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the estimated one-time reporting burden from these respondents, as required by Public Law 109–462 and described in the draft guidance.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addition to discussing the statutory requirement that labels include a domestic address or a domestic phone number, the draft guidance includes recommendations about the location of this information on the label and the recommendation that the label make clear the purpose of this information.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**

INFORMATION section for electronic access to the draft guidance.

Submit written comments on the draft guidance, including comments regarding proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

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 draft guidance entitled ''Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' 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 non-prescription drugs marketed without an approved application. The draft guidance document contains questions and answers relating to the new labeling requirements for dietary supplements under the DSNDCPA.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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 is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on these topics: (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: Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors of dietary supplements marketed in the United States.

The draft guidance is intended to assist the dietary supplement industry in complying with the dietary supplement labeling requirements of section 403(y) of the act (21 U.S.C. 343(y)), which was added by the DSNDCPA.

Section 403(y) of the act requires the label of a dietary supplement being marketed in the United States to include a domestic address or domestic telephone number through which the responsible person may receive a report of a serious adverse event with such dietary supplement. If the label does not include the required domestic address or telephone number, the dietary supplement is misbranded. When the responsible person chooses to provide a domestic address (rather than a telephone 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 identified on the dietary supplement 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 telephone number for adverse event reporting, FDA concludes that the statute requires the telephone number on the product label to include the area code. Without the area code, the telephone 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 for dietary supplement labels to include a domestic address or a domestic telephone number, the draft guidance recommends that the label bear a clear, prominent statement informing consumers that the domestic address or telephone number is for reporting serious adverse events associated with use of the product.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Domestic address or telephone number labeling requirement (21 U.S.C. 343(y))	1,460	15.4616	22,574	4	90,296
FDA recommendation for label statement explaining purpose of domestic address or telephone number	1,460	15.4616	22,574	4	90,296

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total Burden Hours					180,592

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

Using FDA's Labeling Cost Model, FDA estimates that there are 22,574 stockkeeping units (SKUs) for unique dietary supplement pills and liquids for which labels would have to bear the complete domestic address or domestic telephone number of the responsible person for that supplement. This estimate of the number of SKUs for dietary supplements is an underestimate of the total number of dietary supplements on the market because dietary supplements are marketed in a variety of forms other than pills and liquids. However, this is the most comprehensive estimate available to FDA. FDA requests comments on the total number of SKUs for dietary supplements that are marketed in the United States.

In the economic impact analysis of the Dietary Supplement Good Manufacturing Practices final rule (the GMP final rule) FDA estimated that there were about 1,460 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements (June 25, 2007; 72 FR 34752 at 34920). Assuming the 22,574 SKUs are split equally among the firms, then each firm would be responsible for updating about 15 SKUs. The estimate of the number of manufacturers, re-packagers, re-labelers, and holders of dietary supplements from the GMP final rule is FDA's best estimate of the number of firms that are ''responsible persons'' who must comply with the new labeling requirement added by the DSNDCPA; however, it is not a precise estimate because the number of dietary supplement establishments covered by the GMP final rule is likely to be larger than the number of ''responsible persons,'' where a ''responsible person'' is a dietary supplement manufacturer, packer, or distributor whose name is listed on the label of a dietary supplement associated with a serious adverse event (see section 761(b)(1) of the act (21 U.S.C. 379aa–1(b)(1)). Thus, FDA's estimate for number of respondents in table 1 of this document may be over inclusive. FDA requests comments on the number of firms that would be subject to the labeling requirements of the DSNDCPA.

FDA does not know how many of the 22,574 dietary supplement SKUs would have to undergo a label change to include the complete domestic address or domestic telephone number of the responsible person as required by the DSNDCPA. Based on the agency's experience with regulating dietary supplements, FDA believes that some dietary supplement labels (SKUs) already have the full domestic address or telephone number of the responsible person printed on the label and thus will not need to be redesigned to comply with section 403(y) of the act. The agency does not have any information on which to base a quantitative estimate of the number of labels that already meet the requirements of section 403(y) of the act, however. Therefore, FDA is assuming conservatively that all labels will need to be redesigned.

Assuming further that redesigning a dietary supplement label to add a domestic address or telephone number requires one color change, and no analytical tests are performed on the new label, then FDA believes that designing the label change should not take longer than 4 hours per label. This time would be used to assess the current layout of each label and choose the best location for the domestic address or telephone number. Automated printing of the labels should only require a few seconds per label.

In addition to changing their labels to meet the statutory requirement for a domestic address or a domestic telephone number, dietary supplement firms may also choose to adopt the draft guidance's recommendation that the label bear a clear, prominent statement informing consumers that the domestic address or telephone number is for reporting serious adverse events associated with use of the product. In the absence of any information about how many firms are likely to add such an explanatory statement to their dietary supplement labels, FDA is assuming conservatively that the explanatory statement will be added to all dietary supplement labels.

FDA estimates that the burden of including the recommended explanatory statement on the label will be similar to the burden of adding the full domestic address or telephone number to the dietary supplement label. We assume it will take 4 hours per label to assess the current layout of each label and choose the best location for the explanatory statement. Again we assume this label modification would require one color change and that no premarket testing of the label wording would be performed. FDA requests comments on how many dietary supplement firms and products would follow FDA's recommendation to include such an explanatory statement on the product's label. FDA also requests comments on the burden associated with placing this explanatory statement on the dietary supplement label.

The likely overestimate of the total burden caused by FDA's conservative assumption that all dietary supplement labels (SKUs) will be redesigned to add a domestic address or telephone number and to include an explanatory statement for consumers is offset to some degree by the underestimate of the number of SKUs in the marketplace resulting from FDA's lack of information on the number of SKUs for dietary supplements that are sold in a non-liquid or non-pill form. FDA requests comments on the burden estimates presented in table 1 of this document. The agency is especially interested in comments that include information about: (1) The number of dietary supplements marketed in the United States in all forms and (2) the number or percentage of dietary supplements marketed in the United States that will not require a label change to comply with the requirement that dietary supplements bear a complete domestic address or telephone number. The agency would also welcome information on whether dietary supplement firms plan to add the recommended explanatory statement to their product labels.

III. 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.

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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: December 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–6266 Filed 12–27–07; 3:08 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Opioid Treatment Programs (OTPs) Mortality Reporting Form—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), has developed a voluntary reporting form for Opioid Treatment Programs (OTPs) to report mortality data on patients who at the time of death, were enrolled in the Programs that were certified to operate by SAMHSA.

Methadone is a Schedule II controlled substance approved by the Food and Drug Administration for the treatment of opioid dependence and pain. Although it has proven safe and effective, it must be carefully administered and for that reason, treatment of opioid dependence with methadone is provided only through specialized and Federally regulated and accredited clinics, the OTPs. Buprenorphine, a Schedule III controlled ssubstance, is also used in the treatment of opioid addiction by OTPs and office-based physicians.

In recent years, methadone has been associated with an increasing number of deaths around the country. Simultaneously, the use of methadone for pain has increased significantly over the last 5 to 10 years. While the Food and Drug Administration (FDA) maintains oversight of methadone for use in pain, SAMHSA provides oversight of methadone for use in opioid addiction treatment. Currently, there is no national database that tracks mortality among patients receiving methadone in OTPs and as a result, it is not clear whether and to what extent the increase in methadone-associated deaths may be related to treatment in OTPs. MedWatch, a voluntary reporting system maintained by FDA, provides information relevant to its role in its more general oversight of medication and device safety. A similar system is needed within SAMHSA to gather information directly relevant to the agency's mission of overseeing and ensuring safe and effective treatment for patients with opioid dependence.

In order to more accurately understand potential methadone-associated deaths at the OTP level, it is necessary to examine all patient deaths, including those related to buprenorphine. Understanding the actual cause of death of patients enrolled in OTPs can be a challenging task for many reasons, including inconsistencies in methods of reporting causes of deaths across different localities and officials; patients' use of other drugs, including illicit, over-the-counter, and prescription products; and other aspects of the patient's physical and mental condition. The standardized terminology to be used for reporting in the proposed system will contribute to a more precise and relevant analysis of individual cases and higher-level trends. The data will be used by SAMHSA to increase understanding of the factors contributing to these deaths, identify preventable causes of deaths, and ultimately, take appropriate action to minimize risk and help improve the quality of care. Importantly, better data will enable the agency to more proactively manage the oversight of treatment.

The information requested from OTPs should be readily available to any OTP that has met accreditation standards. The OTP should not find any need to otherwise analyze or synthesize new data in order to complete this form.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

Form	Number of facilities (OTPs)	Responses per facility	Burden responses (hours)	Annual burden (hours)
SAMHSA OTP Mortality Report	1,150	2	0.5	1,150

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: December 31, 2007.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. 07–6254 Filed 12–31–07; 8:45 am]

BILLING CODE 4162–20–M