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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 00D-0790]

Draft Guidance for Industry: The Use of Published Literature in Support of New Animal Drug Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry entitled "The Use of Published Literature in Support of New Animal Drug Approval." The draft guidance is intended to fulfill the section of the FDA Modernization Act of 1997 (FDAMA) that requires the agency to issue guidance to clarify the circumstances in which published matter may be the basis for approval of a supplemental application. The draft guidance also clarifies the circumstances in which published literature may be the basis for approval of an original application. The draft guidance is intended to provide specific advice on when FDA may be able to rely on published literature, with or without the submission of underlying data, to support new animal drug approval.

DATES: Submit written comments on the draft guidance for industry by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Copies of the draft guidance may be obtained on the Internet at <http://www.fda.gov/cvm/fda/TOCs/guideline.html>.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20850, 301-594-1620, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(b) of FDAMA (Public Law 105-115) requires FDA to issue guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for articles approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or section 351 of the Public Health Service Act (42 U.S.C. 262). This provision includes a requirement that FDA publish guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application.

This draft guidance for industry clarifies the circumstances in which published literature may be the basis for approval of both original and supplemental new animal drug applications. Specifically, the draft guidance describes the circumstances under which FDA could rely on published literature without access to the underlying data and the circumstances under which the applicant should provide additional information about a published study.

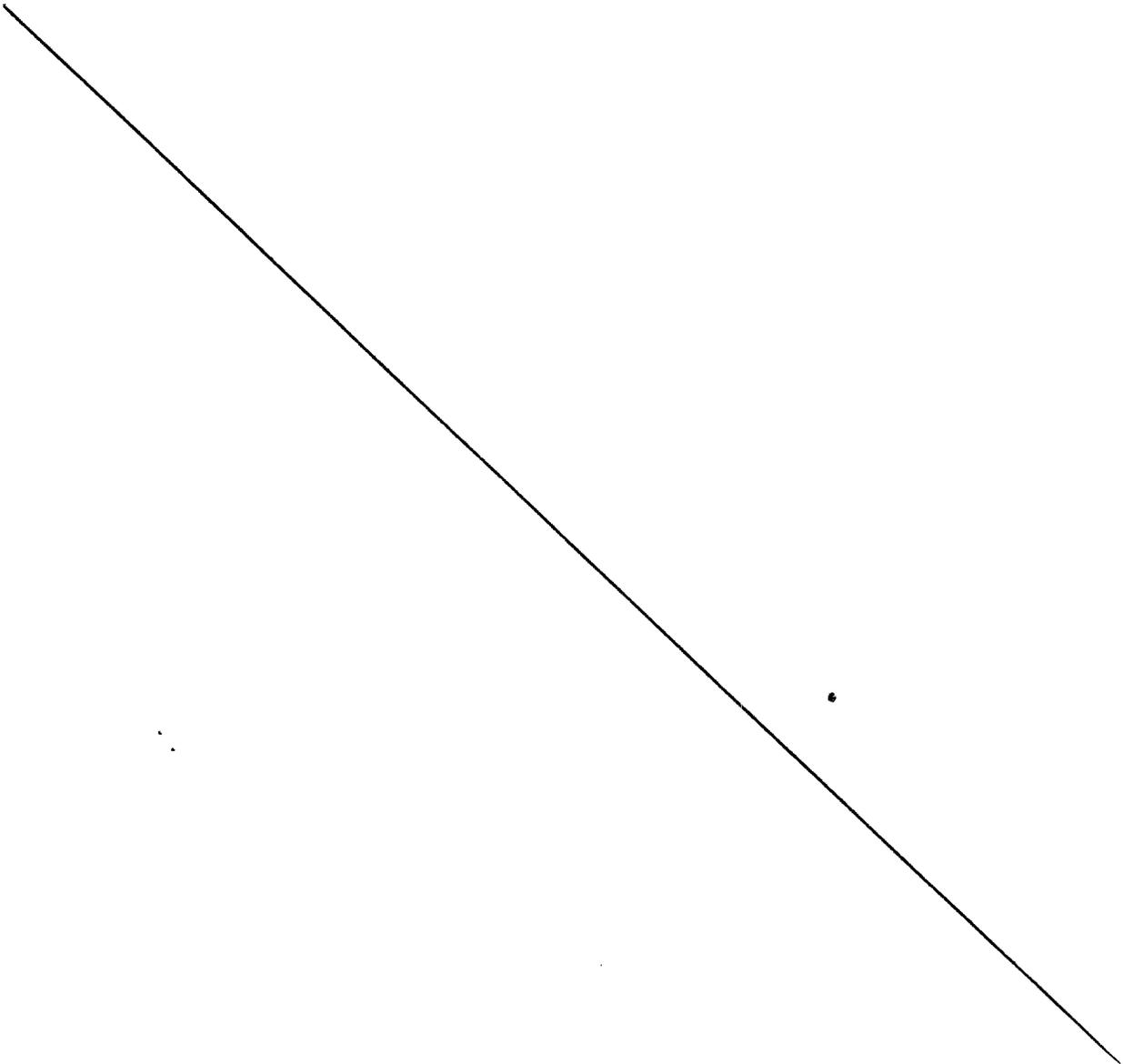
II. Significance of Guidance

This draft guidance represents the agency's current thinking with regard to the use of published literature in support of new animal drug approval. 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 statute, regulations, or both. The agency has developed this draft guidance in accordance with the agency's good guidance

practices (62 FR 8961, February 27, 1997), which set forth the policies and procedures for the development, issuance, and use of guidance documents.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading



of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4-10-00
April 10, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Jim Windsor

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