Animal Generic Drug User Fee Act (AGDUFA) Reauthorization

Public Stakeholder Meeting

October 9, 2026 | 2:30 pm – 3:00 pm

Virtual Format

MEETING PURPOSE

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA hold discussions once every 4 months with representatives of veterinary, patient, and consumer advocacy groups on their views on the reauthorization and their suggestions for changes to the statutory provisions governing the Animal Generic Drug User Fee Act (AGDUFA) program. On May 11, 2026, FDA issued a Federal Register notice requesting that public stakeholders notify FDA of their intent to participate in periodic consultation meetings on the reauthorization.

MEETING SUMMARY

FDA thanked participating stakeholders for expressing their interest in the AGDUFA V stakeholder meetings by responding to the May 11, 2026, Federal Register notice and shared their appreciation for the opportunity to engage.

Meeting Minutes and Resources

FDA encouraged stakeholders to stay informed during the ongoing negotiations by visiting FDA's AGDUFA Meetings page, where AGDUFA meeting minutes are posted. FDA also reminded stakeholders of the opportunity to submit comments to the AGDUFA public docket (see vol. 91 of the Federal Register Notice, pages 20691-93(April 17,2026)), which will remain open for comment until December 1, 2027.

Update on Negotiation Process

The AGDUFA negotiations between FDA and the Generic Animal Drug Alliance (GADA), representing Industry, have progressed to identifying the costs associated with proposals. In addition to identifying and discussing priorities for the upcoming user fee cycle, a major focus of the negotiations is the AGDUFA carryover balance, with FDA and Industry exploring ways to address existing carryover and manage it in the future. The goals letter has not yet been drafted.

Opportunity for Feedback

FDA invited stakeholder feedback. The stakeholder acknowledged their involvement as an industry representative in the negotiations and had no additional comments for this update, but expressed appreciation for the opportunity to ask questions and participate.

Next Steps

FDA will schedule the next update meeting for February 2027.

PARTICIPANTS

Public Stakeholders

Stephanie Batliner	Bimeda

FDA

Erik Mettler	Human Foods Program, Office of Integrated Food Safety System Partnerships (HFP/OIFSSP)
Tim Mueller	OIFSSP
Madeline Faunce	Office of Finance, Budget and Acquisitions (OFBA)
Edward Bonny	OFBA