4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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 Guidance for Industry #209; 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 #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 Guidance for Industry #209." The purpose of this document is to provide information to sponsors of certain antimicrobial new animal drug products who are interested in revising conditions of use for those products consistent with FDA's Guidance for Industry (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: 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, email: william.flynn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 13, 2012 (77 FR 22327), FDA published the notice of availability for a draft guidance entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: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," giving interested persons until July 12, 2012, to comment on the draft guidance. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 13, 2012.

The purpose of this guidance document is to provide information to sponsors of certain antimicrobial new animal drug products who are interested in revising conditions of use for those products consistent with FDA's Guidance for Industry (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. FDA intends to work with affected drug sponsors to help them to voluntarily implement the principles described above through modifications to the approved conditions of use of their new animal drug products. FDA believes a voluntary approach, conducted in a cooperative and timely manner, is the most effective approach to achieve the common goal of more judicious use of medically important antimicrobials in animal agriculture.

FDA recognizes that it is important to identify ways to assess the effect of GFI #209 and GFI #213 over time. FDA currently collects data on the sale and distribution of antimicrobial drugs intended for use in food-producing animals, as well as data on antimicrobial resistance among foodborne pathogens as part of the National Antimicrobial Resistance Monitoring System. FDA is currently working in collaboration with other agencies, including United States Department of Agriculture and the Centers for Disease Control, to explore approaches for enhancing current data collection efforts in order to measure the effectiveness of the strategy. FDA anticipates seeking additional public input as it develops these enhancements.

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

This 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 either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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, and will be posted to the docket at http://www.regulations.gov.

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: December 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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