

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery 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 and Plastic Surgery 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 24, 2006, from 8 a.m. to 5 p.m., and on August 25, 2006, from 9 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512519. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 24, 2006, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an injectable device intended for use in the correction of lipoatrophy of the face in HIV (human immunodeficiency virus) positive patients and a second PMA for the same device intended for use as a filler material to restore soft tissue facial contours such as nasolabial folds. On August 25, 2006, the committee will discuss and make recommendations on the reclassification, to Class II, of a Class III medical device: Cyanoacrylate tissue adhesive. Background information for this meeting, 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/panel> (click on “Upcoming CDRH Advisory Panel/Committee Meetings”). Material for the August 24 and 25 sessions will be posted on August 23, 2006.

Procedure: On August 24, 2006, from 8 a.m. to 5 p.m., and on August 25, 2006, from 9:30 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 on or before August 10, 2006. On August 24, 2006, oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m., approximately 11:45 a.m. and 12:15 p.m., approximately 1:45 p.m. and 2:15 p.m., and approximately 3:45 p.m. and 4:15 p.m. On August 25, 2006, oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before August 10, 2006.

Closed Committee Deliberations: On August 25, 2006, from 9 a.m. to 9:30 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 301-827-7291, 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: July 17, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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