

prepare and submit to CBER each response.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Complete Responses to Clinical Holds	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
CDER	29	approximately 1	41	284	11,644
CBER	78	1.58	123	284	34,932
Total					46,576

<sup>1</sup>There are no capital cost or operating and maintenance costs associated with this collection of information.

Dated: July 17, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-18691 Filed 7-22-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0314]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the regulation requiring manufacturers, packers, and distributors of dietary supplements to notify FDA that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Submit written or electronic comments on the collection of information by September 22, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.fda.gov/ecomments>. Submit written comments to the Division of Dockets Management

(HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under 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 including each proposed extension of an existing 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 comments on: (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 of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

#### Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control Number 0910-0331)—Extension

Section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act (21 U.S.C. 343).

*Description of Respondents:* Businesses or other for-profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	2,500	1	2,500	.75	1,875

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or in labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. This estimate is based on the average number of notification submissions received by the agency in the preceding 12 months.

Dated: July 17, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-18693 Filed 7-22-03; 8:45 am]

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Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 03-17136, appearing on page 40676 in the **Federal Register** of Tuesday, July 8, 2003, the following correction is made:

1. On page 40677, in the first column, under **ADDRESSES**, in the eighth line, “electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro” is corrected to read “faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota”.

Dated: July 17, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-18692 Filed 7-22-03; 8:45 am]

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Safety and Risk Management Advisory Committee would be held on September 18, 2003. On page 38714, in the first column, the *Location* portion of the meeting is amended to read as follows:

*Location:* Holiday Inn, the Ballroom, 8777 Georgia Ave., Silver Spring, MD.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 17, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-18633 Filed 7-22-03; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0069]

**Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 8, 2003 (68 FR 40676). The notice announced that a proposed collection of information had been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information will be used by FDA to determine whether reprocessed single-use devices are substantially equivalent to legally marketed predicate devices. The document was inadvertently published with an error. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy and Planning (HF-27), Food and Drug

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Drug Safety and Risk Management Advisory Committee; Amendment of Notice**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of June 30, 2003 (68 FR 38713). The amendment is being made to reflect a change in the *Location* portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 30, 2003, FDA announced that a meeting of the Drug

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of the Committee:* Neurological Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on August 5, 2003, from 10 a.m. to 5:30 p.m.

*Location:* Holiday Inn, Walker/Whetstone Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact:* Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12513. Please call the Information Line for up-to-date information on this meeting.