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

§ 10.115 as promptly as possible, using a question-and-answer format. The agency believes that, at the present time, it is reasonable to maintain all responses to questions concerning food allergens and FALCPA in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

This guidance represents the agency's current thinking on issues related to FALCPA and food allergens generally that are presented in the guidance. The guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any 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 and the guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18443 Filed 11–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2006–0060]

Privacy Act of 1974; System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act system of records.

SUMMARY: To provide expanded notice and transparency to the public, the Department of Homeland Security, U.S. Customs and Border Protection gives notice regarding the Automated Targeting System, which is the enforcement screening module associated with the Treasury Enforcement Communications System and was previously covered by the Treasury Enforcement Communications System ''System of Records Notice.'' This system of records is subject to the Privacy Act of 1974, as amended (5 U.S.C. 552a).

The Treasury Enforcement Communications System is established as an overarching law enforcement information collection, targeting, and sharing environment. This environment is comprised of several modules designed to collect, maintain, and screen data, conduct targeting, and share information. Among these modules, the Automated Targeting System performs screening of both inbound and outbound cargo, travelers, and conveyances. As part of this screening function, the Automated Targeting System compares information obtained from the public with a set series of queries designed to permit targeting of conveyances, goods, cargo, or persons to facilitate DHS's border enforcement mission.

The risk assessment and links to information upon which the assessment is based, which are stored in the Automated Targeting System, are created from existing information in a number of sources, including, but not limited to: the trade community through the Automated Commercial System or its successor; the Automated Commercial Environment system; the traveling public through information submitted by their carrier to the Advance Passenger Information System; persons crossing the United States land border by automobile or on foot; the Treasury Enforcement Communications System, or its successor; or law enforcement information maintained in other parts of the Treasury Enforcement Communications System that pertain to persons, goods, or conveyances.

As part of the information it accesses for screening, Passenger Name Record (PNR) information, which is currently collected pursuant to an existing CBP regulation (19 CFR 122.49d) from both inbound and outbound travelers through the carrier upon which travel occurs, is stored in the Automated Targeting System. PNR is comprised of data which carriers collect as a matter of their usual business practice in negotiating and arranging the travel transaction.

As noted above, this system of records notice does not identify or create any new collection of information, rather DHS is providing additional notice and transparency of the functionality of these systems.

DATES: The new system of records will be effective December 4, 2006, unless comments are received that result in a contrary determination.

ADDRESSES: You may submit comments, identified by *docket number*, by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments via docket number DH6–2006–0060.
- *Fax:* 202–572–8727.
- *Mail:* Comments by mail are to be addressed to the Border Security Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW. (Mint Annex), Washington, DC 20229. Comments by mail may also be submitted to Hugo Teufel III, Chief Privacy Officer, Department of Homeland Security, 601 S. 12th Street, Arlington, VA 22202–4220.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov*. Submitted comments may also be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, 799 9th Street, NW., 5th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572–8768.