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