4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for the proposed rule and for its information collection provisions.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule, and for the information collection related to the proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," that appeared in the Federal Register of January 16, 2013. We are taking this action to allow interested persons an opportunity to consider the interrelationships between this proposal and the two proposals announced in July 2013 on the Foreign Supplier Verification Program and on Accreditation of Third-Party Auditors/Certification Bodies. We also are taking this action to keep the comment period for the information collection provisions associated with the rule consistent with the comment period for the proposed rule.

DATES: The FDA is extending the comment period on the above proposed rule. Submit either electronic or written comments on the proposed rule by November 15, 2013. Submit comments

on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by November 15, 2013 (see the "Paperwork Reduction Act of 1995" section).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0920 and/or Regulatory Information Number (RIN) 0910-AG36, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section).

Electronic Submissions

Submit electronic comments in the following way

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0920, and RIN 0910-AG36 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this

document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the proposed rule: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166. With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Drive, PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 16, 2013 (78 FR 3646), we published a proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" with a 120-day comment period on the provisions of the proposed rule and a 30-day comment period on the information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501-3520).

OMB and FDA previously received requests for a 90-day extension of the comment period for the information collection provisions of the proposed rule. We considered the requests and extended the comment period for the information collection for 90 days to make the comment period for the information collection provisions the same as that for the proposed rule--i.e., until May 16, 2013 (Federal Register of February 19, 2013, 78 FR 11611). FDA continued to receive comments requesting an extension of the comment period on the proposed rule. Each request conveyed concern that the 120-day comment period did not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. FDA considered the requests and granted a 120-day extension of the comment period for the proposed rule and for the

information collection provisions--i.e., until September 16, 2013 (Federal Register of April 26, 2013, 78 FR 24691). In the Federal Register of July 29, 2013 (78 FR 45729 and 78 FR 45781) we published two proposed rules entitled, "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (Docket No. FDA-2011-N-0143) and "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (Docket No. FDA-2011-N-0146) with a 120-day comment period. These two proposals are related to the proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." Therefore, FDA is granted a 60-day final extension of the comment period for the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" proposed rule to allow interested person an opportunity to consider the interrelationships between the proposals. We also are extending the comment period for the information collection provisions for 60 days to continue to make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule. To clarify, FDA is requesting comment on all issues raised by the proposed rule.

II. Paperwork Reduction Act of 1995

Interested persons may either submit electronic comments regarding the information collection to oira_submission@omb.eop.gov or fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:202-395-7285. All comments should be identified with the title "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food."

III. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule 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: August 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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