SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain information for a total period of 6 years and 3 months. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Clinical Standards and Quality, CMS, Room S2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For the purpose of access, the subject individual should write to the system manager who will require the system name, address, age, gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For the purpose of access, use the same procedures outlines in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above and reasonable identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Records maintained in this system are derived from Carrier and Fiscal Intermediary Systems of Records, Common Working File System of Records, clinics, institutions, hospitals and group practices performing the procedures, and outside registries and professional interest groups.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E5–8331 Filed 1–5–06; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0483]

Guidance for Industry and Food and Drug Administration: Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006; Addendum December 30, 2005; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) published a notice in the **Federal Register** of December 14, 2005 (70 FR 74020) announcing the availability of a guidance document entitled, ''Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.'' The guidance document provided guidance to FDA and the food industry about when and how businesses may request the agency to consider enforcement discretion for the use, on products introduced into interstate commerce on or after the January 1, 2006, effective date for the *trans* fat labeling final rule, of some or all existing label stock that does not declare *trans* fat labeling in compliance with the final rule. This is to notify all interested persons of an addendum to that guidance.

DATES: This guidance is final upon the date of publication. Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. 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*. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julie Moss, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2373, FAX: 301–436–2636.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the availability of a guidance document for industry and FDA entitled, ''Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006,'' in the **Federal Register** of December 14, 2005 (70 FR 74020). Based on the number of requests the agency received asking it to consider enforcement discretion, FDA decided to incorporate an addendum into that guidance. Thus, FDA is issuing this notice to inform all interested persons of the addendum to that guidance.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), we are making available this guidance that states in plain language the factors the agency intends to consider concerning requests for enforcement discretion by small and other businesses regarding compliance with this regulation.

FDA is issuing this guidance as a level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but 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. This document affects the *trans* fat labeling effective date of January 1, 2006, so it is urgent that FDA explains its new enforcement policy before that date. This guidance represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

II. Paperwork Reduction Act of 1995

This final guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0571.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document 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. The guidance and received comments 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*.

Dated: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–116 Filed 1–3–06; 3:14 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management 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: Drug Safety and Risk Management 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 February 9, 2006, from 8 a.m. to 5 p.m. and February 10, 2006, from 8 a.m. to 3 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Victoria Ferretti-Aceto, 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: *ferrettiv@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: Cases of sudden death and serious adverse events including hypertension, myocardial infarction, and stroke have been reported to the agency in association with therapeutic doses of drugs used to treat Attention Deficit Hyperactivity Disorder (ADHD) in both pediatric and adult populations. The few controlled clinical studies of longer term drug treatment of ADHD provided little information on cardiovascular risks. On February 9, 2006, the committee will be asked to discuss approaches that could be used to study whether these products increase the risk of adverse cardiovascular outcomes. On February 10, 2006, the committee will be briefed on developments in the Office of Drug Safety and will receive updates on the Drug Safety Oversight Board and agency actions for the COX–2 selective Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and the risk management program for the isotretinoin products.

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 2006 and scroll down to Drug Safety and Risk Management Advisory Committee).

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 February 2, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 9, 2006, and between approximately 8:15 a.m. and 9:15 a.m. on February 10, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 2006, 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 Victoria Ferretti-Aceto 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: December 27, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–6 Filed 1–5–06; 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.