Dated: November 4, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2912]

Final Guidance for Industry on the Development of Supplemental Applications for Approved New Animal Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#82) entitled ''Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs.'' This guidance explains how and when drug sponsors may use data collected for original new animal drug applications (NADAs) to support the technical sections of a supplemental NADA. The guidance also explains when the Center may, under existing statutes or regulations, require the submission of new data. Finally, the guidance delineates the instances in which a sponsor will generally need to file a new NADA rather than a supplemental application.

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

ADDRESSES: Submit written requests for single copies of the final 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. Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Marilyn N. Martinez, Office of New Animal Drug Evaluation (HFV–130), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577, e-mail: *mmartine@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115) was signed into law. Section 403 of FDAMA requires FDA to provide information regarding approval of supplemental applications for approved products.

Section 403(b)(2) of FDAMA requires that FDA issue guidance on specific data requirements for supplemental NADAs in order to prevent duplication of previously submitted data. In the **Federal Register** of February 8, 2000 (65 FR 6214), FDA announced the availability of a draft guidance for industry entitled ''Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs.'' The draft guidance illustrated the various types of supplemental applications and their dependence on new data. This draft guidance explained how and when drug sponsors could use data accepted in support of an original application to support supplemental applications. The draft guidance also explained when a sponsor should submit a new NADA rather than a supplemental NADA. The agency received no comments on the draft guidance. The content of the final guidance is the same as the draft.

''Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs'' demonstrates the agency's dedication to assisting the sponsor in creating a project development strategy and to fostering a discussion between the sponsor and the agency. With this in mind, the guidance is organized in a user-friendly format with two distinctive sections. The first section separates supplemental applications into two categories: Category I includes applications that do not ordinarily require additional data and category II includes applications that may require additional data. The guidance then lists the 14 types of supplemental applications in each category as well as the instances in which a sponsor generally will need to file a new NADA rather than a supplemental NADA.

The second section is dedicated to clarification of category II supplemental applications and the data to meet the technical section requirements. The data CVM would recommend be submitted for each category II supplement are provided in tables. The tables indicate if: (1) New data will generally be needed, (2) existing data included in a previously approved application will generally suffice, or (3) the nature of the supplemental application will dictate whether or not new data are generally needed. A comment section follows each table providing explanations and suggestions to the sponsor. The guidance also cross-references several FDA documents relating to the processing of supplemental applications, providing further assistance to the sponsor.

This final 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 development of supplemental applications for approved new animal drugs. 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.

II. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this final guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The final 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cvm*.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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