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Certifier A. Corbin

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). The meeting will be open 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 November 21, 2003, from 8 a.m. to 5 p.m.

Location: Gaithersburg 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 12519. Please call the Information Line or access the Internet address of <http://www.fda.gov/cdrh/panelmtg.html> for up-to-date information on this meeting.

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Agenda: The committee will discuss, make recommendations, and vote on two premarket approval applications (PMAs) for injectable devices intended to restore soft tissue facial contours such as nasolabial folds. Background information for each PMA, 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/panelmtg.html>. The material for this meeting will be posted on November 20, 2003.

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 November 7, 2003. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:30 a.m., 11:30 a.m. and 11:45 a.m., 1:15 p.m. and 1:30 p.m., and 4 p.m. and 4:15 p.m. Time allotted for oral public presentations may be limited. Those desiring to make formal oral presentations should notify the contact person before November 7, 2003, 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.

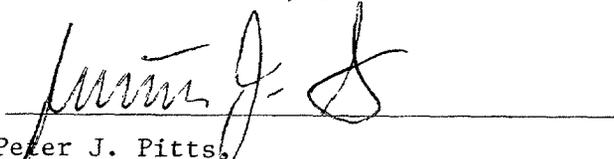
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 301-594-1283, ext. 113, 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: 10/16/03

October 16, 2003.



Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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