



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 16

[Docket No. FDA-2011-N-0146]

RIN 0910-AG66

Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications; 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 entitled "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" that appeared in the Federal Register of July 29, 2013. We are taking this action in response to requests for an extension to allow interested persons an opportunity to consider the interrelationship between this proposed rule and the proposed rule announced in October 2013 entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals." 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: For the proposed rule published on July 29, 2013 (78 FR 45782), submit either electronic or written comments by January 27, 2014. Submit comments on information

collection issues under the Paperwork Reduction Act of 1995 (the PRA) by January 27, 2014 (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0146 and/or Regulatory Information Number (RIN) 0910-AG66, 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 of this document).

#### 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, Docket No. FDA-2011-N-0146, and RIN 0910-AG66 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: Charlotte Christin, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4234, Silver Spring, MD 20993-0002, 240-402-3708.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, [Domini.Bean@fda.hhs.gov](mailto:Domini.Bean@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

#### I. Background

In the Federal Register of July 29, 2013 (78 FR 45782), we published a proposed rule entitled "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" with a 120-day comment period on the provisions of the proposed rule and on the information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501-3520).

FDA has received requests for an extension of the comment period on the proposed rule to allow interested persons an opportunity to consider the interrelationship between this proposed rule and the proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (78 FR 64736, October 29, 2013). FDA has considered the requests and is granting a 60-day extension of the comment period for the "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" proposed rule to allow interested persons an opportunity to consider the interrelationships between the proposed rules. We also are extending the comment period for

the information collection provisions for 60 days 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 [oir\\_submission@omb.eop.gov](mailto:oir_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 "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications."

## 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: November 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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