FDA Notes & News

FDA Launches Pilot Program to Incentivize Manufacturing of Animal Drug Products in the U.S.

The U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) today announced the launch of a pilot program designed to encourage and strengthen domestic manufacturing of animal drug products and active ingredients. This initiative reflects CVM's commitment to supporting a resilient veterinary pharmaceutical supply chain, preventing animal drug shortages, and advancing the FDA's broader efforts to increase American pharmaceutical manufacturing.

The veterinary pharmaceutical supply chain, like its human drug counterpart, relies significantly on active ingredients and finished products manufactured outside the United States. The new pilot program is intended to reduce the risk of supply chain disruptions by prioritizing reviews of animal drug applications where both finished drug products and the active ingredients are manufactured in the U.S.

Key Incentives

- ***Priority Review Consideration for Complete CMC Technical Sections*** This would include priority review consideration for complete Chemistry, Manufacturing and Controls (CMC) technical sections when ***both*** the finished drug product and its active ingredient(s) are manufactured in the United States.
- ***Review of a Second Domestic Active Ingredient Source in Original Application Submission*** Eligible sponsors may include a second domestic source of active ingredient up front as part of an original application or technical section submission, if at least one of the sources is domestically manufactured. This eliminates the need to submit a post-approval supplemental application.

The FDA's animal drug domestic manufacturing pilot is modeled on approaches successfully implemented by the FDA's Center for Drug Evaluation and Research (CDER), including its ANDA Prioritization Pilot, and adapts those frameworks for animal drugs.

CVM intends to monitor the pilot program's effectiveness and may provide additional information or program modifications based on stakeholder experience and feedback.

Interested sponsors should visit CVM Pilot Program to Support Animal Drug Manufacturing in the United States for more information about eligibility and how to contact the Division of Manufacturing Technologies (DMT) within CVM's Office of Generic Animal Drugs (OGAD) or Office of New Animal Product Evaluation (ONAPE).