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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 September 16 and 17, 1999, 8 a.m. to 5 p.m.

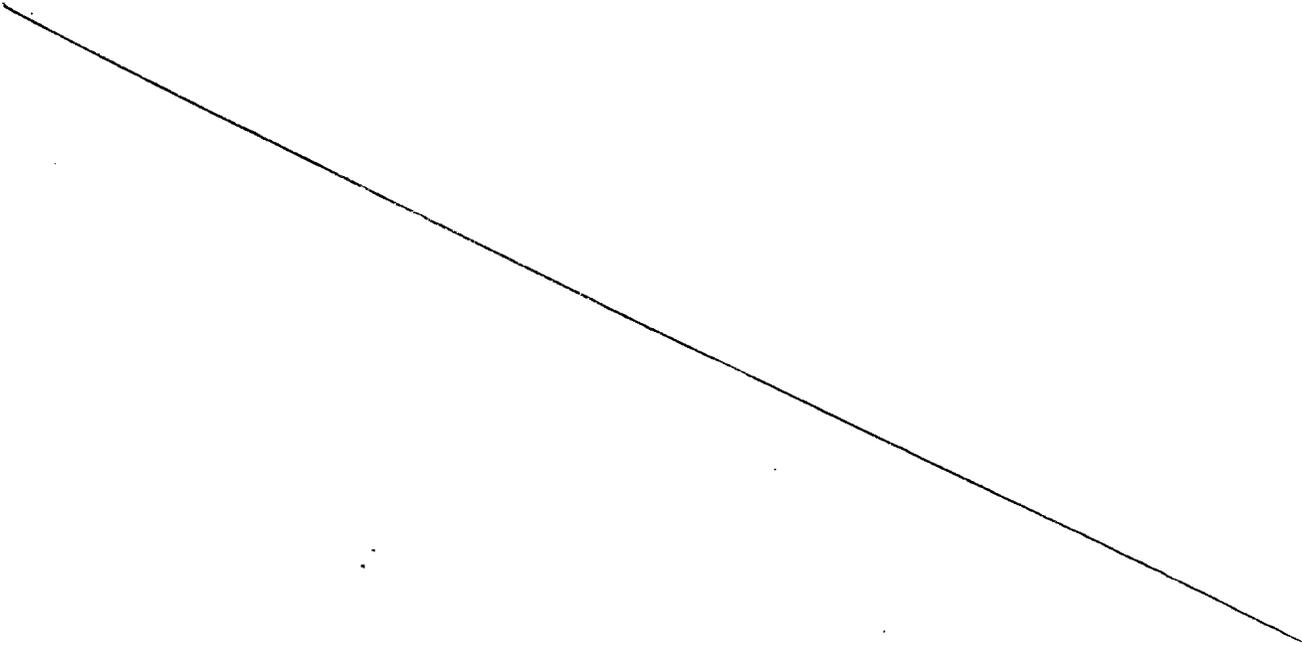
Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

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 September 16, 1999, the committee will discuss: (1) New drug application (NDA) 21-053, UFT® (tegafur and uracil) Capsules, Bristol-Myers Squibb Co., indicated, with leucovorin calcium tablets, for the first-line treatment of metastatic colorectal cancer; and (2) NDA 50-772, Evacet™ (doxorubicin HCl liposome injection), The Liposome Co., Inc., indicated for the first-line treatment of metastatic breast cancer in combination with cyclophosphamide. On September 17, 1999, the committee will discuss: (1) NDA 20-262/S-033, TAXOL® (paclitaxel) Injection, Bristol-Myers Squibb Co., indicated for the adjuvant treatment of node-positive breast cancer

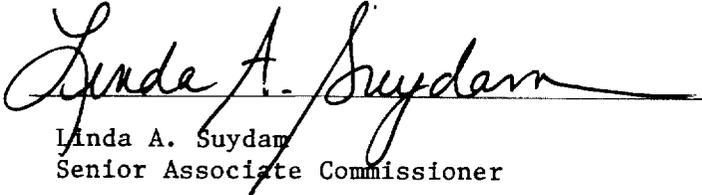
administered sequentially to standard combination therapy; and (2) biologics license application (BLA) 97-1001, Roferon®-A, Hoffman-La Roche Inc., indicated for use as adjuvant treatment of surgically resected malignant melanoma without clinical evidence of nodal disease, American Joint Committee on Cancer stage II (Breslow thickness >1.5 millimeter, N0). In addition, FDA will provide an update on the preliminary results of EST 1690 (ECOG intergroup study of INTRON A for the adjuvant treatment of melanoma) for discussion by the committee.

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 September 8, 1999. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and between approximately 1:15 p.m. and 1:30 p.m. on September 16, 1999, and between approximately 8:15 a.m. and 8:45 a.m., and between approximately 1:15 p.m. and 1:30 p.m. on September 17, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 1999, 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 will be conducted for interested persons who have submitted their request to speak by September 8, 1999, 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: August 13, 1999


Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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