

study goals are to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to graphic warning labels; (2) determine whether consumer responses to graphic warning labels differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate

the relative effectiveness of various graphic images associated with each of the nine warning statements specified in the Tobacco Control Act for achieving each of the communication goals. The information collected from the study is necessary to inform the Agency's efforts to implement the mandatory graphic

warnings required by the Tobacco Control Act.

The experimental study data will be collected from participants of an Internet panel of approximately 43,000 people. Participation in the experimental study is voluntary.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest .....	60	1	60	0.5	30
Screeners .....	15,000	1	15,000	0.016	240
Experimental Survey .....	5,400	1	5,400	0.5	2,700
Total .....					2,970

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 15,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.016 hours), for a total of 240 hours. Fifty-four hundred respondents will complete the full study, estimated to last 30 minutes, for a total of 2,700 hours. The total estimated burden is 2,970 hours (30 hours plus 240 hours plus 2,700 hours).

Dated: March 21, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Development of Animal Models of Pregnancy To Address Medical Countermeasures for Influenza in the "At Risk" Population of Pregnant Women: Influenza as a Case Study; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research and FDA's National Center for Toxicological Research are announcing

a 2-day public workshop entitled "Development of Animal Models of Pregnancy To Address Medical Countermeasures for Influenza in the 'At Risk' Population of Pregnant Women: Influenza as a Case Study." The purpose of this workshop is to provide a forum to carefully consider scientific issues related to selecting animal models for use in evaluating medical influenza countermeasures (anti-influenza drugs) that may be given during pregnancy. Specifically, this workshop will address experimental design issues in selecting the most appropriate animal model that mimics human pregnancy. The goal is to use this model to evaluate how pregnancy changes the pharmacokinetics of anti-influenza drugs in animals and compare those changes to the changes that are known to occur in human pregnancy. The data obtained from using this model may enhance the knowledge base needed to extrapolate the effects of pregnancy on other medical countermeasures.

**DATES:** *Date and Time:* The public workshop will be held on April 30, 2012, from 8:30 a.m. to 5 p.m., and on May 1, 2012, from 8:30 a.m. to 5 p.m.

*Location:* The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Central Shared Use (CSU) Bldg. 2, rm. 2047, Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed, a visitor badge will be issued, and an escort will be provided to the meeting room. Government-issued identification will be needed. For additional information on parking and

security, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

*Contact Person:* For questions about the workshop, please contact Cindy de Sales, [cindy@tepgevents.com](mailto:cindy@tepgevents.com), 240-316-3207.

*Registration:* There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at <http://fda.contractmeetings.com> before April 16, 2012. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. For those without Internet access, please contact Cindy de Sales (see *Contact Person*) to register. Onsite registration is not available.

If you need special accommodations due to a disability, please contact Cindy de Sales (see *Contact Person*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** During seasonal and pandemic influenza outbreaks, pregnant women generally have greater morbidity and mortality than other adults. The data from the 2009 H1N1 influenza pandemic suggested that pregnant women were at increased risk for medical complications. There is limited information regarding the efficacy, pharmacokinetics, optimal dosing, and side effects of anti-influenza drugs that may need to be used during pregnancy. The same is true for most drugs to treat diseases due to other infectious agents.

The anti-influenza drugs have been selected for further study because the influenza virus can infect pregnant women, and oseltamivir, an anti-

influenza drug of the neurominidase inhibitor class, was recommended for treatment of and/or for prophylaxis in pregnant women during the 2009 H1N1 influenza pandemic. In addition, two clinical studies conducted in pregnant women provide some pharmacokinetic data for oseltamivir.

This workshop is open to all interested parties. The target audience includes professionals in the scientific community interested in discussing the challenges of evaluating medical countermeasures for effective and safe use during pregnancy.

The workshop will include plenary and breakout sessions on the scientific challenges in the development of animal models of pregnancy that can be used to address the safety and efficacy of medical countermeasures. Broad topics to be covered in the plenary sessions include: (1) The physiology and pharmacology of pregnancy as it relates to model development; (2) the role of animal models in evaluating medical countermeasures, including influenza therapies, that may be used during pregnancy; and (3) experimental design considerations. Topics of the breakout sessions will include: (1) Animal model selection, (2) design of the pharmacokinetic studies, and (3) additional issues in experimental design.

Background information on the public workshop, registration information, the agenda, and other relevant information will be posted, as it becomes available, on the registration Web site at <http://fda.contractmeetings.com>.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: March 21, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-7290 Filed 3-26-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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:** National Advisory Environmental Health Sciences Council.

**Date:** May 22–23, 2012.

**Open:** May 22, 2012, 8:30 a.m. to 5 p.m.

**Agenda:** Discussion of program policies and issues.

**Place:** Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

**Open:** May 23, 2012, 8:30 a.m. to 9:30 a.m.

**Agenda:** Discussion of program policies and issues.

**Place:** Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

**Closed:** May 23, 2012, 9:45 a.m. to 12:30 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

**Contact Person:** Gwen W. Collman, Ph.D., Director, Division of Extramural Research & Training, National Institutes of Health, Nat. Inst. of Environmental Health Sciences, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541-4980, [collman@niehs.nih.gov](mailto:collman@niehs.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when

applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: [www.niehs.nih.gov/dert/c-agenda.htm](http://www.niehs.nih.gov/dert/c-agenda.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 20, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-7333 Filed 3-26-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; 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:** National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Conference Grants.

**Date:** April 19–20, 2012.

**Time:** 11 a.m. to 3 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:** Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892-7924, 301-435-0287, [carolko@mail.nih.gov](mailto:carolko@mail.nih.gov).

**Name of Committee:** National Heart, Lung, and Blood Institute Special Emphasis Panel; Ancillary Studies in Clinical Trials.