

Application No.	Drug
ANDA 88-932	Reserpine and Hydroflumethiazide Tablets, 0.125 mg/50 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective January 5, 1998.

Dated: November 17, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97-31879 Filed 12-4-97; 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 regulatory issues.

Date and Time: The meeting will be held on December 18, 1997, 8:30 a.m. to 5:05 p.m., and December 19, 1997, 8 a.m. to 4:35 p.m.

Location: Holiday Inn, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Jannette O'Neill-Gonzalez, or Robinette Taylor, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, 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 December 18, 1997, the committee will discuss: (1) New drug application (NDA) supplement 16-295/S-029, Droxia® (hydroxyurea capsules,

USP), for the treatment of sickle cell anemia in adult patients to prevent painful crises and to reduce the need for blood transfusions; and (2) NDA 20-798, Depocyt® (cytarabine lipid-particle injection), for the intrathecal treatment of neoplastic meningitis of patients with solid tumors, lymphoma, or leukemia. On December 19, 1997, the committee will discuss: (1) Biologics licensing application (BLA) supplement 97-0501, Proleukin/Aldesleukin (recombinant human interleukin-2), for the treatment of adult patients with metastatic melanoma; and (2) NDA 20-806, Neomark® (broxuridine for injection), for use as a cell proliferation marker to determine the labeling index in breast cancer.

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 10, 1997. Oral presentations from the public will be scheduled between approximately 8:35 a.m. and 9:05 a.m. on December 18, 1997, and between approximately 8:05 a.m. and 8:35 a.m. on December 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 10, 1997, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the December 18, 1997, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: November 26, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-31808 Filed 12-4-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0442]

Memoranda of Understanding Between the Food and Drug Administration and the United States Department of Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) have revised three memoranda of understanding (MOU's) with regard to control of aflatoxin in peanuts, in-shell Brazil nuts, and in-shell pistachio nuts. The purpose of the MOU's is to set forth the responsibility for aflatoxin testing of domestic and imported raw peanuts, imported in-shell Brazil nuts, and imported in-shell pistachio nuts.

DATES: The MOU's became effective October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Henry Kim, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-0631.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's signed by FDA and other departments, agencies, and organizations shall be published in the **Federal Register**, the agency is publishing three revised MOU's between FDA and USDA that set forth the responsibility for aflatoxin testing of domestic and imported raw peanuts, imported in-shell Brazil nuts, and imported in-shell pistachio nuts.

Dated: November 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

The text of the three MOU's follows: Agreement No.