Dated: December 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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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Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance document entitled ''Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer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 This revised draft guidance is intended to assist the industry in complying with the labeling requirements prescribed for dietary supplement manufacturers, packers, and distributors by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 The revised draft guidance changes the date on which FDA intends to begin enforcing these labeling requirements.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DATES: You can submit written or electronic comments on this revised draft guidance, or any guidance, at any time (see 21 CFR 10.115(g)(5)).

ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint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 Submit written comments on the revised draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the revised draft guidance to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance.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.

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 may be seen 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 revised draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: December 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0025] (formerly Docket No. 2007D–0083)

Guidance for Industry and the Food and Drug Administration; Modifications to Devices Subject to Premarket Approval—the Premarket Approval Supplement Decisionmaking Process; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process.'' The purpose of this guidance is to help industry determine the type of regulatory submission that may be required when a device subject to PMA is modified.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process,'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 240–276–3151. The guidance document may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this guidance to address modifications to devices subject to PMA applications, including changes to device design, device labeling, and the device manufacturing process. This guidance also can be applied when a legally marketed class III device is the subject of a recall or field corrective action and the manufacturer needs to change the device to assure its safety and effectiveness.

In the **Federal Register** of March 27, 2007 (72 FR 14282), FDA invited interested persons to comment on its draft guidance document entitled, ''Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process.'' The five general categories of comments received regarding the draft guidance are as follows: (1) Requests for a clearer interpretation of the regulations as to when a supplement is necessary (i.e., when a change to a device impacts or could impact safety and/or effectiveness); (2) requests for a detailed flowchart that would identify the type of supplement to be submitted based on any specific change for any device; (3) requests for specific definitions for some terms, such as ''substantial clinical data,'' ''significant change,'' and ''limited confirmatory clinical data;'' (4) requests for FDA to include 30-day supplements within the scope of the guidance; and (5) requests for additional examples for many supplement types, as well as for periodic reports. We considered all of the comments and revised the guidance when appropriate.

II. Significance of Guidance

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 ''Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process.'' 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1584) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small