DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0137]

Levothyroxine Sodium Therapeutic Equivalence; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 23, 2005, the comment period for the May 23, 2005, public meeting on the therapeutic equivalence of levothyroxine sodium drug products that was announced in the **Federal Register** of April 20, 2005 (70 FR 20574). The public meeting included FDA staff and representatives of three medical societies: The American Thyroid Association (ATA), the Endocrine Society, and the American Association of Clinical Endocrinologists (AACE). FDA is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments on or before September 23, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–443–5595, e-mail: *cunninghamr@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On May 23, 2005, FDA cosponsored a public meeting on the therapeutic equivalence of levothyroxine sodium drug products. The meeting included FDA staff and representatives of three medical societies: The ATA, the Endocrine Society, and the AACE. The purpose of the meeting was to discuss FDA's regulatory standards and methodological approaches for determining therapeutic equivalence between levothyroxine sodium drug products. FDA asked interested constituencies, including patient advocacy and education groups, and pharmaceutical sponsors, to submit comments by July 23, 2005.

By letter dated July 6, 2005, Abbott Laboratories (Abbott) requested that FDA extend the date for submission of comments. Abbott requested the extension to give interested parties the opportunity to comment meaningfully on the matters discussed at the meeting. The transcript became available on July 12, 2005.

FDA has decided to reopen the comment period until September 23, 2005.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics discussed at the May 23, 2005, meeting. Submit two copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcript

The transcript of the May 23, 2005, meeting is available on FDA's Web site at *http://www.fda.gov/cder/meeting/levothyroxine2005.htm*.

Dated: August 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16241 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

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 September 13, 2005, from 8 a.m. to 5 p.m. and on September 14, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Oncologic Drugs Advisory Committee.)

Agenda: On September 13, 2005, the committee will discuss the following: (1) New drug application (NDA) 21–491, proposed trade name XINLAY (atrasentan hydrochloride) Capsules, Abbott Laboratories, proposed indication for the treatment of men with metastatic hormone-refractory prostate cancer; and (2) NDA 21–743, S003, TARCEVA (erlotinib) Tablets, OSI Pharmaceuticals Inc., proposed indication for the first-line treatment, in combination with gemcitabine, of patients with locally advanced, unresectable or metastatic pancreatic cancer. On September 14, 2005, the committee will discuss the following: (1) NDA 21–880, proposed trade name REVLIMID (lenalidomide), Celgene Corp., proposed indication for the treatment of patients with transfusion-dependent anemia due to low-or intermediate–1–risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; and (2) NDA 21–877, proposed trade name ARRANON (nelarabine) Injection, GlaxoSmithKline, proposed indication for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to, or has relapsed with, at least two chemotherapy regimens.

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 2, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 2:30 p.m. to 3 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 2, 2005, and