SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5303 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 23, 2011 (76 FR 16425), FDA made available a draft guidance entitled “Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods” and gave interested parties an opportunity to submit comments by June 21, 2011. The Agency reviewed and evaluated these comments and has modified the guidance where appropriate.

This guidance is intended for firms that manufacture, process, pack, or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors. The guidance does not apply to egg producers and other persons who are covered by FDA’s final rule “Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation” (21 CFR part 118; the shell egg final rule). The guidance addresses testing procedures for Salmonella spp. in human foods (except shell eggs) and direct-human-contact animal foods, and the interpretation of test results, when the presence of Salmonella spp. in the food may render the food injurious to human health.

FDA issued separate guidances in December 2011 and July 2011, respectively, entitled “Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage and Transportation,” which provides guidance to egg producers on how to comply with certain provisions contained in the shell egg final rule, including provisions for environmental and egg testing for Salmonella Enteritidis; and “Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation,” which responds to questions FDA has received on the shell egg final rule since its publication and includes guidance on environmental and egg testing for Salmonella Enteritidis.

II. Significance of Guidance

The final guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on testing for Salmonella spp. in human foods and direct-human-contact animal foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: March 5, 2012.

Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict application reviews—Biosciences.

Date: March 26, 2012.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA/NIH, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, srinivar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: March 1, 2012.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, March 28, 2012, 4 p.m. to March 29, 2012, 8 p.m., Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852 which was published in the Federal Register on January 17, 2012, 77 FR 2304.

This meeting will now be held at 5635 Fishers Lane, Rockville MD 20852. The meeting is closed to the public.