copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: Janury 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–2354 Filed 2–16–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0283]

Guidance for Industry on Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; 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 (#171) entitled ''Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles.'' This guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance via the Internet at *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Marilyn Martinez, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577, e-mail: *marilyn.martinez@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 3, 2004 (69 FR 46553), FDA published a notice of availability for a draft guidance document entitled ''Draft Guidance for Industry: Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles'' giving interested persons until October 18, 2004, to submit comments on the draft guidance and until October 4, 2004, to comment on the information collection. FDA considered all comments received and, where appropriate, made changes in the guidance. The final guidance differs from the draft guidance in the following ways: (1) The relationship between granting or denying a waiver based on a demonstration of bioequivalence and granting or denying a generic approval based on the safety of a biomass Type A article has been clarified; (2) the nature of the information needed to support, and the applicability of, the ''Comparison of Formulations'' approach described in the guidance has been clarified; (3) the title of table 1 of the guidance has been clarified; (4) one value in table 2 of the guidance has been updated; and (5) other relatively minor editing has been done to clarify the substance of the document. There were no comments directed specifically at the collection of information.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA is announcing that a collection of information entitled ''Guidance for Industry: Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. In the **Federal Register** of October 24, 2005 (70 FR 61451), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this collection of information is 0910–0575. It expires on January 31, 2009. A copy of the supporting statement is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket, and where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments at any time. Submit a single copy of electronic comments or two paper copies of any comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Copies of the guidance document entitled ''Waivers of *In Vivo* Demonstration of Bioequivalence of Certain Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles'' may be obtained from the Center for Veterinary Medicine's Home Page at *http://www.fda.gov/cvm* and from the Division of Dockets Management Web site at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–2291 Filed 2–16–06; 8:45 am]

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