4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0784]

Guidance for Industry on Evaluating the Effectiveness of Anticoccidial 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 guidance for industry #217 entitled "Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals." The guidance provides guidance to industry for designing and conducting clinical effectiveness studies and describes criteria that the Center for Veterinary Medicine (CVM) thinks are the most appropriate for the evaluation of the effectiveness of anticoccidial drugs intended for use in poultry and other food-producing animals. The guidance suggests times during the evaluation of effectiveness when sponsors may wish to consult with CVM.

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:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 23, 2011 (76 FR 72422), FDA published the notice of availability for a draft guidance entitled "Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals," giving interested persons until January 23, 2012, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. No changes other than editorial changes were made to improve clarity. This guidance for industry #217 supersedes the CVM draft guidance for industry #40, entitled "Draft Guideline for the Evaluation of The Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry," dated April 1992. The guidance announced in this notice finalizes the draft guidance dated November 23, 2011.

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 this guidance have been approved under OMB control numbers 0910-0032 and 0910-0117.

IV. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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