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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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Certifier A. Corbin

**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 December 17, 2002, from 12:30 p.m. to 6 p.m. and December 18, 2002, from 8 a.m. to 3:30 p.m.

*Location:* Holiday Inn, Versailles Ballrooms, 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, FAX 301-827-6776, e-mail: SomersK@cder.fda.gov, 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 17, 2002, the committee will discuss biologics licensing application BL STN 125011/0, BEXXAR, Tositumomab (Anti-B1) and Iodine-131-Tositumomab, Corixa Corp., indicated for the treatment of patients

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with relapsed or refractory low-grade, follicular or transformed low-grade, B-cell non-Hodgkin's lymphoma (NHL) including patients with rituximab refractory follicular NHL. On December 18, 2002, the committee will discuss new drug application (NDA) 20-498, S012, CASODEX (150 milligrams bicalutamide), AstraZeneca Pharmaceuticals LP, indicated as: (1) Adjuvant therapy to radical prostatectomy and radiotherapy of curative intent in patients with locally advanced nonmetastatic prostate cancer who have a high risk for disease recurrence, or (2) immediate treatment of localized nonmetastatic prostate cancer in patients for whom therapy of curative intent is not indicated.

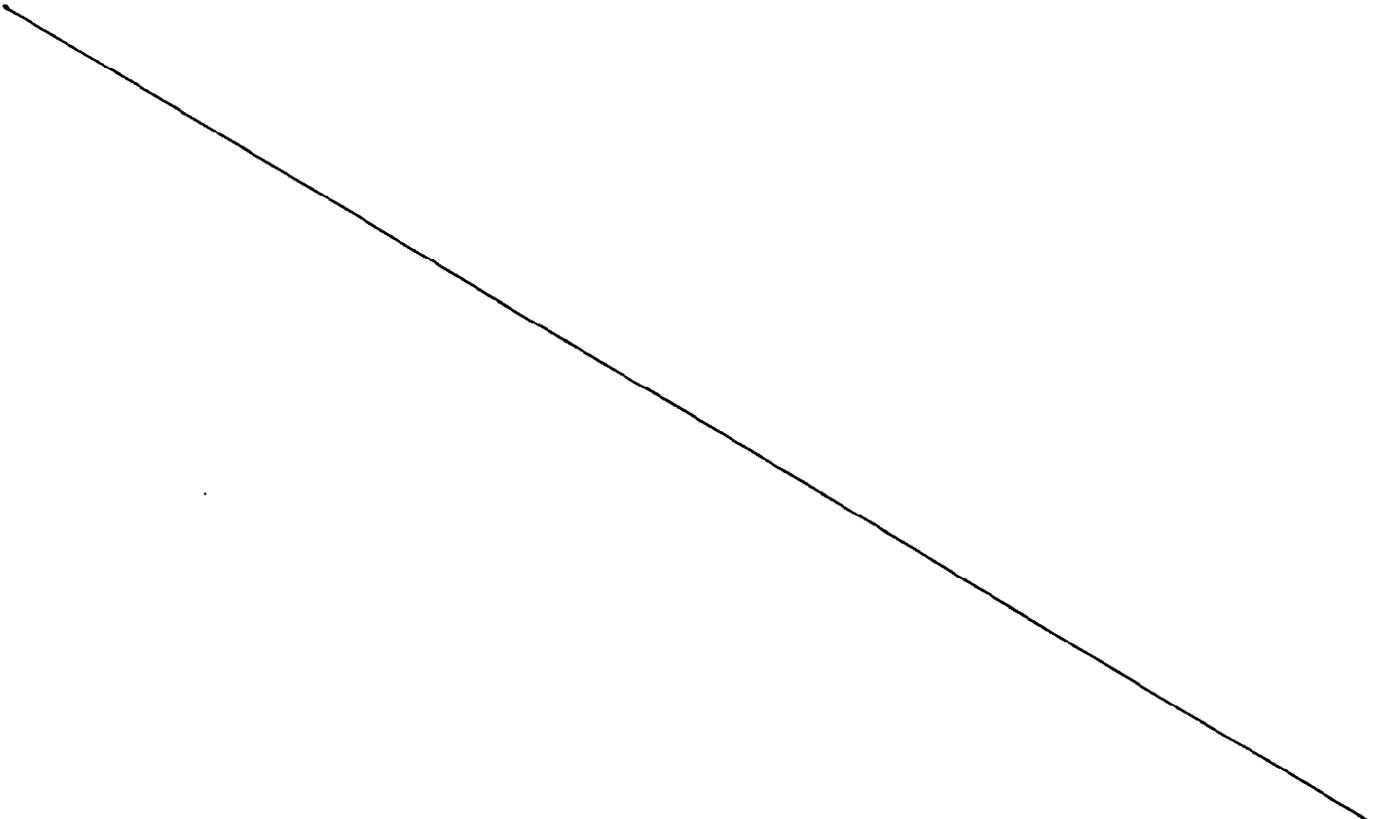
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 10, 2002. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 p.m. on December 17, 2002, and between approximately 8:15 a.m. and 8:45 a.m. on December 18, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 10, 2002, 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 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 December 10, 2002, to address issues specific to the topic before the committee.

Background materials for this meeting will be posted at the Oncologic Drugs Advisory Committee Dockets Web site at [www.fda.gov/ohrms/dockets/ac/acmenu.htm](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm). (Click on the year 2002 and scroll down to the Oncologic

Drugs Advisory Committee meetings.) The background materials for BEXXAR will be posted on December 16, 2002, and the background materials for CASODEX will be posted on December 17, 2002. The slides and transcripts from the meeting will be posted at this same web address about 3 weeks after the meeting.

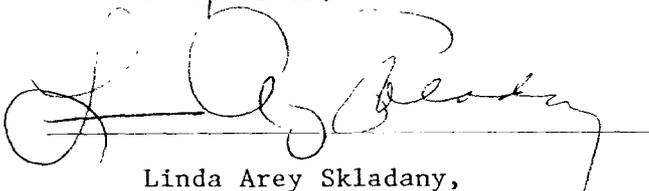
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen M. Templeton-Somers at least 7 days in advance of the meeting.



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

Dated: Nov 15, 2002  
November 15, 2002.



Linda Arey Skladany,  
Senior Associate Commissioner for External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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