

counterterrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of Federally declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medical devices that would be in high demand, and/or would be vulnerable to shortages in specific disaster/emergency situations or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, and support real-time decisionmaking by HHS during actual emergencies or emergency preparedness exercises.

FDA developed "The Emergency Medical Device Shortages Program Survey" in 2002 to support the acquisition of such data from medical device manufacturers. In 2004, CDRH changed the process for the data collection, and the electronic database

in which the data were stored was formally renamed the "Emergency Shortages Data Collection System" (ESDCS). Recognizing that some of the data collected may be commercially confidential, access to the ESDCS is restricted to members of the CDRH Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to two senior managers. Further, the data are used by this defined group only for decisionmaking and planning in the context of a Federally declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices tracked in the ESDCS. In this initial call, the EST member describes the intent and goals of the data collection effort and makes the specific data request. After the initial call, one or more additional followup calls and/or electronic mail correspondence may be required to verify/validate data sent from the

manufacturer, confirm receipt, and/or request additional detail. Although the regulatory officer is the agent who the EST member initially contacts, regulatory officers may designate an alternate representative within their organization to correspond subsequently with the CDRH EST member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities, and raw material/subcomponent sourcing, it is necessary to update the data in the ESDCS at regular intervals. The EST makes such updates on a regular basis, but makes efforts to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The ESDCS will only include those medical devices for which there will likely be high demand during a specific emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
903(d)(2)	125	3	375	0.5	188

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based the burden estimates in table 1 of this document on past experience with direct contact with the medical device manufacturers and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year either to obtain primary data or to verify/validate data. Because the requested data represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: March 2, 2012.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2012-5633 Filed 3-7-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0403]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a collection of information entitled "Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: On August 30, 2011, the Agency submitted a proposed collection of information entitled "Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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]

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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.

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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