TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

[1] 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]

BILLING CODE 4160–01–S

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 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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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 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]

BILLING CODE 4160–01–S

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.