4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0889]

Draft Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (draft GFI #213) entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of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." The purpose of this document is to provide information to sponsors of certain new animal drug products who are interested in developing revised conditions of use for those products consistent with FDA's GFI #209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" and to set timelines for stakeholders wishing to comply voluntarily with this guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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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 final guidance entitled

"The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209) and (2) the availability of a draft proposed regulation for veterinary feed directives.

FDA is announcing the availability of a draft guidance for industry 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). The audience for this draft guidance is sponsors of approved applications for new animal drug products containing medically important antimicrobial new animal drugs for use in or on medicated feed or in drinking water of food-producing animals. The purpose of this draft guidance is to provide sponsors of the affected new animal drug products with more specific information on how to supplement their approved new animal drug applications to align with FDA's recommendations in GFI #209.

Final GFI #209, published elsewhere in this edition of the Federal Register, discusses FDA's concerns regarding the development of antimicrobial resistance in human and animal bacterial pathogens when medically important antimicrobial drugs are used in food-producing animals in an injudicious manner. GFI #209 recommends that the use of medically important antimicrobial drugs be limited to uses in animals that are considered necessary for assuring animal health and include veterinary oversight or consultation (namely through the use of prescription or veterinary feed directive products).

FDA encourages all sponsors of new animal drug products covered by draft GFI #213 to participate in the voluntary program outlined in the draft guidance. FDA believes a voluntary approach, conducted in a cooperative and timely manner, will be a far faster and less burdensome route to achieving the common goal of more judicious use of medically important

antimicrobials in animal agriculture. However, FDA also believes it is critical to see meaningful progress toward reaching this goal. Therefore, in order to ensure an orderly, equitable, and timely transition, draft GFI #213 also includes clear timelines for sponsors of affected products wishing to revise their approved applications.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this 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

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910-0032 and 0910-0669.

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 draft 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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