event report (section 2(e)(3)). The guidance document provides information on the following topics: (1) The minimum data elements that should be included in a serious adverse event report, (2) the label that should be included with the report, (3) reporting formats for paper and electronic submissions, and (4) how and where to submit the reports.

Public Law 109–462 amends the Federal Food, Drug, and Cosmetic Act (the act) to add safety reporting requirements for nonprescription drug products that are marketed without an approved application. In accordance with section 760(b) of the act (21 U.S.C. 379aa), the manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug marketed in the United States without an approved application (referred to as the ''responsible person'') must submit to FDA any report of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug. In addition, the responsible person must submit followup reports of new medical information related to a submitted serious adverse event report that is received within 1 year of the initial report (section 760(c)(2) of the act). Public Law 109–462 also requires certain postmarketing safety report!s for dietary supplements.

In the **Federal Register** of October 15, 2007 (72 FR 58316), FDA announced the availability of a draft guidance of the same title. FDA received several comments on the draft guidance and considered those comments when finalizing the guidance. The guidance announced in this notice finalizes the draft guidance dated October 2007.

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 postmarketing adverse event reporting for nonprescription human drug products marketed without an approved application. 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 have been approved under OMB Control No. 0910–0636.

III. Comments

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

Dated: July 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16738 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0372] (Formerly Docket No. 2007D–0388)

Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The document provides guidance to the dietary supplement industry for complying with the serious adverse event reporting and recordkeeping requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA). Separate guidance, issued by FDA's Center for Drug Evaluation and Research, on reporting for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application, is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on the 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 on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20750. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Vasilios Frankos,Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration,5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 15, 2007 (72 FR 58313), FDA announced the availability of a draft guidance entitled ''Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act'' and gave interested parties an opportunity to submit comments by December 14, 2007. The agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance contains questions and answers relating to the new requirements under the DSNDCPA, concerning the mandatory reporting to FDA of serious adverse events associated with dietary supplements, the minimum data elements to be submitted in such reports, and records of serious and non-serious adverse events reported to a dietary supplement manufacturer, packer, or distributor.

FDA is issuing this guidance as level 1 guidance 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 alternate 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 collection of information in this guidance was approved under OMB control no. 0910–0635.

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.fda.gov/FoodGuidances* or *http://www.regulations.gov*.

Dated: July 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16702 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0312]

Guidance for Institutional Review Boards, Frequently Asked Questions—Institutional Review Board Registration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions — IRB Registration.'' This guidance is intended to assist IRBs in complying with the new requirement for IRB registration. This new rule requires each IRB in the United States that reviews FDA-regulated research to register using an Internet-based registration system that is maintained by the Department of Health and Human Services (HHS). This registration system is a modification of the one currently used by the Office for Human Research Protections (OHRP) for registration of IRBs that are designated by institutions under Federalwide Assurances (FWAs). OHRP has issued a similar rule requiring IRBs designated by institutions under FWAs to register or update their registration information using this modified system.

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

ADDRESSES: Submit written comments on this 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: Jean Toth-Allen, Office of Science and Health Coordination/Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document for IRBs entitled, ''Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions — IRB Registration.'' This guidance is intended to assist IRBs in complying with the new requirement for IRB registration under amended 21 CFR 56.106, which is effective July 14, 2009. Registration will be accomplished through a modified version of the Internet-based registration system used by OHRP for registration of IRBs that are designated by institutions under FWAs. This guidance document addresses basic information, such as why FDA issued the new rule, which IRBs are subject to the new regulation, the type of information to be provided when registering, and implications of non-compliance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is being issued as a level 1 guidance for immediate implementation in accordance with 21 CFR 10.115(g). Prior public participation is not feasible and FDA believes the guidance is necessary to help IRBs better understand their responsibilities under the new registration rule, which will go into effect on July 14, 2009.

II. The Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information required by the FDA new final rule on registration requirements. This collection of information is 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 21 CFR 56.106(b) has been approved under 0990–0279.

III. Comments

Interested persons may submit written or electronic comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). 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 document at either *http://www.fda.gov/oc/gcp/draft.html* or *http://www.fda.gov/ohrms/dockets/default.htm*

Dated: July 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16703 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

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 meetings.

The meetings 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.,