

confidential trade secrets or commercial property such as patentable materials, 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:* National Institute on Drug Abuse Special Emphasis Panel; R25 Review (PAR-07-221).

*Date:* April 29, 2010.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

*Contact Person:* Jose F. Ruiz, Ph.D., Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, 6101 Executive Blvd., Rm. 213, MSC 8401, Bethesda, MD 20892, 301-451-3086, [ruizjf@nida.nih.gov](mailto:ruizjf@nida.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 16, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-9301 Filed 4-21-10; 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 Meetings

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 meetings.

The meetings 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, Member Conflict: SAT and BTSS Study Sections.

*Date:* May 14, 2010.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)

*Contact Person:* Roberto J. Matus, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892. (301) 435-2204. [matusr@csr.nih.gov](mailto:matusr@csr.nih.gov).

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Bioengineering, Technology and Surgical Sciences Study Section.

*Date:* May 17-18, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Khalid Masood, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892. 301-435-2392. [masoodk@csr.nih.gov](mailto:masoodk@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: April 16, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-9314 Filed 4-21-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Food Labeling; 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), Dallas District Office (DALDO), in collaboration with Oklahoma State University (OSU), Robert M. Kerr Food & Agricultural Products Center (FAPC), is announcing a public workshop entitled "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:* The public workshop will be held on May 17 and 18, 2010, from 8 a.m. to 5 p.m.

*Location:* The public workshop will be held at FAPC, OSU, 148 FAPC, Stillwater, OK 74078-6055.

*Contact:* David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, or email: [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

For information on accommodation options, contact conference coordinators Karen Smith or Andrea Graves at FAPC, OSU, 148 FAPC, Stillwater, OK 74078-6055, 405-744-6071, FAX: 405-744-6313, or email:

[karenl.smith@okstate.edu](mailto:karenl.smith@okstate.edu) or [andrea.graves@okstate.edu](mailto:andrea.graves@okstate.edu).

*Registration:* You are encouraged to register by May 3, 2010. The workshop has a \$400 registration fee to cover the cost of facilities, materials, lunch, and breaks. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop 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 \$400 payable to FAPC. If you need special accommodations due to a disability, please contact Karen Smith (see *Contact*) at least 7 days in advance. There are no registration fees for FDA employees. More information is also available online at <http://www.fapc.biz/foodlabeling.html>. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

*Registration form instructions:* To register, please complete the online registration form at <http://www.fapc.biz/forms/foodlabeling.htm>.

*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. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** The 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 DALDO. DALDO presents the 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 ORA's Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. The 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 the 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 articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include the following: (1) Mandatory label elements, (2) the Food Allergen Labeling and Consumer Protection Act of 2004, (3) nutrition labeling requirements, (4) health and nutrition claims, and (5) special labeling issues such as exemptions. FDA expects that participation in the public workshop will provide regulated industry with greater understanding of the agency's regulatory and policy perspectives on food labeling and increase voluntary compliance with labeling requirements.

Dated: April 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-9288 Filed 4-21-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

**AGENCY:** National Institutes of Health (NIH), PHS, DHHS.

**ACTION:** Notice of a proposed action under the *NIH Guidelines*.

**SUMMARY:** In March 2009, the NIH Office of Biotechnology Activities (OBA) published a proposal to revise the *NIH Guidelines for Research with Recombinant DNA Molecules (NIH Guidelines)* to address biosafety for research with synthetic nucleic acids (74 FR 9411). The proposal included amending the scope of the *NIH Guidelines* to specifically encompass research with synthetic nucleic acids. In addition, in consultation with the NIH Recombinant DNA Advisory Committee (RAC), OBA proposed changes to several other sections of the *NIH Guidelines*, including Section III-E-1, which addresses containment for work with partial viral genomes in tissue culture. In response to public comments received on the proposed changes to Section III-E-1 (74 FR 9411), a substantively revised proposal has been developed and OBA is seeking additional comment on this Section. After comments are received on this revised proposal and reviewed at a public RAC meeting, OBA will publish a final notice of action for Section III-E-1 and the other proposed revisions included in the March 2009 **Federal Register** (FR) notice.

Section III-E-1 of the *NIH Guidelines* allows investigators to proceed with certain tissue culture experiments under Biosafety Level 1 (BL1) containment upon registration of the experiment with an Institutional Biosafety Committee (IBC). Under the current *NIH Guidelines*, an investigator can initiate an experiment in tissue culture at BL1 containment if no more than two-thirds of the full viral genome is present and the preparation is free of "helper virus," *i.e.*, a virus that could be used to rescue infectious, replication competent virus. Experiments performed under III-E-1 apply to viruses in all Risk Groups except for *Variola major* or *Variola minor* (smallpox, alastrim, whitepox—Section III-D-3-d). In the March 2009 FR, OBA proposed to reduce the portion of the genome that could be present to less than one-half due to concerns that synthetic techniques might lead to functional viruses that contained less than two-thirds of a full viral genome. Based on the comments received in response to the FR notice of March 2009, discussions at a public stakeholder meeting on June 23, 2009 [see URL: [http://oba.od.nih.gov/rdna\\_rac/rac\\_pub\\_con.html](http://oba.od.nih.gov/rdna_rac/rac_pub_con.html)] and further consultations with the RAC, OBA is amending its original proposal to include additional criteria for lowering containment. These new criteria will

allow containment to be lowered to BL1 for experiments performed in tissue culture when more than one-half of the genome is present, as long as the function of critical viral genes is sufficiently understood to allow the determination that a complete deletion in one or more essential viral capsid, envelope or polymerase genes required for cell-to-cell transmission of viral nucleic acids will effectively impair viral replication. The deletion(s) must be designed such that it is not possible to rescue critical functions through homologous recombination. If such a deletion is not feasible or practical, an experiment may also be included under Section III-E-1 if the recombinant viral genome contains less than one-half of the full viral genome. As explained in the March 2009 proposal, this latter criterion would only apply to Risk Group (RG) 3 and RG4 viruses (*see NIH Guidelines* Appendix B) as the *NIH Guidelines* currently exempt research with less than one-half of the genome of RG1 or RG2 virus (*NIH Guidelines* Appendices C-I and C-I-A).

In light of this substantive change from the original proposal, OBA is seeking further comment on this revised proposal.

**DATES:** The public is encouraged to submit written comments on this proposed action. Comments may be submitted to OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION**. All comments should be submitted by June 1, 2010. All written comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985, weekdays between the hours of 8:30 a.m. and 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** If you have questions, or require additional information about these proposed changes, please contact OBA by e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov), or telephone at 301-496-9838. Comments can be submitted to the same e-mail address or by fax to 301-496-9839 or mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985. Background information may be obtained by contacting NIH OBA by e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** *Background:* Section of III-E of the *NIH Guidelines* addresses experiments for which IBC notification is required at the time the research is initiated. Experiments covered in this section of