

Dated: March 21, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0146]

Draft Guidance for Industry and Reviewers on How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry and reviewers (#119) entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug." This draft guidance is neither final nor is it in effect at this time. This draft guidance announces the Center for Veterinary Medicine's (CVM) policy regarding the circumstances under which CVM intends to discontinue review of submissions filed during the investigation of a new animal drug, notify the sponsor that review has been discontinued, and remove the submission from the queue.

DATES: Submit written comments on the draft guidance at any time; however, comments should be submitted by July 3, 2001, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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 requests. See the **SUPPLEMENTARY INFORMATION** section for

electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld (HFV-100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1620, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance for industry (#119) entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug." This guidance announces CVM's policy regarding the circumstances under which CVM intends to discontinue review of submissions filed during the investigation of a new animal drug, notify the sponsor that review has been discontinued, and remove the submission from the queue.

CVM's Office of New Animal Drug Evaluation (ONADE) currently has a significant backlog in the number of submissions pending review. This has prompted ONADE to look at its review process. ONADE found that one of the significant inefficient uses of reviewer resources is the number of submissions received by ONADE that require significant additional information or rehabilitation in order for ONADE to complete its review. ONADE's practice has been to keep a submission "active" pending the submission of additional information from sponsors.

Instead of keeping deficient submissions "active" pending the submission of additional or revised information, ONADE intends to handle them under the policy set out in this draft guidance. If ONADE finds minor deficiencies, ONADE should request an amendment. But, if ONADE finds that a submission is significantly deficient, ONADE should notify the sponsor that it intends to discontinue review of the submission and remove it from the queue. This policy will permit ONADE to focus on reviewing quality submissions that contain all the information necessary for ONADE to evaluate the submission, thereby facilitating new animal drug approvals.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on handling deficient submissions filed during the investigation of a new animal drug. 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

This draft guidance 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 document. Submit written comments to ensure adequate consideration in preparation of the final document by July 3, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft guidance document entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug" may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>.

Dated: March 28, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2001.

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Date and Time: April 26, 2001; 8:30 a.m.—5 p.m.; April 27, 2001; 8:30 a.m.—3 p.m.

Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.

The meeting is open to the public.

Agenda: Invited comments from Nursing Organizations regarding nursing workforce and shortage issues followed by discussion.