

Dated: January 25, 2007.

Robert Sargis,

Reports Clearance Officer.

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BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0239]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infectious Disease in Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Infectious Disease in Xenotransplantation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 31, 2006 (71 FR 63768), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0456. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-1550 Filed 1-31-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0408]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is reannouncing the invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this notice is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit written or electronic requests for participation in this program by March 5, 2007. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address of the site you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, you should submit a request to participate in the program to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to <http://www.fda.gov/dockets/ecomments>.

If your biologics facility responded to the previous RSVP notice announced in the **Federal Register** of April 11, 2006 (71 FR 18340), and your facility wishes to continue to be considered for this year's program, please notify CBER of your continued interest by sending an e-mail to matt@cber.fda.gov.

FOR FURTHER INFORMATION CONTACT:

Lonnie Warren-Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, e-mail: matt@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and timely delivery of biological products to patients. To support this primary goal, CBER has initiated various training and development programs to promote high performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to improve: (1) Its understanding of current industry practices, and regulatory impacts and needs; and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005, and through these annual notices, is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest, as well as encouraging new interested parties to apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including, for example, blood and tissue establishments. The visits may include packaging facilities, quality control and pathology/toxicology laboratories, and regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

All travel expenses associated with the site visits will be the responsibility of CBER; therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with CBER or another agency for which we have a memorandum of understanding.

Dated: January 22, 2007.
Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. E7-1576 Filed 1-31-07; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

University of Arkansas/Food and Drug Administration Food Labeling 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, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas (UA), is announcing a public workshop entitled "UA/FDA Food Labeling Workshop." This public workshop is intended to

provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on April 10, 2007, from 8 a.m. to 5 p.m., and on April 11, 2007, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Continuing Education Center, 2 East Center St., Fayetteville, AR (located downtown).

Contact: David Arvelo, Small Business Representative, 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.

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479-575-4221, FAX: 479-575-2165, or e-mail: seideman@uark.edu.

Registration: You are encouraged to register by March 23, 2007. The

University of Arkansas has a \$150 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. 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 \$200 payable to: "The University of Arkansas." If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the following form and submit along with a check or money order for \$150 payable to the "The University of Arkansas." Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

UNIVERSITY OF ARKANSAS/FOOD AND DRUG ADMINISTRATION FOOD LABELING WORKSHOP REGISTRATION FORM

Name: _____

Affiliation: _____

Mailing Address: _____

City/State/Zip Code: _____

Phone: _____

Fax: _____

E-mail: _____

Special Accommodations Required: _____

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested at cost 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 labeling inquiries from small food manufacturers and startups originating

from the area covered by the FDA Dallas District Office. The SWR SBR presents these workshops 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 SBR 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 requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on agency position as