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

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.

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 Johanna Clifford at 301–827–7001, 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: August 10, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–16331 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Acting Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on April 1, 2005, through June 30, 2005.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Acting Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

1. Timothy Millet on behalf of Joshua Millet, Boston, Massachusetts, Court of Federal Claims Number 05–0426V
2. Diane Conoly on behalf of Sharp Conoly, Boston, Massachusetts, Court of Federal Claims Number 05–0427V
3. Elizabeth Thomassen on behalf of Aeryn Thomassen, Boston, Massachusetts, Court of Federal Claims Number 05–0428V
4. Michael Collins on behalf of Jacob Collins, Boston, Massachusetts, Court of Federal Claims Number 05–0429V
5. Lane Massey on behalf of Jennifer Massey, Boston, Massachusetts, Court of Federal Claims Number 05–0430V
6. Tasha Randall on behalf of Dorion Johnson, Boston, Massachusetts, Court of Federal Claims Number 05–0431V
7. Brenda McLain on behalf of Cayden McLain, Boston, Massachusetts, Court of Federal Claims Number 05–0432V
8. Johnielle Barren on behalf of Jonathan Chandler Barren, Mobile, Alabama, Court of Federal Claims Number 05–0433V
9. Nahid Ramezani and Amir Poushangi on behalf of Rashim Poushangi, Baltimore, Maryland, Court of Federal Claims Number 05–0435V