



Animal Generic Drug User Fee Act (AGDUFA) Reauthorization

FDA and Industry Group GADA (Generic Animal Drug Alliance)

August 26, 2026 | 12:30 pm – 2:00 pm

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

MEETING PURPOSE

Pursuant to section 742(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 Generic Animal Drug Alliance (GADA), to negotiate recommendations for the reauthorization of the Animal Generic Drug User Fee Act (AGDUFA) program, AGDUFA V. This was the third meeting. The purpose of the meeting was to address old business from the prior meeting and to discuss several proposals for AGDUFA V presented by FDA.

MEETING SUMMARY

Old Business

- Calendar Planning: FDA and Industry discussed upcoming dates, in-person vs. virtual meetings, meeting lengths, and meeting format.
- GADA Data Request: FDA stated that the agency was completing its response to Industry's data request.
- SharePoint Site: FDA announced that the external access SharePoint website had been provisioned. FDA will email instructions on access to the site and its use to Industry.

Office of Generic Animal Drugs (OGAD) Program Presentation

FDA presented on proposed enhancements to systems and research programs for AGDUFA V.

- Animal Drugs @ FDA – Proposed System Improvements
 - FDA noted that several of its data systems were outdated, vulnerable and near end-of-life. FDA proposed key improvements to its systems to improve data accuracy and reliability, streamline access to regulatory information, provide greater market transparency, support future generic drug development, reduce compliance and continuity risk, and grant long term scalability.
 - Industry inquired whether FDA would need to update other data systems if FDA upgraded Animal Drugs @ FDA. FDA explained that the planned enhancements would integrate with other CVM modernization efforts, including integration with the review system and review workflow, maintaining the data in a central repository, and connecting to a cloud database. FDA noted that these enhancements are in progress.
 - FDA noted it intends to seek feedback from Industry during the requirements

gathering and development process to develop a system that meets both FDA and Industry's needs, that Industry will use, and that Industry would be willing to support.

- Industry suggested that Animal Drugs @ FDA benefits the whole animal drug industry, not just generics, and asked if it is also on the table for the ADUFA negotiations. FDA noted the feedback and will also raise the concept during ADUFA negotiations.
- Industry requested additional information on estimated costs for this proposal in order to evaluate cost vs benefit. FDA agreed to provide these estimates.
- Generic Animal Drug Research Program
 - FDA is seeking to position itself and the industry for the future by investing in a research program to expand the landscape of approvals and remove impediments regarding generic animal drug development. In introducing the concept, FDA noted that forward-looking assessment of issues, such as animal drugs coming off patent as well as investigating scientific barriers to approvals of current applications (i.e., chewable tablets, novel dissolution conditions) would inform the research agenda.
 - FDA highlighted the success of the Generic Drug User Fee Amendments (GDUFA) Science and Research program as a precedent for OGAD's proposal, citing its success in reducing barriers to approval across a variety of drugs products.
 - FDA proposed using a portion of the carryover to fund the OGAD research program. FDA intends to partner with Industry to identify research targets and collaboratively prioritize a list of research projects to address key barriers to generic animal drugs development. The benefits of this proposal include expanded generic animal drug access, Chemistry, Manufacturing, and Controls (CMC) challenge resolution, reduced animal use, and transparent regulatory expectations. FDA also noted the research program would address foundational scientific questions and is not designed to resolve sponsor-specific drug development issues.
 - Specifically on the translation of science into regulatory information, Industry suggested it could be helpful for FDA to address existing gaps in the United States Pharmacopeia (USP) as they relate to animal drugs.
- Paragraph IV Certification
 - FDA explained that sponsors are increasingly filing Paragraph IV certifications. When they do, the first sponsor to file receives 180-day exclusivity that begins when they start marketing the drug. FDA noted that many sponsors don't fully understand how this exclusivity affects their approval timelines or ability to market a product. To address this, FDA is proposing greater transparency by updating FDA's website to indicate when an ANADA with Paragraph IV certification has been submitted. This update will publish information about reference listed new animal drugs in which one of more sponsors has filed such an ANADA. This information will allow all sponsors, including those who are not first to file, to better understand the potential impact on their animal drug product.
 - Industry asked clarifying question about the current process and whether the proposed enhancements, which appeared to be a relatively small ask, would entail significant costs. FDA noted that tracking activity across individual cases is labor intensive, but that the education plan could reduce existing inefficiencies and result in cost savings. FDA also noted that the proposal may or may not represent

a high-cost area or require additional funding but could be addressed in the goals letter due to the underlying resource implications.

FDA discussed its intent to reduce the amount of carryover over time and considered opportunities to use carryover funds for one-time investments, noting research and IT improvements as potential areas for such investment.

Lastly, FDA stated that the agency will provide cost estimates at a future session.

Next Steps

The next meeting will be scheduled for September 9, 2026. FDA informed Industry that they could expect FDA's response to the data request soon. FDA added that the schedule would be revised with additional discussion topics and time for review of FDA's responses to Industry's data request. It is expected that future topics will be driven by GADA's data request.

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
Fernando Bertazzo	GADA (Virbac Corporation)
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
Julie Bailey	Office of Generic Animal Drugs (OGAD)
Renee Blosser	OGAD
Aila Albrecht	OGAD
Scott Fontana	Office of New Animal Product Evaluation (ONAPE)
Lauren Feeney	OGAD
Jennifer Caruso	Office of Chief Counsel (OCC)
Angela Granum	Office of Finance, Budget, and Acquisitions (OFBA)
Madeline Faunce	OFBA
Edward Bonny	OFBA