application. This time is consistent with the current recordkeeping requirements for other information related to marketing applications for human drugs, biologics, and medical devices. Currently, sponsors of covered studies must maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to clinical investigators' file.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
54.6	1,000	1	1,000	.25	250

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

Dated: July 19, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–18479 Filed 7–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0175]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by August 24, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. The ''Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals'' will provide information on the frequency, nature, and scope of reuse and reprocessing of single-use medical devices by U.S. hospitals. The survey will provide statistically reliable estimates of the number of U.S. hospitals that are currently reusing and internally reprocessing single-use medical devices, whether they have registered with FDA, whether they are aware of the FDA educational materials on the reuse of single-use medical devices, and, if they are not currently internally reprocessing single-use devices, whether they have reused and reprocessed single-use medical devices in the past 3 years.

FDA will use these results to estimate the number of U.S. hospitals that reused and reprocessed single-use medical devices in the past, and those that currently reuse and internally reprocess single-use medical devices. This information will help FDA design its inspection plan, modify its education program, and evaluate the economic impact of current and future policies regarding single-use medical devices. The respondents to this collection of information will be U.S. hospitals.

In the **Federal Register** of April 30, 2001 (66 FR 21399), the agency requested comments on the proposed collection of information. No comments regarding paperwork were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR TELEPHONE SURVEY[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
5,272	1	5,272	0.125	659

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

This is a one-time survey. The burden estimate for the telephone survey is based on a pretest of a preliminary survey instrument administered to nine hospitals. The number of respondents, total annual responses, and the total burden hours in this notice differs from the numbers in the notice published on April 30, 2001 (66 FR 21399). This is because the number of hospitals to be surveyed has changed based on more current estimates of the number of hospitals in the United States.

Dated: July 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–18426 Filed 7–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support Drugs 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). The meeting will be open to the public.

Name of Committee: Anesthetic and Life Support Drugs 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 September 13 and 14, 2001, from 8 a.m. to 5 p.m.

Location: University of Maryland, Shady Grove Campus, multi-purpose room, Bldg. 9630, Gudelsky Dr., Rockville, MD.

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. 1091), 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 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days, the committee will discuss the medical use of opiate analgesics in various patient populations, including pediatric patients and patients with chronic pain of nonmalignant etiology, as well as the risk to benefit ratio of extending opiate treatment into these populations. It will also address concerns regarding the abuse potential, diversion and increasing incidence of addiction to opiate analgesics, especially to the modified release opiate analgesics.

Procedure: 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 August 17, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on September 13, 2001, and between approximately 9 a.m. and 10 a.m. on September 14, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 17, 2001, 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.

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

Dated: July 19, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–18478 Filed 7–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology 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). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology 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 17, 2001, from 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD.

Contact: Jeffrey W. Cooper, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220, ext. 121, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a device for the treatment of fecal incontinence. Background information and questions for the committee will be available to the public on August 16, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

Procedure: 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 August 9, 2001. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m., and between approximately 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 9, 2001, 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.

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

Dated: July 19, 2001.

Linda A Suydam,

Senior Associate Commissioner for Policy.

[FR Doc. 01–18425 Filed 7–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0281]

Medical Devices; A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures.'' This draft guidance is intended to assist the medical device industry and FDA staff in implementing a pilot premarket review program that may reduce some of the burden on manufacturers associated with current conflicting format and content requirements in different countries. The proposed pilot program will evaluate the utility of two documents created by the Global Harmonization Task Force (GHTF), Study Group 1 (SG1), entitled ''Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)'' and ''Essential Principles of Safety and Performance of Medical Devices'' (Essential Principles). The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this draft