**Animal Generic Drug User Fee Act (AGDUFA) Reauthorization**

**FDA and Industry Group GADA (Generic Animal Drug Alliance)**

September 23, 2026 | 9:00 am – 12:00 pm / 1:00 pm – 3:00 pm

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

**MEETING PURPOSE**

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 fifth meeting. The purpose of the meeting was to address old business from the prior meeting and to discuss proposals for AGDUFA V presented by FDA and Industry.

**MEETING SUMMARY**

**Old Business**

- Questions from Prior Proposals: FDA informed Industry that for Industry's questions arising from prior meetings regarding proposal-related costs, the agency anticipated some would be addressed during today's meeting, with others to be addressed at a later meeting as additional information is gathered to provide a comprehensive cost package.
- SharePoint Site: FDA announced that the main industry points of contact were granted permissions to the SharePoint site and an FDA guest access invitation email had been sent. FDA will use the next round of meeting minutes to test the system.

**FDA Presentation: Capacity Planning Adjustment Approach**

FDA presented the proposal to transition from the current workload adjuster model to a modernized capacity planning adjustment (CPA) for AGDUFA V. FDA noted that using a CPA approach would better align resources with actual workload demands and future program needs. FDA discussed the history of CPA in the agency, the relative impact of CPA over time, implementation of the proposal in CVM (including staffing, machine learning models, and IT infrastructure), methodology, and the forecasting of workload and resource needs. FDA expects the CPA to provide greater economies of scale and efficiencies.

Industry asked several clarifying questions and also inquired about past hurdles to improving Workload Adjusters in other programs. FDA explained that earlier challenges included limited

data science expertise and IT infrastructure, including the need to build data pipelines, develop code and system connections, and integrate data into an analytical platform. FDA noted that these challenges were addressed with the implementation of the CPA in other programs, and that the Agency has since developed staff expertise in data science and machine learning, and implemented the necessary analytical infrastructure. FDA stated that these existing capabilities could be leveraged for AGDUFA. FDA also acknowledged industry's concern that the smaller dataset associated with Generic Animal Drugs may be an impediment to implementing a CPA approach but noted that the CPA has been successfully implemented in other similarly sized user fee programs. Industry requested development and maintenance costs be assessed prior to any decision and expressed the view that cost and effort may outweigh the benefit given the comparatively small size of the program. FDA agreed to further review options based on available data for discussion at a future meeting.

**GADA Presentation: AGDUFA V Proposals**

Industry presented several proposals for AGDUFA V. Industry proposed revising AGDUFA review timelines, modifying user fee distribution, modifying sponsor fee categorization, reducing the burden and timeline for bioequivalence waivers, establishing a biosimilar task force, establishing a stop-clock mechanism, publishing publicly tissue residue analytical methods, implementing notice of Paragraph IV certification, and implementing submission type confirmation letters. FDA asked clarifying questions regarding the proposals and indicated that the agency would consider the information provided and develop counterproposals for discussion at a future meeting.

**Next Steps**

Industry and FDA agreed to not hold a meeting on October 7, 2026. The next meeting will be scheduled for October 13, 2026. FDA will report back on the impact and cost of proposals.

**PARTICIPANTS**

**Industry**

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| Stephanie Batliner | GADA (Bimeda Inc.) |
| Kim Huls | GADA (Cronus Pharma LLC) |
| Kim Armstrong | GADA (Huvepharma, Inc.) |
| Courtney Arumugam | GADA (Bimeda Inc.) |
| Kathy DeMarco | GADA |
| Fernando Bertazzo | GADA (Virbac Corporation) |
| Heather Sedlacek | GADA |

**FDA**

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| Erik Mettler | Human Foods Program, Office of Integrated Food Safety System Partnerships (HFP/OIFSSP) |
| Tim Mueller | OIFSSP |

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| Julie Bailey | Office of Generic Animal Drugs (OGAD) |
| Renee Blosser | OGAD |
| Aila Albrecht | OGAD |
| Lauren Feeney | OGAD |
| Stephanie Bowman | OGAD |
| Charli Spellane | Office of New Animal Product Evaluation (ONAPE) |
| Amy Hall | ONAPE |
| Jennifer Caruso | Office of Chief Counsel (OCC) |
| Olufunmilayo Ariyo | Office of Finance, Budget, and Acquisitions (OFBA) |
| Joshua Barton | OFBA |
| Madeline Faunce | OFBA |
| Edward Bonny | OFBA |
| Paul Gibney | OFBA |