

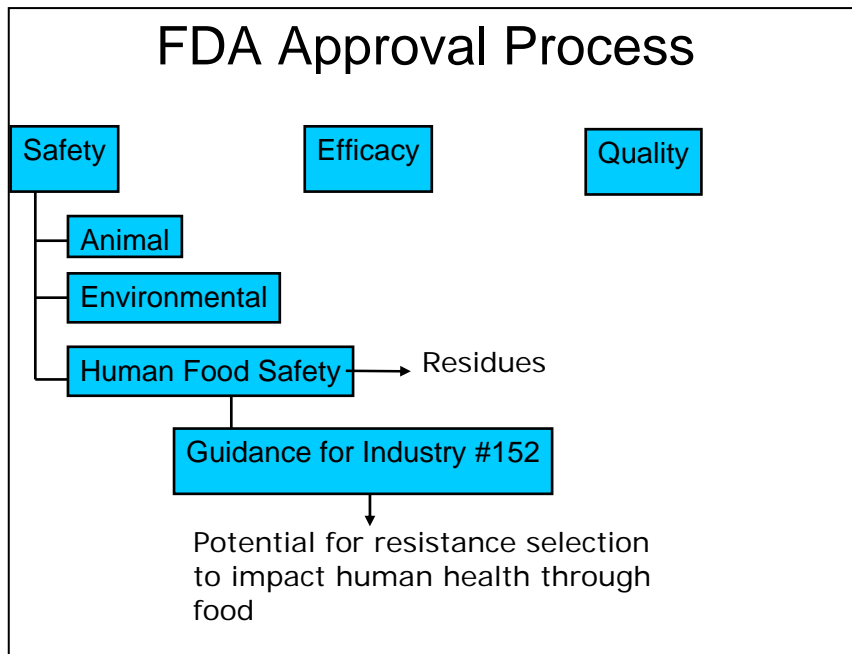
FDA'S Approval Process for Food Animal Antibiotics: Tougher Than for Human Antibiotics

More than a decade of time and tens of millions of dollars are dedicated to research before an animal health company can obtain approval of an antibiotic for use in food-producing animals. The approval process is a stringent, science-based regulatory review by U.S. government authorities.

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. The standards and process for reviewing an antibiotic used in animals is the same as that for an antibiotic used in humans in most respects.

Each process includes a **safety assessment**, requiring sponsors to submit data showing use of the antibiotic is safe for the human or animal in which it is to be used. However, **the safety assessment for food animals is more stringent than that for human antibiotics in three respects:**

Figure 1.



- 1) While FDA conducts a risk-benefit assessment for human antibiotics in which it weighs benefits against risks, there is no consideration of benefits in the review

of antibiotics used in food animals. This means the risk to human health for products under ¹review must be extremely low since FDA does not consider any benefits to offset the risks.

2) Food Safety: The safety assessment for food animal antibiotics requires sponsors to submit human food safety studies to ensure meat from animals treated with the antibiotic will be safe for human consumption. Data from these studies are used to establish withdrawal periods, or periods prior to harvest during which antibiotics cannot be used to ensure there are no residues above tolerance levels in the final product.

3) Preventing the Spread of Antibiotic Resistance: In 2003 FDA implemented an additional safety measure that “outlines a comprehensive, evidence-based approach to preventing antimicrobial resistance that may result from the use of antimicrobial drugs in animals.”¹ This process was a priority action item in the U.S. Public Health Action Plan. Significantly, in addition to all proposed antibiotics submitting to this process, CVM is in the process of working with animal health companies to examine all existing approved products using this new methodology.

Both the animal and human approval processes require an **efficacy assessment** refers to the submission of data from geographically diverse, statistically-designed studies showing the product will work in the way it is intended to provide clinical improvement or cure.

Finally, both processes require a **quality or manufacturing assessment** consisting of facility inspections, assurance of product stability, adherence to Good Manufacturing Practices and other procedures to assure the agency the sponsor can manufacture the product in the approved form.

¹ FDA News, October 23, 2003