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.

[FR Doc. E6–19886 Filed 11–22–06; 8:45 am]

BILLING CODE 4160–01–S

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*, 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.

[FR Doc. E6–19895 Filed 11–22–06; 8:45 am]

BILLING CODE 4160–01–S

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

entitled ''Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers: Decorative, Non-Corrective Contact Lenses'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ernest N. Smith, Center for Devices and Radiological Health (HFZ–331), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance outlines FDA's current thinking on the application of device requirements to decorative, non-corrective contact lenses under the act. Decorative, non-corrective contact lenses are intended to change the normal appearance of the eye, such as to make brown eyes appear green. Although some of these products are covered by premarket notifications (510(k)s) filed under section 510(k) of the act (21 U.S.C. 360(k)) or premarket approval applications (PMAs) filed under section 515 of the act (21 U.S.C. 360e), other products have been sold without FDA premarket review and have been labeled for distribution without a prescription, proper fitting by a qualified eye care professional, and ongoing professional supervision.

Decorative, non-corrective contact lenses, like all other contact lenses, can cause a variety of eye injuries or conditions. For example, lens wear has been associated with corneal ulcers, conjunctivitis, and allergic reactions. Because of these risks, contact lenses, including decorative, non-corrective contact lenses, are not safe for use except under the supervision of a qualified eye care professional licensed by law to direct the use of such devices.

President Bush signed Public Law 109–96 into law on November 9, 2005. The legislation provides that ''[a]ll contact lenses shall be deemed to be devices under section 201(h) [of the act].'' The Senate report that accompanied the bill that became Public Law No. 109–96 explains the basis for this legislation. ''Some non-corrective, decorative contact lenses have not been approved by FDA and are sold without a prescription. Previously, FDA regulated these non-corrective contact lenses under its cosmetic authority in chapter VI of the [act]. These contact lenses present a public health threat. S. Rep. 109–110, at 2 (2005).''

As a result of this legislation, decorative contact lenses that are not the subject of an approved PMA, cleared 510(k), or exemption for investigational use are in violation of federal law. Specifically, such devices are adulterated under section 501(f)(1)(B) of the act (21 U.S.C. 351(f)(1)(B)) and misbranded under section 502(o) of the act (21 U.S.C. 352(o)). Adulterated and misbranded devices are subject to enforcement action under the act, including seizure, injunction, and civil money penalties. Manufacturers, distributors, and importers of non-corrective contact lenses that are not currently approved or cleared by FDA should cease distribution of the devices and submit the appropriate application or submission to FDA for approval or clearance if they wish to distribute non-corrective contact lenses. Guidance for 510(k) submissions and PMA applications for contact lenses is available at *http://www.fda.gov/cdrh/devadvice/3122.html*. Non-corrective contact lenses are also subject to general controls, including the Quality System regulation (QS regulation, part 820 (21 CFR part 820)).

FDA is implementing this guidance document immediately because prior public participation is not feasible or appropriate due to the need to provide guidance to implement Public Law 109-96, which was effective upon enactment on November 9, 2005.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP regulation (21 CFR 10.115). The guidance represents the agency's current thinking on decorative, non-corrective contact lenses regulated as devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Decorative, Non-Corrective Contact Lenses'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1613 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 820 have been approved under OMB control number 0910–0073, the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–19887 Filed 11–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0481]

Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by Small Children; Recommended Maximum Level and Enforcement Policy, Availability; and Supporting Document: Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently By Small Children; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by Small Children; Recommended Maximum level and Enforcement Policy,'' and a supporting document entitled ''Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently By Small Children.'' The guidance provides a maximum recommended lead level in candy likely to be consumed frequently by small children. FDA considers the recommended maximum level to be protective of human health and to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients. The guidance states FDA's commitment to take enforcement action against candy containing lead at levels that may pose a health risk. These two documents are intended to assist candy manufacturers in achieving reduced lead levels in their products consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practicably be obtained.

DATES: The guidance and supporting documents are final upon the date of publication. However, you may submit written or electronic comments concerning the guidance and/or supporting document any time.

ADDRESSES: Submit written requests for single copies of the guidance and/or supporting document to the Office of Plant and Dairy Foods (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments concerning the guidance and/or supporting document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance and supporting document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2022, FAX 301–436–2651, or e-mail: *michael.kashtock@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 27, 2005 (70 FR 76462), FDA made available a draft guidance for industry entitled ''Lead in Candy Likely to Be Consumed Frequently by Small Children; Recommended Maximum Level and Enforcement Policy'' and a draft supporting document entitled ''Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently By Small Children'' and gave interested parties an opportunity to submit comments by March 13, 2006. The agency considered received comments as it finalized this guidance and supporting document.

This guidance provides a recommended maximum lead level in candy likely to be consumed frequently by small children. FDA considers the maximum recommended level to be protective of human health and to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients. In response to comments on the draft guidance, this guidance clarifies FDA's commitment to take enforcement action against candy containing lead at levels that may pose a health risk. FDA notes that it is rescinding previous guidance provided in a 1995 letter to the industry regarding an enforcement level for lead in candy because the level cited in the 1995 letter is no longer regarded as consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained. In addition, this guidance reiterates FDA's enforcement policy toward the use of lead based ink on candy wrappers as stated in the 1995 letter to the industry.

FDA also is announcing the availability of a supporting document entitled ''Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently by Small Children.'' The supporting document provides additional background and rationale for the recommended maximum level. These two documents are intended to assist candy manufacturers in achieving reduced lead levels in their products consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents FDA's current thinking on lead levels in candy that are achievable with the use of good manufacturing practices in the production of candy and candy ingredients and that also provide for the protection of human health. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**). If you cannot identify the appropriate FDA staff, call the telephone number listed in the title page of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic