TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours Per Record-keeper	Total Hours
807.31	16,200	4	64,800	.50	32,400
Total Burden Hours					32,400

[1]The burdens are explained as follows:

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 9,450 hours, and recordkeeping burden hours for respondents is estimated to be 32,400 hours. The estimates cited in the tables above are based primarily upon the annual FDA accomplishment report, which includes actual FDA registration and listing figures from fiscal year (FY) 2003. These estimates are also based on FDA estimates of FY 2003 data from current systems, conversations with industry and trade association representatives, and from internal review of the documents referred to in the previous tables.

According to 21 CFR part 807, all owners/operators are required to list, and establishments and U.S. agents are required to register. Each owner/operator has an average of two establishments, according to statistics gathered from FDA's registration and listing database. The database has 25,100 active establishments listed in it. Based on past experience, the agency anticipated that approximately 7,300 registrations will be processed during the first year, and 3,100 thereafter. FDA anticipates reviewing 200 historical files annually.

Dated: October 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24192 Filed 10–28–04; 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 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 November 30, 2004, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on premarket approval application for a device intended for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: On November 30, 2004, from 8:30 a.m. to 5 p.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 9, 2004. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 30, 2004, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to pending issues and applications.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–24191 Filed 10–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0453]

Draft Revised Compliance Policy Guide ''Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05);'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revision of the compliance policy guide (CPG) entitled ''Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act.'' The draft CPG provides guidance on the

applicability of the Federal Import Milk Act (FIMA) to imported milk and cream.

DATES: Submit written or electronic comments on the draft revised CPG by November 29, 2004. General comments on agency guidance documents are welcome any time.

ADDRESSES: Submit written requests for single copies of the draft revision of the CPG entitled ''Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Esther Lazar, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1485, FAX: 301–436–2632.

SUPPLEMENTARY INFORMATION:

I. Background

The FIMA (21 U.S.C. 141 *et seq.*) prohibits the importation into the United States of milk and cream without a valid permit from the Secretary of Health and Human Services. FDA is revising the CPG to clarify and update its policy regarding which dairy products require permits under the FIMA. As explained in the draft CPG, FDA intends to consider the following dairy products to be subject to the FIMA's permit requirement for importation into the United States:

- Milk, lowfat milk, skim milk, fortified milk, flavored milk, concentrated milk, evaporated milk, sweetened condensed milk, ultra filtered milk.
- Cream, half-and-half, heavy cream, light cream, and light whipping cream.

FDA does not intend to require a FIMA permit for the following dairy products:

- Sour cream, cultured milk, acidified milk, yogurt, cheese, ice cream, and eggnog.
- Dried milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, and other dehydrated milk products.
- Any dairy product for which a permit is otherwise required, if it has been processed and packaged in hermetically sealed containers so as to be commercially sterile in accordance with the requirements of 21 CFR 108.35 and 21 CFR part 113.

FDA has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft guidance is being issued as a level 1 draft guidance consistent with GGPs. The draft revised CPG represents the agency's current thinking on the applicability of the FIMA to imported milk and cream. 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 statues 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 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.

III. Electronic Access

A copy of the draft revised CPG may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the draft revised CPG and may be accessed at *http://www.fda.gov/ora* under ''Compliance Reference.''

Dated: October 22, 2004.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–24153 Filed 10–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans

SUMMARY: In compliance with the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

Proposed Collection: Title: Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will obtain information on policies, programs, and practices for colorectal cancer screening among health plans in the U.S. The purpose of the study is to assess (1) Health plan policies, programs, and practices for colorectal cancer screening; (2) health plan activities in response to the National Committee on Quality Assurance's new Health Employer Data Information Set measure for colorectal cancer screening; and (3) characteristics of health plans and plan policies and activities that may be associated with higher rates of colorectal cancer screening. A questionnaire will be administered by mail or Internet using a national sample of health plans. Study participants will be health plan medical directors or administrators, and they will select their preferred response mode. Burden estimates are as follows:

Estimated number respondents	Estimated number responses per respondent	Average burden hours per response	Estimated total annual burden hours
520	1	0.333	173

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (a) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility;