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.*

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In the **Federal Register** of March 14, 2011 (76 FR 13629), FDA published the notice of availability for a draft guidance entitled ''Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for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