4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 225, 500, 507, and 579

[Docket No. FDA-2011-N-0922]

RIN 0910-AG10

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of proposed rulemaking that appeared in the Federal Register of October 29, 2013 (78 FR 64736), entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals " and its information collection provisions. We are taking this action in response to requests for an extension to allow interested persons more time to comment given that in addition to the proposed preventive control requirements, the proposed current good manufacturing practice (CGMP) requirements are also new to the animal food industry, unlike the human food industry.

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: FDA is extending the comment period on the proposed rule and its information collection provisions. Submit either electronic or written comments on the proposed rule and the information collection by March 31, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0922 and/or Regulatory Information Number (RIN) 0910-AG10, 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 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-0922, and RIN 0910- AG10 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: Kim Young, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-2207.

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.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 29, 2013, we published a proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" 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. The requests conveyed concern that the current 120-day comment period does not allow time to develop a meaningful response to the proposed rule because, unlike the human food industry, in addition to the proposed preventive controls, the proposed CGMPs are new to the animal food industry. The requests also stated an extended comment period would allow interested persons an opportunity to consider the interrelationship between this proposed rule and the proposed rules entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (78 FR 45729, July 29, 2013) and "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (78 FR 45782, July 29, 2013). FDA has considered the requests and is granting an extension of the comment period to March

31, 2014, for the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" proposed rule to allow interested persons additional time to submit comments. We also are extending the comment period for the information collection provisions to March 31, 2014, 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 Food for Animals."

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: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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