

FDA Notes & News

Defining Durations of Use for Certain Medically Important Antimicrobial Drugs for Food-Producing Animals.



The U.S. Food and Drug Administration has [finalized Guidance for Industry \(GFI\) #273: Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals](#). The guidance provides recommendations for how animal drug sponsors may voluntarily establish defined durations of use for certain antimicrobial drugs that are important in human medicine (medically important antimicrobial animal drugs) and have one or more indications that currently lack a defined duration of use. This applies only to medically important antimicrobial drugs in feed for food producing animals.

This guidance is intended for sponsors of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) containing antimicrobial drugs:

- (1) important to human medicine (medically important antimicrobial drugs),
- (2) for use in or on the medicated feed of food-producing animals, and
- (3) that are currently approved with one or more indications that have an undefined duration of use.

Medically important antimicrobial drugs and undefined duration of use are discussed further in section III. Scope of this guidance. The framework outlined in this guidance is intended to facilitate voluntary changes to have all medically important antimicrobial new animal drugs administered in alignment with the principles of judicious use.

Establishing appropriately defined durations of use to mitigate the development of antimicrobial resistance is consistent with previous and ongoing efforts by FDA to protect public health by promoting the judicious use of medically important antimicrobial drugs in animals. This guidance provides specific recommendations on how sponsors may facilitate changes to the approved conditions of use of affected products in support of ongoing efforts to mitigate the development of antimicrobial resistance.