

of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| Standard No.   | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 9 <sup>2</sup> | 500                | 1                             | 500                    | 92                 | 46,000      |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>Includes the use of Forms FDA 3519 and 3520.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| Standard No.            | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|-------------------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 3,4, and 6 <sup>2</sup> | 500                  | 1                                  | 500                  | 5                      | 2,500       |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>The standards incorporate the best program management practices currently in use in the regulatory community. The recommended policies, procedures, and standard operating procedures contained in the various national standards are considered usual and customary management practices for State, local, and tribal agencies that regulate the retail segment of the food industry.

Dated: June 20, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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BILLING CODE 4160-01-S

## 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 July 17, 2001, 10 a.m. to 5 p.m.

*Location:* Hilton, Salons D and E, 620 Perry Pkwy., Gaithersburg, MD.

*Contact:* 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:* The committee will discuss, make recommendations, and vote on a premarket approval application for an interactive wound and burn dressing. Background information, including the agenda and questions for the committee, will be made available to the public on July 16, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

*Procedure:* On July 17, 2001, from 10:30 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 3, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 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.

*Closed Committee Deliberations:* On July 17, 2001, from 10 a.m. to 10:30 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 19, 2001.

**Bonnie Malkin,**

*Special Assistant to the Senior Associate Commissioner.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Anesthesiology and Respiratory Therapy 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:* Anesthesiology and Respiratory Therapy 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 16, 2001, 10 a.m. to 5 p.m.

*Location:* Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD.

*Contact:* Michael Bazaral, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8611, ext. 140, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the