TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 601.91(b)(2)(iii) | 1 | 1 | 1 | 1 | 1 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 25, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–18445 Filed 11–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Cellular, Tissue and Gene Therapies 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). At least one portion of the meeting will be closed to the public.

*Name of Committee*: Cellular, Tissue and Gene Therapies 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 by teleconference on November 20, 2006, from 2:15 p.m. to approximately 5 p.m.

*Location*: National Institutes of Health (NIH), Bldg. 29, rm. 121, 9000 Rockville Pike, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the specified location. A speakerphone will be provided at the specified location for public participation in the meeting. Important information about transportation, directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm*. Visitors must show two forms of identification, one of which must be a Government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Due to the limited available parking, visitors are encouraged to use public transportation. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

*Contact Person*: Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research, (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On November 20, 2006, the committee will meet in open session to hear updates of research programs in the Laboratory of Immunobiology and the Laboratory of Immunology, Office of Biotechnology Products, Center for Drug Evaluation and Research.

*Procedure*: On November 20, 2006, from 2:15 p.m. to approximately 4:30 p.m., the meeting is open to the public. 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 on or before November 13, 2006. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 13, 2006.

*Closed Committee Deliberations*: On November 20, 2006, from approximately 4:30 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a report of intramural research programs.

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 Gail Dapolito 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: October 27, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning*

[FR Doc. E6–18472 Filed 11–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Pediatric Oncology Subcommittee of the 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*: Pediatric Oncology Subcommittee of the 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 6, 2006, from 8:30 a.m. to 5 p.m.

*Location*: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, 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.

*Agenda*: The subcommittee will consider endpoints for trials intended to support the approval of new drugs to treat pediatric brain tumors. The background material will become available no later than the day before the meeting and will be posted on FDA's Website at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. under the heading ''Oncologic Drugs Advisory Committee.'' (Click on the year 2006 and scroll down to the previously named committee meeting).

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before November 21, 2006. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 21, 2006.

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 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: October 26, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E6–18442 Filed 11–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005D–0490]**

## Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability of guidance.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance document entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4).'' The guidance explains, using a question and answer format, FDA's current thinking on a number of issues related to the regulation of food allergens, including implementation of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

**DATES:** Submit written or electronic comments on the agency guidance at any time.

**ADDRESSES:** Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Rhonda R. Kane, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371, or by e-mail: *rhonda.kane@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The FALCPA (Public Law 108–282) amends the Federal Food, Drug, and Cosmetic Act (the act) and requires that the label of a food product that is, or that contains, an ingredient that bears or contains a ''major food allergen'' declare the presence of the allergen as specified by FALCPA. FALCPA defines a ''major food allergen'' as one of eight foods or food groups or a food ingredient that contains protein derived from one of those foods or food groups. A food ingredient may be exempt from FALCPA's labeling requirements if it does not cause an allergic response that poses a risk to human health or if it does not contain allergenic protein. FALPCA's labeling requirements apply to products labeled on or after January 1, 2006.

### II. Discussion

FDA has received numerous questions about the application of FALCPA's requirements to food products. To explain FALCPA's requirements as well as FDA's current thinking on several issues relating to the regulation of food allergens, on October 5, 2005, FDA posted on the agency's Web site the first edition of a guidance entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004'' (*http://www.cfsan.fda.gov/~dms/alrguid.html*). This guidance was subsequently updated in December 2005 (Edition 2) and April 2006 (Edition 3). The guidance that is the subject of this document ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4),'' responds to additional questions about FALCPA and food allergens. The revised guidance is intended to share FDA's current thinking on the additional questions presented in the guidance.

Given the nature of the revisions to the guidance, FDA is issuing the guidance as a level 1 guidance. Consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, FALPCA's labeling requirements apply to products labeled on or after January 1, 2006. Clarifying FDA's current thinking on the additional issues presented by FALCPA's implementation will help facilitate the food industry's compliance with FALCPA's requirements.

FDA expects to continue to receive questions regarding the implementation of FALCPA and the regulation of food allergens generally. The agency intends to respond to these inquires under