

OMB has now approved the information collection and has assigned OMB control number 0910–0626. The approval expires on February 28, 2015. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: March 2, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012–5632 Filed 3–7–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–D–0112]

#### **Guidance for Industry on Chemistry, Manufacturing, and Controls Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #216 entitled “Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use.”

The purpose of this document is to provide recommendations on what documentation to submit to support the CMC information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**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 on the guidance 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:**

Michael J. Popek, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8269, email: [michael.popek@fda.hhs.gov](mailto:michael.popek@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

In the **Federal Register** of March 14, 2011 (76 FR 13629), FDA published the notice of availability for a draft guidance entitled “Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use” giving interested persons until May 30, 2011, to comment on the draft guidance. FDA received one comment on the draft guidance. No substantive changes were made in finalizing this guidance document.

The guidance announced in this notice finalizes the draft guidance dated March 14, 2012.

##### **II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance 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**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control number 0910–0032.

##### **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. 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.

##### **V. Electronic Access**

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

Dated: March 5, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012–5629 Filed 3–7–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–D–0091]

#### **Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance entitled “Guidance for Industry: Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods.” The document provides guidance to firms that manufacture, process, pack, or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors. This 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.” The guidance addresses testing procedures for *Salmonella* species (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.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition, (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the

**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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2022.

#### **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.*

[FR Doc. 2012-5628 Filed 3-7-12; 8:45 am]

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#### **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.

Dated: March 1, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy*

[FR Doc. 2012-5683 Filed 3-7-12; 8:45 am]

**BILLING CODE 4140-01-P**

#### **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](mailto: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.*

[FR Doc. 2012-5680 Filed 3-7-12; 8:45 am]

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