

Dated: November 5, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-30457 Filed 11-13-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine 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: Veterinary Medicine 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 December 10 and 11, 1998, 8:30 a.m. to 4 p.m.

Location: Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Jacquelyn L. Pace, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6650, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12546. Additional information about the meeting will be provided on the Center for Veterinary Medicine Internet Home Page (<http://www.fda.gov/cvm>) after November 1, 1998. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss a proposed framework on how to evaluate the potential public health hazard from resistant pathogens and resistance genes associated with the use of antimicrobials in food animals.

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 December 3, 1998. Oral presentations from the public are tentatively scheduled for the morning of December 11, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact

person before December 3, 1998, 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.

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

Dated: November 5, 1998.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 29, 1998. The meeting will be open to the public. The amendment is being made to cancel the entire session on November 17, 1998. There are no other changes.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 29, 1998 (63 FR 58054), FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on November 16 and 17, 1998. On page 58054, beginning in the second column, the *Date and Time*, *Agenda*, and *Procedure* portions of this meeting are amended and the *Closed Committee Deliberations* portion is removed to read as follows:

Date and Time: The meeting will be held on November 16, 1998, 8:30 a.m. to 5:30 p.m.

Agenda: On November 16, 1998, the committee will discuss: (1) New drug application (NDA) 20-886 Panretin® (alitretinoin) Gel 0.1%, Ligand

Pharmaceuticals, Inc., indicated for the first-line topical treatment of cutaneous lesions in patients with acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma; and (2) NDA 21-041 DepoCyt™ (cytarabine liposome injection), DepoTech Corp., indicated for the intrathecal treatment of lymphomatous meningitis.

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 November 9, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9 a.m., and 1:45 p.m. and 2 p.m. on November 16, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 1998, 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, an open public session will be conducted for interested persons who have submitted their request to speak by November 9, 1998, to address issues specific to the submission or topic before the committee.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0535]

Agency Information Collection Activities; Announcement of OMB Approval; Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards (IRB's)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards (IRB's)" has been approved by the Office of Management and Budget (OMB) under