

August 5, 2026 | 10:00 am – 12:00 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). FDA's meetings with GADA, which tentatively are planned to run through March 2027, will satisfy the requirement in section 742(d)(1)(F) of the FD&C Act. This was the second meeting. The overall purpose of the meeting was to discuss old business from the prior meeting, hear FDA present on agency-wide financial priorities and Shared Services, and discuss priorities for future meetings.

MEETING SUMMARY

Old Business

- SharePoint Site: FDA is working on an externally accessible SharePoint website to allow FDA and the GADA negotiating team to mutually share and edit documents dynamically.
- Last Meeting Minutes: The meeting minutes from the July 23rd meeting were sent for posting today, August 5th. An email will be sent to all attendees when this occurs.
- Ground Rules: The ground rule regarding communications with Congress was discussed further. FDA and Industry clarified that ground rule establishes that both parties will inform each other of communications with Congress to allow for good faith negotiations and communications as well as align both FDA's and Industry's intentions. A stated goal of this ground rule is to prevent parallel discussions with Congress that might lead to difficulties later in the process.

Agency-wide Financial Priorities / Shared Services

FDA presented on several financial topics.

- Shared Services
    - FDA explained that under the reorganization recently announced in the Federal Register, FDA would centralize administrative functions as a means to standardize and harmonize operations. As it relates to user fee finances, this move to centralize is expected to result in shifts in funding from the FDA Centers to the Shared Services line, which will be reflected in the financial reports.
    - In response to GADA questions regarding appropriate allocations between

AGDUFA and ADUFA, FDA replied that each Center's share of shared services is determined based on consumption of those services, and then the cost is split proportionally across funding sources. The agency will provide additional information on Shared Services funding across all user fee programs based on the published data in the financial reports.

- Budget Authority vs. User Fees
    - FDA provided data on the amount of user fee and budget authority spending across major user fee programs. GADA noted that some user fee programs differed greatly in their allocation spending and asked if there are differences in activities covered across those programs. FDA noted there are differences in allowable activities and both parties agreed to discuss this topic further at a future meeting.
- Inflation
    - FDA discussed proposals to standardize the inflation methodology across user fee programs by replacing the compound inflation multiplier with an annual inflation adjustment, adopting a common consumer price index data point for the non-payroll portion of the inflation adjustment, and standardizing the methodology for the proportion of the inflation adjustment attributed to personnel compensation and benefits.
    - In response to GADA's question about standardization and position leveling across the agency, FDA provided a link (Title 21: Career Fields & Pay | FDA) to GADA regarding guidance for Title 21 Career Fields.
    - FDA agreed to begin data modeling what fees would have looked like in prior years under this change to inform future discussions.
- Capacity Planning Adjustment (CPA)
    - FDA provided an overview of its proposal to replace the workload adjuster with a CPA. FDA explained that a CPA would use advanced predictive analytics for workload forecasts instead of a lagging average, estimate FTE needs based on actual level of effort for submissions, and adjust for specific review activity instead of total target revenue. FDA noted that in PDUFA the scale of upward adjustments has been smaller using capacity planning adjustments than under the old workload adjustment paradigm. FDA, in responding to GADA concerns about level of effort on the part of reviewers, in reviewing the number of and various types of submissions, stated that there would be more discussion on having indicators of effort and workload.
    - GADA expressed concerns about updating the workload adjuster, noting they felt many of its issues had been fixed in previous cycles and that Industry will be sensitive to adjustments. Industry asked if the CPA could adjust down, and FDA noted that current implementations only allow for upward adjustments because it is intended to fund FTE, which is a long-term cost, for sustained increases in workload.
    - FDA further noted that moving to capacity planning adjustments is an agency-wide goal, but that its implementation may involve a pilot program to see the impact before full implementation.

- Operating Reserve Adjustment
    - FDA noted that implementing annual operating reserve adjustments is expected to be effective in managing the level of carryover and preventing the carryover

amount from ballooning going forward. FDA noted that in other programs with large carryover balances, they were reduced through a combination of targeted investments (e.g., IT investments) and slowly bringing down the ceiling for carryover.

- Recognizing that the size of the AGDUFA carryover is unusually large and immediate implementation of an operating reserve adjustment could lower application fees in such a way to drive industry submission activity, FDA suggested implementation of the operating reserve adjustment in the final year of AGDUFA V. FDA offered a possible approach to lower the balance over AGDUFA V with a mix of targeted investments and a reduction in product and sponsor fees only in the first 4 years, before the operating reserve adjustment (which would impact all fee types) is introduced in year five.
- Currently, AGDUFA provides only for a final year adjustment; an annual operating reserve adjustment is not in place. With this proposal, an annual operating reserve adjustment with both a floor and ceiling would be put in place.

- Final Target Revenue
  - FDA provided a summary of target revenue setting that would incorporate the proposed changes.

Further Discussion on Priorities to Inform Negotiation Schedule

GADA indicated that it plans to send FDA a list of questions and data requests. FDA asked GADA to provide context with their submitted questions to allow for greater understanding of GADA's requests.

FDA stated that the agency plans to have CVM specialists develop proposal papers and presentations showing overall concepts and providing perspectives that may be beneficial to both FDA and Industry. FDA asked GADA to prepare questions, engage in discussions, and bring ideas to the meetings as priorities are being set during the negotiation cycle. FDA plans to share the proposed meeting dates for the full negotiation cycle after the meeting for GADA's consideration.

Regarding the scope of negotiations, FDA emphasized that reauthorization of AGDUFA focuses on process improvements and modernization first. Financial discussions would then be based on any variations to current practices. Policy and legislative activities 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 clarified that negotiation discussions could include the AGDUFA program more broadly (for example, performance goals) but will not discuss policy matters unless topics relate to user fees. In areas of overlap between funding, policy, and review effectiveness, there would be discussions as to how to handle the overlap. FDA added that the separation was intended to maintain the focus of user fee negotiations on areas within scope of AGDUFA but were not intending to create separate parallel discussions within FDA so that Industry would not need to repeat its conversations.

Next Steps

The next meeting will be scheduled for August 26, 2026, tentatively from 10am to 12pm. GADA would follow-up to confirm the time. FDA will be sending a proposed agenda for GADA review. The proposed agenda will list Old Business, Gathering Priorities, Discussion of Two Proposals

(Animal Drugs @ FDA Systems Improvements and OGAD Research Program). FDA anticipates that meeting lengths will be adjusted upon identification of topic priorities and the anticipated amount of time each topic will require for discussion.

PARTICIPANTS

Industry

Stephanie Batliner	GADA (Bimeda Inc.)
Ben Moses	GADA (Dechra Veterinary Products LLC)
Kim Huls	GADA (Cronus Pharma LLC)
Kim Armstrong	GADA (Huvepharma, Inc.)
Courtney Arumugam	GADA (Bimeda Inc.)
Kathy DeMarco	GADA
Melanie Archer	GADA (Norbrook, Inc.)
Heather Sedlacek	GADA

FDA

Erik Mettler	Human Foods Program, Office of Integrated Food Safety System Partnerships (HFP/OIFSSP)
Tim Mueller	OIFSSP
Andrew Becher	Office of Chief Counsel (OCC)
Jennifer Caruso	OCC
Angela Granum	Office of Finance, Budget, and Acquisitions (OFBA)
Madeline Faunce	OFBA
Edward Bonny	OFBA