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.