labeling requirements of section 403(y) of the act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or domestic telephone number that is required to appear on the product label under section 403(y) of the act; and (3) that FDA intends to begin enforcing the labeling requirements of section 403(y) of the act for products labeled on or after September 30, 2010.

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the labeling of dietary supplements as required by the DSNDCPA. It 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.

II. Paperwork Reduction Act of 1995

This 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 collections of information in this guidance were approved under OMB control no. 0910–0642.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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 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 at *http://www.cfsan.fda.gov/guidance.html*.

Dated: August 26, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21094 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0429] (formerly Docket No. 2007D–0496]

Guidance for Industry on Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' This guidance is intended to assist industry in complying with the labeling requirements for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application established by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA). Separate guidance, issued by the Center for Food Safety and Applied Nutrition on complying with the labeling requirements for dietary supplements, is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 2201, Rockville, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5488, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' On December 22, 2006, the President signed into law DSNDCPA (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The law also amended the act to add section 502(x) (21 U.S.C. 352(x)), which requires the label of an OTC drug product marketed in the United States without an approved application to include a domestic address or domestic telephone number through which the product's manufacturer, packer, or distributor may receive reports of serious adverse events associated with its use.

In the **Federal Register** of January 2, 2008 (73 FR 196), FDA announced the availability of a draft version of the guidance containing questions and answers relating to the new labeling requirements under Public Law 109–462 for OTC drugs marketed without an approved application. In addition to providing guidance for industry on how to comply with the labeling requirements in section 502(x) of the act, the draft guidance stated that FDA intended to begin enforcing the requirements of section 502(x) for OTC human drugs marketed without an approved application labeled on or after January 1, 2009. Although interested parties can comment on any guidance at any time, to ensure that the agency would have the opportunity to consider comments on the draft guidance before beginning work on the final version of the guidance, FDA requested that interested parties submit comments by March 3, 2008. On December 11, 2008 (73 FR 75436), FDA announced the availability of a revised draft guidance to notify industry and other members of the public that it intended to exercise enforcement discretion with regard to the labeling requirements of section 502(x) of the act for an additional 1-year period (i.e., for OTC drug products marketed without an approved

application that are labeled on or after January 1, 2010), because the agency was still in the process of finalizing the guidance. The agency has now completed its review and evaluation of the comments received and has modified the guidance where appropriate.

The document provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or domestic telephone number that is required to appear on the product labeling under section 502(x) of the act (21 U.S.C. 352(x)); and (3) that FDA intends to begin enforcing the labeling requirements of section 502(x) of the act for products labeled on or after September 30, 2010.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 collections of information in this guidance were approved under OMB control no. 0190–0640.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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 are available for public examination 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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/* default.htm or *http://www.regulations.gov*.

Dated: August 26, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21093 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism, Initial Review Group Biomedical Research Review Subcommittee.

Date: October 26–27, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Philippe Marmillot, PhD, Scientific Review Officer, National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Rm. 2019, Bethesda, MD 20892. 301–443–2861. *marmillotp@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271 Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: August 24, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–20860 Filed 8–31–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review; Group Neuroscience Review Subcommittee.

Date: November 16–17, 2009.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel—Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Beata Buzas, PhD, Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm 2081, Rockville, MD 20852, 301–443–0800, *bbuzas@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271 Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: August 24, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–20865 Filed 8–31–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as