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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Hospital and Personal Use 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: General Hospital and Personal Use 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 2, 1999, 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Martha T. O'Lone, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss possible revisions to the 1995 draft guidance entitled "Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices With Sharps Injury Prevention Features." The committee will also discuss the development of guidance for needle-free devices such as jet injectors intended for the delivery of drugs and biologics and the need for and content of educational programs to encourage the safe and effective use of these devices. Single copies of the 1995 draft guidance are available

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to the public by calling 1-800-899-0381 or 301-827-0111, and requesting Facts-on-Demand document number 934, or on the Internet using the World Wide Web (WWW) ‘‘<http://www.fda.gov/cdrh/ode/doc934.pdf>’’.

Procedure: On August 2, 1999, from 8:30 a.m. to 5 p.m., the meeting is 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 July 23, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. and between approximately 3:45 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those individuals desiring to make formal oral presentations should notify the contact person by July 23, 1999, 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 August 2, 1999, 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)) regarding pending issues and applications.

FDA regrets that it was unable to publish this notice 15 days prior to the August 2, 1999, General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

2).

Dated: July 16, 1999
July 16, 1999

Linda A. Suydam

Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jen Windsor

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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