Animal Generic Drug User Fee Act (AGDUFA) Reauthorization

FDA and Industry Group GADA (Generic Animal Drug Alliance)

July 23, 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 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 GADA to deliver their initial perspectives on AGDUFA V.

MEETING SUMMARY

Welcome and Introductions

FDA outlined the topics for the meeting noting that the agency was seeking an engaged discussion with Industry on AGDUFA V negotiations. FDA emphasized that reauthorization of AGDUFA focuses on user fee funding, not FDA policy. The negotiating teams from FDA and Industry introduced themselves. Erik Mettler and Timothy Mueller were recognized as FDA lead negotiators, and Stephanie Batliner was recognized as the GADA lead negotiator.

Ground Rules Discussion

The ground rules that will govern AGDUFA V negotiations were discussed.

Regarding the scope of negotiations, FDA stated that the focus is on user fee provisions, funding, and the goals letter. FDA said that the agency would not discuss policy changes during the negotiations, but those areas which impact funding may be discussed. FDA also advised that if Industry wishes to add participants to the negotiations, they should notify FDA at least 5 days in advance to allow FDA to prepare. FDA indicated it intends to bring Agency subject matter experts for presentation and discussion on relevant topics and would also provide 5 days' notice.

FDA and Industry agreed on the timelines for providing agendas and meeting materials in advance of the meetings and for reviewing meeting minutes. Meeting minutes will summarize any substantive proposal and significant controversies or differences of opinion in enough detail to ensure external stakeholders understand what was discussed and are important for transparency.

FDA and Industry discussed communications with outside parties during negotiations. Regarding Animal Drug User Fee Act (ADUFA) and AGDUFA reauthorizations occurring concurrently, Industry noted that GADA and AHI (Animal Health Institute) had many shared members and objectives. FDA agreed that the two Industry groups could coordinate and indicated it also intended to coordinate across the two negotiations.

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 Congress on other topics.

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

Negotiation Structure

FDA outlined a schedule with two negotiation meetings in August of 2026 followed by meetings occurring on a cycle every two weeks. Subject matter experts from the Center for Veterinary Medicine (CVM) will be joining during pre-determined negotiation meetings to provide CVM's perspective and an understanding of CVM's processes. FDA emphasized that the CVM presentations will be shared in advance and are intended to encourage dialogue.

FDA Perspective and Goals on AGDUFA V

FDA broadly discussed the agency's perspective and goals. Carryover was the first topic to be discussed with the main questions focusing on how to address carryover in a way that does not upend FDA or Industry. Reducing the carryover balance may require changes to user fees which could affect submissions, and FDA noted there may be an opportunity to make one-time investments in negotiated enhancements using the carryover balance. Industry stated that Industry generally would like to see the carryover balance reduced.

The next topic was FDA's shared service model. FDA noted that most infrastructure support services are moving to FDA's Office of Operations. The particular impacts that the move to shared services would have on AGDUFA will be discussed in future meetings. FDA also noted restoring staffing to FY 2024 levels is an important goal for the Agency.

FDA then discussed innovation and how to leverage innovation to get safe, effective generic animal drugs to market quickly. FDA noted opportunities to modernize Animal Drugs @ FDA to enhance FDA and Industry decision making. Additional process modernization efforts could include new IT solutions, data submission processing, transparency around communications, which could be opportunities for one-time use of carryover funding.

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

Industry Perspective and Goals on AGDUFA V

Industry began with its mission statement for negotiations focusing on efficient, predictable, and

timely processes that prioritize transparency, accountability, and economic feasibility. It was noted that Industry represents a broad range of companies, that they are striving for a program that is equitable across the Industry, and that their membership is focused on fairness and equity.

Industry noted they felt returning staffing in the program to FY 2024 levels to ensure appropriate levels of service in the program is an important goal. They also expressed a desire to see more parity in the amount of budget authority going into the AGDUFA program relative to other user fee programs and specifically ADUFA. They noted the generic animal drug Industry plays a major role in public health responses, for example in the screwworm response, but is not being appropriated the same funds.

Lastly, Industry also raised the topic of carryover. As it related to potential investments from carryover in enhancements, Industry noted it was important that ADUFA and AGDUFA negotiations around IT infrastructure proceed in lockstep.

Next Steps

Future negotiation meetings are to be scheduled for Wednesdays with the next scheduled meetings to be August 5th and August 26th. Meeting will be held every two weeks thereafter. Agendas will lay out key priorities, presentations, and goals. The revised ground rules are expected to be updated and sent out by July 30th. Response to the updated ground rules is due by August 4th.

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.)
Fernando Bertazzo	GADA (Virbac Corporation)
Ted Sullivan	GADA
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
Angela Granum	Office of Finance, Budget, and Acquisitions (OFBA)
Madeline Faunce	OFBA
Edward Bonny	OFBA