a hard copy. Please use the document number 1781 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations.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 807, subpart E are currently approved under OMB control number 0910–0120; the collections of information in 21 CFR 56.115 are currently approved under OMB control number 0910–0130; the collections of information in 21 CFR part 812 are currently approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 are currently approved under OMB control number 0910–0485.

V. 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. It is no longer necessary to send two copies of mailed 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.

Dated: June 15, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2012–15025 Filed 6–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0419]

Draft Guidance for Industry on Active Controls in Studies To Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #204 entitled ''Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals.''

This draft guidance advises industry on the use of active controls in studies intended to provide substantial evidence of effectiveness of new animal drugs for use in companion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: 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 August 20, 2012.

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 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: Lisa M. Troutman, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8322, *lisa.troutman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #204 entitled ''Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals.'' The purpose of this draft guidance is to provide information to clinical investigators who conduct studies using active controls and have a basic understanding of statistical principles. The draft 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 draft guidance compares studies that use active controls to studies that use either placebo concurrent controls or untreated concurrent controls, and it uses these comparisons to illustrate the advantages and disadvantages of using a study with an active control. Examples are provided to illustrate some of the different outcomes that are possible when employing active controls in studies.

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 number 0910–0032.

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: June 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14988 Filed 6–19–12; 8:45 am]

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