

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: 45 CFR 1304 Head Start Program Performance Standards.

OMB No. 0970-0148.

Description: Head Start Program Performance Standards require Head Start and Early Head Start Programs and Delegate Agencies to maintain program records. The Administration for Children and Families, Office of Head Start, is proposing to renew, without changes, the authority to require certain record keeping in all programs as provided for in 45 CFR 1304 Head Start

Program Performance Standards. These standards prescribe the services that Head Start and Early Head Start programs provide to enrolled children and their families.

Respondents: Head Start and Early Head Start grantees and delegate agencies.

ANNUAL BURDEN ESTIMATES

	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Instrument	2,590	16	41.8	1,732,192

Estimated Total Annual Burden Hours:

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 17, 2006.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0453]

Food Defense Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in co-sponsorship with the Risk Management Small Business Development Center (RMSBDC), is announcing a public workshop entitled "Food Defense Workshop." This public workshop is intended to provide information about food defense, the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and other related subjects to FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants).

Date and Time: This public workshop will be held on March 29, 2007, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hoblitzelle Auditorium at the Bill Priest Campus of El Centro College, 1402 Corinth St., Dallas, TX 75215.

Contact: David Arvelo, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, Suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, or e-mail: david.arvelo@fda.hhs.gov.

Registration: Registration by March 15, 2007, is encouraged. The RMSBDC has a \$20 registration fee to cover the cost of facilities and refreshments.

Please submit your registration as soon as possible. Those accepted into the workshop will receive confirmation. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$25, payable to RMSBDC. If you need special accommodations due to a disability, please contact David Arvelo (see the *Contact* section of this document) at least 7 days in advance.

Registration Form Instructions: To register, please complete the RMSBDC registration form and submit along with payment to RMSBDC, Attn: Saira Roberts, 1402 Corinth St., Dallas, TX 75215. You may fax the completed registration form to RMSBDC at 214-860-5867. To obtain a copy of the registration form, please call RMSBDC at 214-860-5887 or 214-860-5849. The registration form is also available online at <http://www.ntsfdc.org/>.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Workshop handouts may be requested through the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food defense inquiries from FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants) originating from the area covered by the FDA Dallas District Office. The SWRO is presenting this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include

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]

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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, 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]

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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