

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Respondents/form name                                          | Number of respondents | Number of responses per respondent | Average burden per response (hours) | Total burden (in hrs) |
|----------------------------------------------------------------|-----------------------|------------------------------------|-------------------------------------|-----------------------|
| Phase II: College Student Survey .....                         | 200                   | 1                                  | 2                                   | 400                   |
| Phase II: Late Adolescent Survey .....                         | 50                    | 1                                  | 2                                   | 100                   |
| Phase II: Early Adolescent Survey .....                        | 50                    | 1                                  | 1                                   | 50                    |
| Phase III: Follow-up Focus Group of Prevention Educators ..... | 20                    | 1                                  | 3                                   | 60                    |
| Phase III: Follow-up Focus Group of College Students .....     | 10                    | 1                                  | 2.5                                 | 25                    |
| Phase III: Follow-up Focus Group of Late Adolescents .....     | 10                    | 1                                  | 3                                   | 30                    |
| Phase III: Follow-up Focus Group of Early Adolescents .....    | 10                    | 1                                  | 3                                   | 30                    |
| Phase IV: Confirmatory Survey of College Students .....        | 500                   | 1                                  | 2                                   | 1000                  |
| Phase IV: Confirmatory Survey of Late Adolescents .....        | 200                   | 1                                  | 2                                   | 400                   |
| Phase IV: Confirmatory Survey of Early Adolescents .....       | 200                   | 1                                  | 1                                   | 200                   |
| <b>Total</b> .....                                             |                       |                                    |                                     | <b>2410</b>           |

Dated: June 23, 2010.

**Carol Walker,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2010-15780 Filed 6-28-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0094]

#### **Draft Guidance: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (#209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” This draft guidance is intended to inform the public of FDA’s current thinking on the use of medically important antimicrobial drugs in food-producing animals.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 30, 2010.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-

addressed adhesive label to assist that office in processing your requests. Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD) (HFM-40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or e-mail: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

#### **FOR FURTHER INFORMATION CONTACT:**

William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9084, e-mail: [william.flynn@fda.hhs.gov](mailto:william.flynn@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance (#209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” Antimicrobial drugs have been widely used in human and veterinary medicine for more than 50 years, with tremendous benefits to both human and animal health. The development of resistance to this important class of drugs, and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious public health threat. Misuse and overuse of antimicrobial drugs creates selective evolutionary pressure that enables antimicrobial resistant bacteria to increase in numbers more rapidly

than antimicrobial susceptible bacteria and thus increases the opportunity for individuals to become infected by resistant bacteria. Because antimicrobial drug use contributes to the emergence of drug resistant organisms, these important drugs must be used judiciously in both animal and human medicine to slow the development of resistance. Using these drugs judiciously means that unnecessary or inappropriate use should be avoided. Although efforts to assure judicious use should be directed at all uses of antimicrobial drugs, the focus of this document is on the use of medically important antimicrobial drugs in food-producing animals.

In regard to the use of antimicrobial drugs in animals, concerns have been raised by the public and components of the scientific and public health communities that a significant contributing factor to antimicrobial resistance is the use of medically important antimicrobial drugs in food-producing animals for production or growth-enhancing purposes. This document summarizes some of the key scientific reports on the use of antimicrobial drugs in animal agriculture and outlines FDA’s current thinking on strategies for assuring that medically important antimicrobial drugs are used judiciously in food-producing animals in order to help minimize antimicrobial resistance development.

Based on a consideration of the available scientific information, FDA is making a number of recommendations regarding the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. These recommendations include phasing in such measures as follows: (1) Limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring

animal health and (2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health. Collaboration involving both the public and animal health communities on the development and implementation of such strategies is needed to assure that the public health is protected while also assuring that the health needs of animals are addressed.

This draft guidance discusses FDA's general public health concerns regarding the potential impact of certain uses of medically important antimicrobial drugs in food-producing animals on the development of antimicrobial resistance, and provides two broad recommendations regarding such use. The agency intends to issue further guidance in the near future to provide more specific information on approaches for implementing the recommendations outlined in this draft guidance.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

## IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

Dated: June 10, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-15289 Filed 6-28-10; 8:45 am]

**BILLING CODE 4160-01-S**

## 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: Neuroendocrinology and Fetal Alcohol.

*Date:* July 13, 2010.

*Time:* 1 p.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:* Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892, 301-435-1119, [mselmanoff@csr.nih.gov](mailto:mselmanoff@csr.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.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Language and Communication.

*Date:* July 14, 2010.

*Time:* 2 p.m. to 4 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:* Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301-435-2309, [pluded@csr.nih.gov](mailto:pluded@csr.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.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; ARRA: Member Conflict in Cognition and Perception Competitive Revisions.

*Date:* July 14, 2010.

*Time:* 12 p.m. to 2 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:* Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301-435-2309, [pluded@csr.nih.gov](mailto:pluded@csr.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.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Drug Development and Therapeutics.

*Date:* July 19-20, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Hungyi Shau, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, 301-357-9099, [Hungyi.Shau@nih.gov](mailto:Hungyi.Shau@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: June 23, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-15784 Filed 6-28-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, 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