



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0094]

Guidance for Industry on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI #209) entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals." This guidance is intended to inform the public of FDA's current thinking on the use of medically important antimicrobial drugs in animal agriculture.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

## FOR FURTHER INFORMATION CONTACT:

William T. Flynn,  
Center for Veterinary Medicine (HVF-1),  
Food and Drug Administration,  
7519 Standish Pl.,  
Rockville, MD 20855,  
240-276-9084,  
[William.flynn@fda.hhs.gov](mailto:William.flynn@fda.hhs.gov).

## SUPPLEMENTARY INFORMATION:

## I. Background

This document is related to two documents published elsewhere in this issue of the Federal Register, wherein FDA is announcing: (1) The availability of a draft guidance entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209" (draft GFI #213); and (2) the availability of a draft proposed regulation for veterinary feed directives.

In the Federal Register of June 29, 2010 (75 FR 37450), FDA published the notice of availability for a draft guidance entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," giving interested persons until August 30, 2010, to comment on the draft guidance. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. Minor editorial changes were made to improve clarity.

The Agency was pleased to receive a number of comments that were generally supportive of the concepts outlined in draft GFI #209. However, other comments were more critical, based largely on the guidance's lack of specificity related to implementation issues. FDA decided not to make any substantive changes to GFI #209 but rather to address specific issues related to implementation through issuance of a separate draft guidance document, draft GFI #213, that would afford additional opportunity for public comment. As noted earlier, a notice of availability for draft GFI #213 is published elsewhere in this issue of the Federal Register.

The guidance announced in this notice finalizes the draft guidance dated June 28, 2010.

## II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

## IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: April 5, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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