

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 23, 2010, 5:30 p.m. to 6 p.m. The River Inn, 924 25th Street, NW., Washington, DC 20037 which was published in the **Federal Register** on July 15, 2010, 75 FR 41212.

The meeting will be held August 6, 2010. The meeting time and location remain the same. The meeting is closed to the public.

Dated: July 19, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-18053 Filed 7-22-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Neuroscience.

Date: August 10, 2010.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol Hamelink, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 19, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-18052 Filed 7-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the AHRQ Grants for Health Services Research Dissertation Program (R36) applications are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: AHRQ Grants for Health Services Research Dissertation Program (R36) applications.

Dates: August 12, 2010 (Open on August 12 from 10 a.m. to 10:15 a.m. and closed for the remainder of the meeting).

Place: Agency for Healthcare Research and Quality, John Eisenberg Bldg, 540 Gaither Road, Conference Room TBD, Rockville, MD 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or

minutes of the nonconfidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427-1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: July 13, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010-17798 Filed 7-22-10; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0371]

Voluntary Registration by Authorized Officials of Non-Covered Retail Food Establishments and Vending Machine Operators Electing To Be Subject to the Menu and Vending Machine Labeling Requirements Established by the Patient Protection and Affordable Care Act of 2010

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: Section 4205 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) established requirements for nutrition labeling of standard menu items for restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items (hereinafter "chain retail food establishments"), and for certain foods sold in vending machines operated by an operator that owns or operates 20 or more vending machines (hereinafter "chain vending machine operators"). Under the Affordable Care Act, retail food establishments and vending machine operators not covered by section 4205 of the Affordable Care Act may elect to become subject to its requirements by registering biannually with FDA. Congress required that, within 120 days of enactment of the Affordable Care Act (March 23, 2010), FDA issue a **Federal Register** notice specifying the terms and conditions for implementation of voluntary registration, pending promulgation of regulations. FDA is issuing this notice to assist restaurants and similar retail food establishments and vending machine

operators that are not subject to the menu labeling requirements of section 4205 of the Affordable Care Act, but choose to register to become subject to them, in voluntarily registering with FDA, pending promulgation of regulations.

DATES: Submit electronic or written comments by October 21, 2010.

ADDRESSES: Submit electronic comments on the notice to <http://www.regulations.gov>. Submit written comments on the notice to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen Lewis, Center for Food Safety and Applied Nutrition (HFS-608), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2148.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4205 of the Affordable Care Act (Public Law 111-148) requires restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items (hereinafter “chain retail food establishments”) to disclose specific nutrition information about certain food items offered for sale. Section 4205 also requires that calorie information be disclosed for certain food articles sold in vending machines operated by an operator that owns or operates 20 or more vending machines (hereinafter “chain vending machine operators”). For chain retail food establishments, as that term is used in this notice, and for vending machines regardless of how many vending machines the operator owns or operates, section 4205 preempts State and local nutrition labeling laws unless they are “identical” to the requirements imposed by section 4205.

This notice is to explain how retail food establishments and vending machine operators not otherwise subject to the provisions of section 4205 may voluntarily elect to become subject to them. In future actions, FDA will provide information to the public and the regulated communities about the new requirements in section 4205.

II. Terms and Conditions for Implementation of Voluntary Registration

A. Why is the section 4205 voluntary registration program being established?

Congress provided in section 4205 of the Affordable Care Act that restaurants and similar retail food establishments and vending machine operators not covered by section 4205 may elect to become subject to its requirements by registering biannually (every other year) with FDA. Congress required FDA to publish a notice in the **Federal Register**, within 120 days of enactment of the Affordable Care Act (March 23, 2010), specifying the terms and conditions for implementation of voluntary registration, pending promulgation of regulations.

B. What is the effect of voluntary registration under section 4205?

Unlike chain retail food establishments (as that term is used in this document), restaurants and similar retail food establishments that are not covered by section 4205 can still be regulated under State and local nutrition labeling laws that are not “identical to” the Federal requirements. If these restaurants and similar retail food establishments voluntarily register, they will no longer be subject to State or local nutrition labeling requirements unless those requirements are identical to Federal requirements. Vending machine operators are in a different position; under section 4205, no State or locality may have a requirement concerning vending machines that is not “identical to” the Federal requirements, regardless of how many vending machines the operator owns or operates (section 403A(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(4))). Therefore, whether a vending machine operator has or has not registered, it cannot be subject to State or local nutrition labeling requirements that are not identical to the Federal requirements. However, Congress expressly provided in section 4205 that vending machine operators not subject to the requirements of the law might elect to be subject to them by registering with FDA.

C. Who must register?

No restaurant or similar retail food establishment, or vending machine operator, is required to register under section 4205. However, if a restaurant or similar retail food establishment, or vending machine operator not otherwise subject to the provisions of section 4205 elects to be subject to the Federal

requirements of that section, registration must be by an authorized official.

D. Who is an authorized official of a restaurant or similar retail food establishment, or of a vending machine operator?

The authorized official of a restaurant or similar retail food establishment or of a vending machine operator may be the owner, operator, agent in charge, or any other person authorized by the restaurant or similar retail food establishment or vending machine operator to register the restaurant, similar retail food establishment and/or vending machine operator with FDA under section 4205.

E. Should a separate registration be submitted for every location at which a restaurant or similar retail food establishment is operating?

Section 4205 applies to restaurants or similar retail food establishments that are part of a chain with 20 or more locations, doing business under the same name (regardless of the type of ownership of the locations, e.g., individual franchisees), and offering for sale substantially the same menu items.

Restaurants, similar retail food establishments, and operators of vending machines doing business at one or more but fewer than 20 locations can register to be subject to section 4205. If a restaurant or similar retail food establishment has more than one but fewer than 20 locations that are doing business under the same name, regardless of the type of ownership of the locations, which offer for sale substantially the same menu items, an authorized official may register multiple locations within the group of restaurants or retail food establishments on a single registration form. Alternatively, an authorized official of an individual restaurant or retail food establishment may register just that restaurant or retail food establishment.

F. When will the registration process begin and how often must the authorized official register?

FDA will accept registrations beginning July 21, 2010, on a continuous basis. The authorized official must register every other year with FDA, and the registration will automatically expire if not renewed.

G. What information must be provided for the registration of restaurants or similar retail food establishments?

Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information:

- The name, address, phone number, e-mail address, and contact information for the authorized official;

- The name, address, and e-mail address of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;

- All trade names the restaurant or similar retail food establishment uses;
- Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

- Certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 4205.

As described in section II.I of this document, FDA has created and made available at a Web site, <http://www.fda.gov/menulabeling>, a form that contains fields requesting this information. Registrants must use this form to ensure that complete information is submitted.

H. What information must be provided for the registration of vending machine operators?

Authorized officials for vending machine operators must provide FDA with the following information:

- The name, address, phone number, e-mail address, and contact information for the vending machine operator;
- The address of each vending machine owned or operated by the vending machine operator, and the name and contact information, including e-mail address, of the location in which each vending machine is located;

- Preferred mailing address (if different from location address), for purposes of receiving correspondence; and

- Certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 4205.

As described in section II.I of this document, FDA has created and made available at a Web site, <http://www.fda.gov/menulabeling>, a form that contains fields requesting this information. Registrants must use this form to ensure that complete information is submitted.

I. How do authorized officials of restaurants, similar retail food establishments, and vending machine operators register?

Authorized officials of restaurants, similar retail food establishments, and/or vending machine operators electing to be subject to the section 4205 requirements can register by visiting <http://www.fda.gov/menulabeling>. FDA prefers that the information be submitted by e-mail by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by e-mail to [http://menulawregistration@fda.hhs.gov](mailto:menulawregistration@fda.hhs.gov). If e-mail is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and send it to FDA either by faxing the completed form to 301-436-2804 or mailing it to the Center for Food Safety and Applied Nutrition, Compliance Information Branch (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

J. Will each registrant receive a confirmation of the registration?

Initially, FDA will not provide automatic confirmation of registrations. We recommend that registrants save a copy of the completed form and evidence that it has been transmitted to FDA electronically, by fax, or by mail.

K. What does it mean to be "registered"?

Pending promulgation of regulations, FDA considers that an authorized official of any restaurant or similar retail food establishment, or of any vending machine operator, that completely and accurately provides the information described in response to sections II.G and II.H of this document, has registered the restaurant or similar retail food establishment, or vending machine operator.

L. How will future changes to the voluntary registration program be announced?

FDA is required to propose regulations implementing the provisions of section 4205. We intend to include in those proposed regulations further specifications about the voluntary biannual registration of restaurants, similar retail food establishments, and vending machine operators that are not otherwise subject to the requirements of section 4205.

III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in the Federal Food, Drug and Cosmetic Act and established by section

4205 of the Affordable Care Act. 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 section 4205 of the Affordable Care Act have been approved under OMB control number 0910-0664.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this notice. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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: July 20, 2010.

David Dorsey,
Acting Deputy Commissioner for Policy,
Planning and Budget.

[FR Doc. 2010-18123 Filed 7-21-10; 11:15 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Transport of Laboratory Personnel Potentially Exposed to Infectious Agents From Fort Detrick, Frederick, MD to the National Institutes of Health Clinical Research Center, Bethesda, MD; (NIH Transportation EIS); Record of Decision

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services (DHHS), has decided, after completion of a Final NIH Transportation EIS and a thorough consideration of the public comments on the Draft NIH Transportation EIS, to implement the Proposed Action, which was identified as the Preferred Alternative in both the Draft EIS and the FEIS. This action involves the transport of laboratory personnel suspected of having potential occupational exposure to infectious agents under study at the NIBC located at Fort Detrick, Maryland, to the Special Clinical Studies Unit at the NIH Bethesda, Maryland Campus for observation and, if necessary, treatment.

FOR FURTHER INFORMATION CONTACT:
Valerie Nottingham, Chief of
Environmental Quality Branch, DEP,