

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]

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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]

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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