Executive Order 13179, issued on December 7, 2000, delegated authorities assigned to ''the President'' under the Act to the Departments of Labor, Health and Human Services, Energy and Justice. The Department of Health and Human Services (DHHS) was delegated the responsibility of establishing methods for estimating radiation doses received by eligible claimants with cancer applying for compensation. NIOSH is applying the following methods to estimate the radiation doses of individuals applying for compensation.

In performance of its dose reconstruction responsibilities, under the Act, NIOSH is providing voluntary interview opportunities to claimants (or their survivors) individually and providing them with the opportunity to assist NIOSH in documenting the work history of the employee by characterizing the actual work tasks performed. In addition, NIOSH and the claimant may identify incidents that may have resulted in undocumented radiation exposures, characterizing radiological protection and monitoring practices, and identify co-workers and other witnesses as may be necessary to confirm undocumented information. In this process, NIOSH uses a computer assisted telephone interview (CATI) system, which allows interviews to be conducted more efficiently and quickly as opposed to a paper-based interview instrument. Both interviews are voluntary and failure to participate in either or both interviews will not have a negative effect on the claim, although voluntary participation may assist the claimant by adding important information that may not be otherwise available.

NIOSH uses the data collected in this process to complete an individual dose reconstruction that accounts, as fully as possible, for the radiation dose incurred by the employee in the line of duty for DOE nuclear weapons production programs. After dose reconstruction, NIOSH also performs a brief, voluntary final interview with the claimant to explain the results and to allow the claimant to confirm or question the records NIOSH has compiled. This will also be the final opportunity for the claimant to supplement the dose reconstruction record.

At the conclusion of the dose reconstruction process, the claimant submits a form to confirm that the claimant has no further information to provide to NIOSH about the claim at this time. The form notifies the claimant that signing the form allows NIOSH to forward a dose reconstruction report to Department of Labor (DOL) and to the claimant, and closes the record on data used for the dose reconstruction. Signing this form does not indicate that the claimant agrees with the outcome of the dose reconstruction. The dose reconstruction results will be supplied to the claimant and to the DOL, the agency that will utilize them as one part of its determination of whether the claimant is eligible for compensation under the Act.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours)	Total response burden hours
Initial interview	4,200	1	1	4,200
Conclusion Form	8,400	1	5/60	700
Total				4,900

Dated: December 5, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–29322 Filed 12–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Advisory Committee on HIV and STD Prevention and Treatment

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment, Department of Health and Human Services, has been renewed for a 2-year period through November 25, 2010.

FOR FURTHER INFORMATION CONTACT: contact Kevin Fenton, M.D., Ph.D., Executive Secretary, CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment, Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop E07, Atlanta, Georgia 30333, telephone (404) 639–8000 or fax (404) 639–8600.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–29325 Filed 12–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Revision 1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance entitled ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug

Consumer Protection Act: Revision 1.'' This revised draft 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. The revision of the draft guidance changes the date on which FDA intends to begin enforcing these labeling requirements. 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: You can submit written or electronic comments on this revised draft guidance, or any guidance, at any time (see 21 CFR 10.115(g)(5)).

ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the revised draft 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 revised draft 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, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance entitled ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Revision 1.'' On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (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 issued a draft guidance document containing questions and answers relating to the new labeling requirements under Public Law 109–462 for OTC drugs marketed without an approved application. Although interested parties can comment on any guidance at any time, to ensure that the agency considered 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. FDA is still working to finalize the guidance.

Because the agency is still in the process of finalizing the guidance, FDA is issuing this revised draft guidance to notify industry that it intends to exercise enforcement discretion with regard to these labeling requirements for an additional 1-year period. The draft guidance issued on January 2, 2008, stated that FDA intended to begin enforcing the requirements of section 502(x) of the act for OTC drug products marketed without an approved application that are labeled on or after January 1, 2009. The revised draft guidance remains identical to the draft guidance issued on January 2, 2008, with respect to all topics except that it states that FDA intends to begin enforcing the labeling requirements of section 502(x) of the act for OTC drug products marketed without an approved application that are labeled on or after January 1, 2010.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval.

To comply with this requirement, FDA's notice in the **Federal Register** announcing the availability of the draft guidance gave notice of the proposed collections of information in the draft guidance. The notice included an analysis and burden estimate for these proposed collections of information and provided 60 days for public comment under the PRA. Because this revised draft guidance makes no change, other than to change the date on which FDA intends to begin enforcing the labeling requirements of section 502(x) of the act for OTC drug products marketed without an approved application, FDA is not providing a revised PRA analysis and burden estimate in this notice.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the revised draft 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*.

Dated: December 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29301 Filed 12–8–08; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0209] (formerly Docket No. 2007D–0491)

Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Revision 1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance document entitled ''Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Revision 1.'' This revised draft guidance is intended to assist the industry in complying with the labeling requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA). The revised draft guidance changes the date on which FDA intends to begin enforcing these labeling requirements. Separate guidance, issued by the Center for Drug Evaluation and Research on labeling requirements for nonprescription (over-the-counter) human drugs marketed without an approved application, is announced elsewhere in this issue of the **Federal Register**.

DATES: You can submit written or electronic comments on this revised draft guidance, or any guidance, at any time (see 21 CFR 10.115(g)(5)).

ADDRESSES: Submit written requests for single copies of the revised draft 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 requests. Submit written comments on the revised draft 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 revised draft guidance to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft 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

FDA is announcing the availability of a revised draft guidance entitled ''Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Revision 1.'' On December 22, 2006, the President signed into law the 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 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States 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 197), FDA announced the availability of a draft guidance entitled ''Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' 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 it began work on the final version, FDA requested that interested parties submit comments on the draft guidance by March 3, 2008.

Because the agency is still in the process of finalizing the guidance, FDA is issuing this revised draft guidance to notify the dietary supplement industry and other members of the public that it intends to exercise enforcement discretion with regard to the labeling requirements of section 403(y) of the act for an additional 1-year period. The draft guidance issued on January 2, 2008 stated that FDA intended to begin enforcing the requirements of section 403(y) of the act for dietary supplements labeled on or after January 1, 2009. This revised draft guidance remains identical to the draft guidance issued on January 2, 2008, in all respects except that it states that FDA intends to begin enforcing the labeling requirements of section 403(y) of the act for dietary supplements labeled on or after January 1, 2010.

FDA is issuing this revised draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance represents the agency's current thinking on 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

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA's notice in the **Federal Register** announcing the availability of the draft guidance (73 FR 197) also gave notice of the proposed collections of information in the draft guidance, included an analysis and burden estimate for these proposed collections of information, and provided 60 days for public comment under the PRA. Because this revised draft guidance makes no change, other than to change the date on which FDA intends to begin enforcing the labeling requirements of section 403(y) of the act for dietary supplements, FDA is not providing a revised PRA analysis and burden estimate in this document.