

FDA Notes & News

FDA Finalizes Guidance on Evaluating Safety of Antimicrobial Animal Drugs Based on Their Importance in Human Medicine



The U.S. Food and Drug Administration has issued the final version of **Guidance for Industry (GFI) #152, Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.**

Antimicrobial resistance (AMR) occurs when bacteria evolve to survive exposure to drugs designed to kill them, making infections harder to treat. Because some of the same classes of antimicrobials used in animals are also important to treating human infections, the FDA evaluates the potential AMR risk to people when reviewing new animal drug applications for antimicrobial drugs.

GFI #152 outlines a qualitative risk assessment framework for the FDA to evaluate whether and to what degree a given antimicrobial drug used in food-producing animals could pose a risk to human health through the food supply. It also includes Appendix A, which ranks antimicrobial drugs by their relative importance to human medicine, placing each into one of three categories: critically important, highly important, or important. These rankings help inform the risk assessment but are not intended to serve as a standalone risk management tool.

The FDA first issued GFI #152 in 2003. Since then, new antimicrobial drugs have been developed, disease patterns have shifted, and prescribing practices have evolved. All these factors can affect how important a given antimicrobial drug class is to human health. To better reflect these developments over time, the FDA considered public comments received on a concept paper and through a public meeting in 2020, then issued a draft revised guidance in 2022. The FDA considered feedback on that draft revised guidance when finalizing the guidance released today.

The final guidance updates several aspects of the draft revised version, including more detailed description of hazard characterization; combining sections discussing risk management and the application of risk management strategies; clarifying that Appendix A medical importance rankings are not intended to be used as a standalone guide for risk management decisions; and addressing why the FDA excludes topicals in the rankings of medically important antimicrobial drugs.

The overall scope and purpose of GFI #152 remains the same as it was in 2003: it serves as the FDA's primary framework for evaluating potential antimicrobial resistance risks from animal drug use in food-producing animals.