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

guidance and the related GHTF documents by September 24, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures'' and related GHTF documents to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written or electronic comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is conducting a pilot premarket review program and is soliciting participation from the medical device industry. The pilot program is intended to evaluate the utility of a draft document that was prepared by the GHTF, SG1, to help harmonize the different requirements for premarket submissions in various countries. The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The purpose of the GHTF is to: (1) Encourage convergence in regulatory practices relating to ensuring the safety, effectiveness/performance, and quality of medical devices; (2) promote technological innovation; and (3) facilitate international trade. The GHTF Web site at: http://www.ghtf.org describes its organization, goals, and procedures. The GHTF draft document describes an internationally harmonized format and content for premarket submissions, e.g., premarket approval applications (PMAs) and 510(k) submissions, based on conformity to the Essential Principles document. The Essential Principles are a GHTF-derived list of both general and specific safety and performance recommendations for medical devices.

The announcement of the pilot premarket review program consists of the FDA draft guidance, which is the subject of this notice, and three related documents for comment appended to the FDA draft guidance: (1) A draft letter to the global medical device industry announcing the pilot program; (2) the draft STED document created by GHTF, SG1; and (3) the GHTF final document entitled ''Essential Principles of Safety and Performance of Medical Devices.''

The draft guidance document is intended to assist the medical device industry in completing a submission to FDA that uses the draft STED format and is also in accordance with U. S. requirements. The announcement letter describes specifics regarding the proposed pilot premarket program. The Essential Principles document is referenced in the draft STED document.

Four of the founding members of the GHTF are participating in the pilot program. They include the United States, Canada, Australia, and the European Union. Each of the participants will provide specific directions for implementing the pilot program within its jurisdiction.

The GHTF wants to assess the international utility of the draft STED document. Therefore, SG1 of the GHTF encourages manufacturers to prepare and submit, if submission is required, STEDs for the same device to as many of the four participating GHTF member countries as possible. SG1 also encourages manufacturers to try the draft STED format for different classes of devices that are candidates for the pilot program.

FDA intends to process premarket submissions in the draft GHTF harmonized format within statutory time limits and with review times comparable to other submissions for similar products. There will be no expedited review of submissions, unless the device merits such a process under current policies.

FDA plans to conduct the pilot program for 1 year. The pilot program will begin on the date of publication of the final FDA guidance document. FDA will assess how the pilot is proceeding during its course and may choose to decline receipt of additional submissions using the draft STED format in order to assess the initial experiences. At the end of the pilot, FDA and other GHTF participants will analyze the outcome to determine whether the draft STED document is a viable alternative to current premarket submission procedures, and if the program should be continued or expanded. FDA will post on its Web site a report of the outcome of the pilot program.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on one possible way to evaluate and apply GHTF recommendations related to premaket submissions to FDA. 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 applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document announcing the pilot is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive a copy of the draft guidance entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. 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 the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by September 24, 2001. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 13, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–18480 Filed 7–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–10024]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection; *Title of Information Collection:* Development of Survey Instrument for Special Populations; *Form No.:* HCFA–10024 (OMB# 0938–NEW); *Use:* Development of Survey Instrument for Special Populations; *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 2,160; *Total Annual Responses:* 2,160; *Total Annual Hours:* 498.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hca.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Alison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 27, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–18553 Filed 7–24–01; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: Proposed Project: U.S. Component of the 2001/2002 World Health Organization Study of Health Behavior in School Children (WHO–HBSC): New

The Office of Data and Information Management (ODIM), Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), will participate on behalf of the United States in the 2001/2002 WHO Study of Health Behavior in School Children. The information proposed for collection will be used by MCHB, HRSA, and the National Institutes of Health (NIH) to increase understanding of adolescent health to improve the quality of health programs and services. This cross-national research study will collect survey data to study adolescent health status and behaviors in relation to their social and supportive environment. Types of data will include measures of physical activity, body size, nutrition, social inequality, diversity, injury, violence, and perceptions of peers, school, and family as a supportive environment.

The estimated response burden is as follows:

Survey	Number of respondents	Responses per respondent	Hours per response	Total burden hour
Students	17,172	1	.75	12,879
Administrator	755	1	.25	189
School Staff	744	1	.5	372
Survey	18,671	.....	.....	13,440

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.