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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0419]

Guidance for Industry on Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion 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 #204 entitled "Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals." This guidance advises industry on the use of active controls in studies intended to provide substantial evidence of effectiveness of new animal drugs for use in companion animals. The intent of the guidance is to provide information to clinical investigators who conduct studies using active controls and have a basic understanding of statistical principles.

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In the Federal Register of June 20, 2012 (77 FR 37059), FDA published the notice of availability for a draft guidance entitled "Draft Guidance for Industry on Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals," giving interested persons until August 20, 2012, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to stakeholder comments, FDA provided one additional example and clarified other examples in the Appendix section of the guidance. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 20, 2012.

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 number 0910-0032.

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: October 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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