Antibiotic Approval Process | FACT SHEET

Healthy Animals, Healthy People

A safe and wholesome food supply starts with healthy animals. Therefore, it is critical that livestock veterinarians, ranchers and farmers have access to effective antibiotics to maintain animal health.

All antibiotics labeled for use in livestock production have passed a stringent FDA approval process and have been shown to be safe and effective.

The **Center for Veterinary Medicine (CVM)**, a branch of the **Food and Drug Administration (FDA)**, is responsible for ensuring that animal drugs are safe and effective, and manufactured to the highest quality standards under the guidance of the Federal Food, Drug and Cosmetic Act.

For any new food animal antibiotic to be approved, a **New Animal Drug Application (NADA)** must be initiated, typically by the drug manufacturer.

- The NADA process is a stringent, science-based regulatory review overseen by FDA veterinarians, animal scientists and biologists.
- The NADA process includes three components:

Safety assessment

NADA approval requires a sponsor to submit an average of 75 different studies to prove an antibiotic's safety.

Human food safety: NADA sponsors must provide empirical evidence that food derived from treated animals is safe for human consumption. Reviews now also include a comprehensive, evidence-based approach to address antibiotic resistance.

Target animal safety: Research must confirm the antibiotic is safe for the animals that will be treated.

Environmental safety: A drug manufacturer must measure and prove that a proposed product and its metabolized byproducts do not harm the environment in any way.

Efficacy assessment

Data is submitted from geographically diverse, statistically-designed studies showing the product will work in the ways intended, which include controlling and treating clinical disease.

Quality assessment

This component of the approval process consists of facility inspections, assurance of product stability, adherence to Good Manufacturing Practices and other procedures to assure FDA the NADA sponsor can manufacture the product in the approved form.

Ongoing monitoring

Continued assurance for the effective and safe use of antimicrobials include residue monitoring at meat harvest facilities by the Food Safety Inspection Service (FSIS). Additionally, the U.S. Department of Agriculture (USDA), FDA and the Centers for Disease Control and Prevention (CDC) collaborate to collect data through the National Antimicrobial Resistance Monitoring System (NARMS). Manufacturers of approved antibiotics also are required annually to submit a comprehensive report to FDA detailing the drug's active ingredients, distribution, proposed usage and any new scientific data related to product safety.

Additional safeguards

As with human medicines, all animal medicines, including antibiotics, are subject to ongoing evaluation through science-based risk assessments after they have been approved by FDA.

Antibiotics are required to go through a comprehensive, multi-step scientific review by FDA to ensure animal health and human food safety. Approved products must be continually proven safe to remain on the market.

Learn more at: www.ExploreBeef.org

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