

working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's guidance, requirements, and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) that requires outreach activities by Government agencies directed to small businesses.

The goal of this public workshop is to present information that will enable FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants) to better understand the regulations authorized by the Bioterrorism Act, and food defense guidance, especially in light of growing concerns about food defense. Information presented will be based on agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop include the following: (1) Food defense awareness, (2) ALERT: The Basics, (3) FDA actions on bioterrorism legislation (food supply), (4) food recalls, (5) crisis management, and other related topics. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of FDA regulations and guidance related to food defense and increase voluntary compliance and food defense awareness.

Dated: November 17, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Medical Devices Dispute Resolution 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:** Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

**Date and Time:** The meeting will be held on December 15, 2006, from 9 a.m. to 5 p.m.

**Location:** Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

**Contact Person:** Nancy Collazo-Braier, Office of the Center Director (HFZ-1), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3959,

[nancy.braier@fda.hhs.gov](mailto:nancy.braier@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014510232. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The committee will discuss, make recommendations, and vote regarding a scientific dispute between the agency and Acorn Corp. related to the approvability of a premarket approval application for the CorCap Cardiac Support Device for patients with dilated cardiomyopathy. Background information for the topic, including the attendee list, 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).

**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 on or before December 1, 2006. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and between approximately 1 p.m. and 1:30 p.m. on December 15, 2006. 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 December 1, 2006.

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 Ann Marie 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: November 17, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D-0451]

#### Guidance for Industry, Food and Drug Administration Staff, Eye Care Professionals, and Consumers; Decorative, Non-Corrective Contact Lenses; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers: Decorative, Non-Corrective Contact Lenses." This guidance document explains recently enacted legislation under which all contact lenses are deemed devices within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). All contact lenses, including decorative, non-corrective contact lenses, require premarket approval or clearance by FDA and may be dispensed only upon a lawful prescription order by an eye care professional. Although this guidance document is being immediately implemented, the agency welcomes comments at any time in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document