

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Display Date 6-28-02 @ 3:10

Publication Date 7-3-02

Certifier R. LEDESMA

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 July 8, 2002, from 1 p.m. to 5 p.m., and July 9, 2002, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Ballroom, 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.

*Agenda:* On July 8, 2002, the committee will discuss and make recommendations on the classification of a preamendment device, the silicone elastomer for scar management. The committee will also discuss and make recommendations on the reclassification of a transitional class III device, the absorbable hemostatic agent and dressing device intended for hemostasis during

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surgical procedures. On July 9, 2002, FDA and two manufacturers of approved saline inflatable breast implant devices will present postmarket information to the committee for their consideration. Background information for each day's topic, 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>. Material for the July 8, 2002, session will be posted on July 5, 2002; material for the July 9, 2002, session will be posted on July 8, 2002.

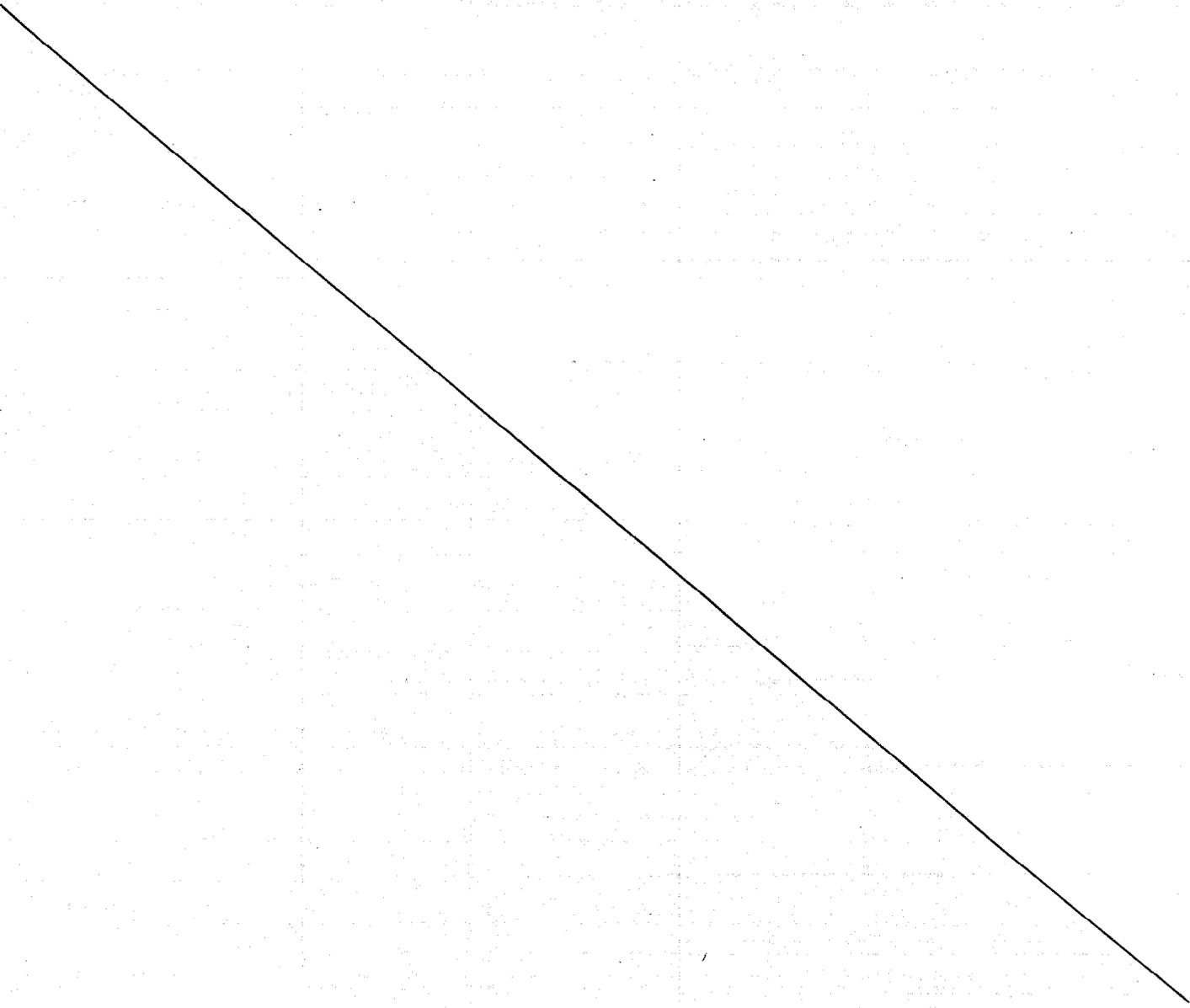
*Procedure:* On July 8, 2002, from 1:30 p.m. to 5 p.m., and on July 9, 2002, from 8 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 5, 2002. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:15 p.m. and 4 p.m. and 4:30 p.m. on July 8, 2002; and between approximately 8:30 a.m. and 10:30 a.m. on July 9, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by July 5, 2002, 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 July 8, 2002, from 1 p.m. to 1:30 p.m., the meeting will be closed to permit discussion and review of 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 301-594-1283, ext. 113, by July 5, 2002.

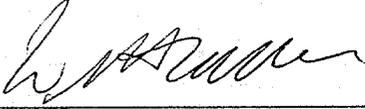
FDA regrets that it was unable to publish this notice 15 days prior to the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs 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: June 25, 2002  
June 25, 2002.



William K. Hubbard,  
Senior Associate Commissioner for Policy,  
Planning, and Legislation.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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