and each was returned to the agency as undeliverable.

In a certified, return-receipt letter sent to Bestblood, Ltd., dated March 4, 1998, at both addresses mentioned previously and returned as undeliverable, FDA indicated that an attempt to conduct an inspection at the facility was unsuccessful. The letter advised the firm that, under 21 CFR 601.5(b)(1) and (b)(2), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection required under § 600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, proceedings for license revocation may be instituted. FDA also indicated that a meaningful inspection could not be made at the establishment and issued to the firm a notice of FDA's intent to revoke U.S. License No. 1116 and announced its intent to offer an opportunity for a hearing.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of April 15, 1999 (64 FR 18623), a notice of opportunity for a hearing on a proposal to revoke the licenses of Bestblood, Ltd. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility because it was no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061 Rockville, MD 20852. The notice provided the firm 30 days to submit a written request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The firm did not respond within the 30-day time period with a written request for a hearing. The 30-day time period prescribed in the notice of opportunity for a hearing and in the regulations, may not be extended. No other comments were received.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68) the establishment license (U.S. License No. 1116) and the product licenses issued to Bestblood, Ltd., are revoked, effective February 8, 2000.

Dated: January 13, 2000.

**Mark Elengold,**

*Deputy Director for Operations, Center for Biologics Evaluation and Research.*

[FR Doc. 00–2768 Filed 2–7–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Oncologic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 16, 2000, from 8:30 a.m. to 5:30 p.m., and March 17, 2000, from 8 a.m. to 1 p.m.

*Location:* Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person:* Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On March 16, 2000, the committee will discuss: (1) New drug application (NDA) 21–063, Eloxatin® (oxaliplatin), Sanofi Pharmaceuticals, Inc., indicated for the first-line treatment of patients with advanced colorectal cancer in combination with 5–U based chemotherapy; and (2) NDA 20–571/SE1–009, Camptosar® Injection (irinotecan hydrochloride injection), Pharmacia and Upjohn Co., indicated as a component of first-line therapy for patients with metastatic carcinoma of the colon or rectum. On March 17, 2000, the committee will discuss NDA 21–174, gemtuzumab zogamicin, Wyeth-Ayerst Laboratories, indicated for the treatment of patients with CD33 positive acute myeloid leukemia in relapse.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 8, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and 1:30 p.m. and 1:45 p.m. on March 16, 2000, and between approximately 8:15 a.m. and 8:45 a.m. on March 17, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by March 8, 2000, to address issues specific to the submission or topic before the committee.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 28, 2000.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 00–2770 Filed 2–7–00; 8:45 am]

**BILLING CODE 4160–01–F**

## 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.

**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 May 8, 2000. Written comments on the existing guidance entitled ''CVM's Program 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 (Pub. L. 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 May 8, 2000, 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 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: January 24, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–2767 Filed 2–7–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel.

*Date:* February 28, 2000.

*Time:* 1:30 pm to 6 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

*Contact Person:* Joyce A. Hunter, PHD, NIH, NHLBI, DEA, Rockledge Center, II, 6701 Rockledge Drive, Suite 7192, Bethesda, MD 20892–7924, (301) 435–0287.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 31, 2000.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 00–2757 Filed 2–7–00; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and