Dated: December 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–6268 Filed 12–27–07; 3:08 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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Draft Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the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 This draft guidance is intended to assist industry in complying with the labeling requirements for nonprescription (over-the-counter (OTC)) human drugs marketed without an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

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by March 3, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, addressStreet5630 Fishers Lane, rm. 1061, placeCityRockville, StateMD PostalCode20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 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.'' 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 draft guidance document contains questions and answers relating to the new labeling requirements under Public Law 109–462 for OTC drugs marketed without an approved application.

This 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. 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 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

III. 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 is publishing notice of the proposed collection of information set forth as follows.

With respect to the following collection of information, FDA invites comment on the following: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act for Nonprescription Drug Products Marketed Without an Approved Application.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the act) appears on the label of a nonprescription drug marketed in the United States.

Burden Estimate: FDA is requesting public comment on the estimated one-time reporting burden from these respondents, as required by Public Law 109–462 and described in the draft guidance. This guidance document discusses the labeling requirements of section 502(x) of the act (21 U.S.C. 352(x)), which was added by Public Law 109–462.

Section 502(x) of the act requires the label of an OTC drug product marketed without an approved application in the United States to include a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event associated with the product. If the label does not include the required domestic address or phone number, the drug product is misbranded. When the responsible person chooses to provide a domestic address (rather than a phone number) for adverse event reporting, FDA concludes that the statute requires the product label to bear a full U.S. mailing address that includes the street address or P.O. Box, city, state, and zip code of the responsible person (i.e., the manufacturer, packer, distributor, or retailer whose name appears on the label). This labeling requirement helps to ensure that any mailed adverse event report will reach the responsible person. Similarly, when the responsible person chooses to provide a domestic phone number for adverse event reporting, FDA concludes that the statute requires the phone number on the product label to include the area code. Without the area code, the phone number is incomplete and does not serve its intended purpose of enabling the consumer to contact the responsible person to report a serious adverse event.

In addition to discussing the statutory requirement that labels include a domestic address or a domestic phone number, the draft guidance includes recommendations about the location of this information on the label and the recommendation that the label make clear the purpose of this information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

	No. of Respondents	Frequency per Response	Total Responses	Hours Per Response	Total Hours
Domestic address or phone number labeling requirement (21 U.S.C. 502(x)) and recommendation to clarify its purpose	200	500	100,000	4	400,000

[1] There are no capital costs or maintenance and operating costs associated with this collection of information.

As indicated in Table 1 of this document, we estimate that approximately 200 manufacturers will revise approximately 100,000 labels total to add a full domestic address and a domestic telephone number, and should they choose to adopt the draft guidance's recommendation, to add a statement identifying the purpose of the domestic address or telephone number. We specifically request comments on these estimates. FDA believes that designing the label change should not take longer than 4 hours per label. Automated printing of the labels should only require a few seconds per label.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance, including comments regarding proposed collection of information. 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 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

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

Dated: December 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–6267 Filed 12–27–07; 3:08 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing 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.'' This draft guidance is intended to assist the dietary supplement 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). 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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 3, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist the office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY**