

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1994-D-0007]

Guidance for Industry: Studies To Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is considering revising the guidance entitled "Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds," and is seeking comments on this guidance before revisions are made.

DATES: Submit electronic or written comments by January 13, 2014.

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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Xin Li, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6863, xin.li@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

One of the key objectives of Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds (GFI #80) is to help sponsors design efficacy studies to support the submission of Food Additive Petitions (FAPs) for food additives intended for anti-Salmonella use in food for animals. We would like to revise GFI #80 because science, technology, and FDA policy have changed since this guidance was last revised.

GFI #80 currently addresses only chemical food additives intended to maintain feeds or feed ingredients Salmonella-negative. We intend to

expand the scope of this guidance to address other categories of food additives beyond chemical food additives, and to cover all food for animals, including pet food.

Before we revise the content of GFI #80 we intend to consider your answers to the following questions:

1. What intended technical effects can we expect to see in FAPs submitted to FDA for anti-Salmonella use of the food additives in food for animals?

2. How should efficacy studies be designed for the intended technical effects described in your response to question 1?

3. Should experimental lots of animal food used in both laboratory and field studies be Salmonella-negative, but not sterile, prior to inoculation?

4. What inoculation levels of Salmonella are appropriate for experimental lots of animal food used in laboratory and field studies? Please justify your comment with scientific evidence.

5. What methods should be used to inoculate experimental lots of animal food used in laboratory and field studies?

6. What sampling criteria should be used to provide statistical confidence that Salmonella will be captured among samples collected? Please justify your comment with scientific evidence.

7. What methods should be used to enumerate the level(s) of Salmonella in animal food?

8. What are the key elements for designing field studies?

9. What are the difficulties faced by sponsors when designing and conducting field studies?

10. What types of facilities are available to conduct field studies?

Electronic versions of GFI #80 are in the docket at <http://www.regulations.gov> and on FDA's Web site at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-27194 Filed 11-13-13; 8:45 am]

BILLING CODE 4160-01-P

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, December 04, 2013, 01:00 p.m. to December 04, 2013, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 05, 2013, 78 FR 214 Pg. 66371.

The meeting will start on December 3, 2013 at 12:00 p.m. and end December 3, 2013 at 5:00 p.m.

The meeting location remains the same. The meeting is closed to the public.

Dated: November 7, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-27172 Filed 11-13-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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: National Institute of Mental Health Special Emphasis Panel; Fellowships and Dissertations.

Date: December 6, 2013.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301-451-2356, gavinevanskm@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 7, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-27171 Filed 11-13-13; 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; Brain Injury and Neurovascular Pathologies.

Date: December 2, 2013.

Time: 1:00 p.m. to 6:00 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: Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892-7846, 301-435-1254, yakovleva@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: December 10, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301-437-7872, jenkinsml2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: December 10-11, 2013.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@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: November 7, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-27170 Filed 11-13-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2013-0030; OMB No. 1660-0046]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (i.e., the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before December 16, 2013.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to oir.submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598-3005, facsimile number (202) 646-3347, or email address FEMA-Information-Collections-Management@dhs.gov.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: Emergency Management Institute (EMI) Independent Study Course Enrollment Application.

Type of information collection: Revision of a currently approved information collection.

Form Titles and Numbers: FEMA Form 064-0-9, Emergency Management Institute (EMI) Independent Study Course Enrollment Application.

Abstract: The EMI Independent Study program office collects data from FEMA Form 064-0-9 to create and update student records and provide students with credit for training completion. The system also allows FEMA to track completions and failures of course exams. The data on the electronic form will be encrypted and sent to the server to be parsed into the Independent Study database.

Affected Public: Individuals and households, business or other for-profit, not for profit institutions, farms, Federal government, State, local or tribal government.

Estimated Number of Respondents: 2,148,746.

Estimated Total Annual Burden Hours: 4,297,492.

Estimated Cost: There are no annual capital, start-up, and operation or maintenance costs associated with this collection.

Dated: November 7, 2013.

Charlene D. Myrthil,

Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2013-27264 Filed 11-13-13; 8:45 am]

BILLING CODE 9111-72-P