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: April 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09763 Filed 4–24–13; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA–2011–N–0921]

RIN 0910–AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment periods.

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, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' that appeared in the **Federal Register** of January 16, 2013. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments on the proposed rule. 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 comment period for the proposed rule published January 16, 2013, at 78 FR 3504, is extended. In addition, the comment period for the information collection issues in the proposed rule, extended February 19, 2013, at 78 FR 11611, is further extended. Submit either electronic or written comments on the proposed rule by September 16, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by September 16, 2013 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0921 and/or Regulatory Information Number (RIN) 0910–AG35, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 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 and Docket No. FDA–2011–N–0921, and RIN 0910–AG35 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 ''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: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Picard 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 3504), we published a proposed rule entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' 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 Paperwork Reduction Act of 1995 (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 has now received comments requesting an extension of the comment period on the proposed rule. Each request conveyed concern that the current 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. FDA has considered the requests and is granting a 120-day extension of the comment period for the proposed rule. FDA believes that a 120-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. We also are extending the comment period for the information collection provisions for 120 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 ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.''

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: April 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09761 Filed 4–24–13; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2012–N–1258]

Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a document that we made available for public comment by notification in the **Federal Register** of January 16, 2013. We are taking this action to make the comment period for the draft RA conform to the comment period for proposed rules entitled ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food'' (the proposed preventive controls rule) and ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (the proposed produce safety rule). Elsewhere in this issue of the **Federal Register**, we are announcing a 120-day extension of the comment period for the proposed preventive controls rule and the proposed produce safety rule.

DATES: The comment period for the document published January 16, 2013, at 78 FR 3824, reopened March 13, 2013, at 78 FR 15894, is extended. Submit either electronic or written comments by September 16, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 16, 2013 (78 FR 3824), we published a notification with a 30-day comment period announcing the availability of, and requesting comment on, a document entitled ''Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.'' The purpose of the draft RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. Interested persons were originally given until February 15, 2013, to comment on the draft RA.

We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA. In the **Federal Register** of January 16, 2013 (78 FR 3824), we announced that we had used the results of the draft RA to propose to exempt certain food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until May 16, 2013, to comment on the proposed preventive controls rule.

We previously received requests to allow interested persons additional time to comment on the draft RA. Two requesters had considered that the comment period for the draft RA should conform to the comment period of the proposed preventive controls rule. (One of these requesters further requested that the comment period conform to that of the proposed produce safety rule, which published in the **Federal Register** of January 16, 2013 (78 FR 3504), and other major rulemakings that we would be conducting under FSMA but were not yet published.) We considered the requests and reopened the comment period for the draft RA until May 16, 2013—i.e., the same date as that for the proposed preventive controls rule and the proposed produce safety rule (**Federal Register** of March 13, 2013, 78 FR 15894).

We have now received comments requesting an extension of the comment period on the proposed preventive controls rule and the proposed produce safety rule. Each request conveyed concern that the current 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to those proposed rules. We have considered the requests and, elsewhere in this issue of the **Federal Register**, we are granting a 120-day extension of the comment period for those proposed rules. We are extending the comment period for the draft RA for 120 days to continue to make the comment period for the draft RA conform to the comment period for the proposed preventive controls rule and the proposed produce safety rule.

II. Request for Comments

Interested persons may submit either electronic comments regarding the draft RA 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.*