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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-2912]

**Review of Supplemental Applications for Approved New Animal Drugs; Center Responsibility and Standards for Prompt Review; Availability of Draft Guidance**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** As required by the Food and Drug Administration Modernization Act of 1997 (FDAMA), the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) is making available information regarding the approval of supplemental applications for approved new animal drugs. CVM is publishing standards for the prompt review of supplemental applications and referencing an existing guidance that describes how supplemental applications may qualify for priority review. CVM is also designating an individual within the Center who is responsible for encouraging the prompt review of supplemental applications and for working with sponsors to facilitate the development and submission of data to support supplemental applications. Further, CVM is describing its efforts to collaborate with other organizations and persons to identify published and unpublished studies that may support supplemental applications and to encourage sponsors to submit supplemental applications based on such studies. In addition, CVM is announcing the availability of a draft guidance entitled "Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs." This draft guidance explains how drug sponsors can use data submitted in support of an original application to support supplemental applications.

**DATES:** Written comments should be submitted by *[insert date 90 days after date of publication in the Federal Register]*. Written comments on the existing guidance entitled "CVM's Program

NAD 1

Policy and Procedures Guide 1240.3135,” which describes how supplemental applications qualify for priority review, may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of “Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs” or “CVM’s Program Policy and Procedures Guide 1240.3135” to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. Copies of the draft guidance and the existing guidance may be obtained on the Internet at <http://www.fda.gov/cvm>.

Submit written comments on the draft guidance, “Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs” to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on CVM’s “Program Policy and Procedures Guide 1240.3135” to the Policy and Regulations Team (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.

**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 Place, Rockville, MD 20855, 301-827-7577.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 403 of the FDAMA (Public Law 105-115) instructs FDA to provide certain information regarding approval of supplemental applications for approved products. Among other things, section 403 requires that FDA do the following: (1) Section 403(a) requires that the agency publish standards for the prompt review of supplemental applications; (2) section 403(b)(1) requires that FDA provide guidance to “clarify circumstances in which published matter may be the basis for the approval of a supplemental application;” (3) section 403(b)(2) requires that FDA provide guidance that specifies “data requirements that will avoid duplication of previously submitted data

by recognizing the availability of data previously submitted in support of an original application.”

(4) section 403(b)(3) requires that FDA provide guidance that defines supplemental applications that are eligible for priority review; (5) section 403(c) requires that FDA designate an individual within each Center to be responsible for encouraging the prompt review of supplemental applications and working with sponsors to facilitate development and submission of data to support supplemental applications; and (6) section 403(d) requires the implementation of programs and policies to foster collaboration between FDA and other organizations and persons to identify published and unpublished studies that might support supplemental applications and to encourage sponsors to submit supplemental applications based on such studies.

This document and the guidance documents discussed in it fulfill the requirements of section 403(a), (b)(2), (b)(3), and (c). This document also discusses FDA’s continuing efforts at collaboration as required by section 403(d). Section 403(b)(1) will be addressed in a future **Federal Register** notice.

## **II. Section 403(a): Standards**

Section 403(a) of FDAMA requires that FDA publish “standards for the prompt review of supplemental applications submitted for approved articles \* \* \*” The legislative history of this section indicates that these performance standards should cover supplements submitted for changes in product use.

Section 512 (c) (1) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(1)) sets a 180-day time frame for review of new animal drug applications (NADA’s). This time frame applies to all applications, including supplements to approved applications.

The agency intends to use the performance goals set forth in the fiscal year (FY) 2001 performance plan to fulfill the requirement of the FDAMA that it establish standards for the prompt review of efficacy supplements. In FY 2000, the agency’s goal is to review and act on 65 percent of NADA’s and abbreviated new animal drug applications (ANADA’s), including supplemental applications, within 180 days of receipt. For FY 2001, the goal is 70 percent.

To facilitate prompt reviews, CVM encourages sponsors of supplemental applications to work closely with CVM personnel through presubmission conferences or other means to aid CVM in assuring that supplemental applications are reviewed promptly.

### **III. Section 403(b)(2)(i): Specify Data Requirements That Will Avoid Duplication of Previously Submitted Data by Recognizing the Availability of Data Previously Submitted in Support of an Original Application**

CVM has developed and is announcing the availability of a draft guidance, “Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs” that represents the agency’s current thinking. The Center designates two categories of supplemental new animal drug applications (NADA’s), Category I and Category II. Ordinarily, for Category I supplemental NADA’s, FDA does not require a reevaluation of any of the safety or effectiveness data in the parent application. For Category II supplemental NADA’s, FDA may ordinarily require drug sponsors to submit new data. Therefore, the Center may be required to reevaluate certain safety or effectiveness data in the original application. The draft guidance lists the types of supplemental NADA’s that fall into each of the categories, and it provides an overview of issues that drug sponsors should consider with respect to safety and effectiveness data and data supporting the environmental and manufacturing controls technical sections when seeking the approval of Category II supplemental NADA’s.

The draft guidance is organized by type of Category II supplement. For each type (e.g., a change in the amount of drug administered per dose), the document provides a table and comments. The table lists each technical section for which information would be required for approval of the supplement and whether the information in a previously approved application is sufficient or new information would be needed. Comments provide additional information to assist the sponsor. In this way, the draft guidance specifies data requirements that will avoid duplication of previously submitted data. It also refers drug sponsors to related guidance documents that will aid them in the preparation of supplemental NADA’s.

This draft guidance 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 requirement of the applicable statute, regulations, or both.

#### **IV. Section 403(b)(3): Define supplemental applications that are eligible for priority review**

When CVM determines that a product represents an important advance in animal health, it may expedite the review of original and supplemental applications. The circumstances in which CVM may make such a determination are outlined in an existing guidance entitled “ CVM Program Policy and Procedures Guide 1240.3135,” available at the address above.

#### **V. Section 403(c): Responsibilities of Centers**

FDA has designated the following individual within CVM to be responsible for encouraging prompt review of supplemental applications for approved articles and for working with sponsors to facilitate the development and submission of data to support the approval of supplemental applications in accordance with section 403(c) of FDAMA:

Director, Office of New Animal Drug Evaluation (ONADE), Center for Veterinary Medicine, (HFV-100), Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, 301-594-1620.

#### **VI. Section 403(d): Collaboration to Identify Published and Unpublished Studies**

CVM currently collaborates with the U.S. Department of Agriculture (USDA) National Research Support Project #7 (NRSP-7) and others, including state agencies, extension agents, universities, the National Coordinator for Aquaculture NADA's, and other USDA agencies, to encourage sponsors to make supplemental applications for minor use new animal drugs by encouraging development of Public Master Files (PMF's). Minor use new animal drugs are drugs used in minor animal species or drugs used in any animal species for the control of a disease that occurs infrequently or occurs in limited geographic areas. Minor species are defined in 21 CFR 514.1(d). PMF's contain public data from unpublished and published studies that can be used

in conjunction with data already available in a major use product's original NADA to support a supplemental NADA. The majority of approved minor use drugs have been approved as supplements to products approved for use in major species.

In a notice entitled "Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses; Availability" published in the **Federal Register** (63 FR 58056, October 29, 1998), CVM proposed other methods of collaboration to make data available for minor use supplemental applications.

In addition, CVM frequently participates in discussions with animal industry trade associations to help clarify the new animal drug approval process. These discussions encourage university researchers and others to identify or initiate studies that may be used to support supplemental applications.

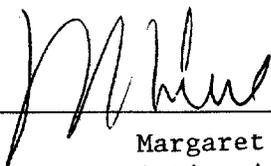
## **VII. Comments**

The draft guidance discussed in section III of this document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Written comments may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the **Federal Register***), to ensure adequate consideration in preparation of the final document. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in

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the heading of this document. A copy of the document 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: 1/24/00  
January 24, 2000



Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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