must also be determined. Loads must be determined for critical fuel and payload distributions and centers of gravity. Nose gear loads, as well as airframe loads, must be determined. The airplane must support these loads as described in § 25.305.

Issued in Renton, Washington, on February 12, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–03679 Filed 2–15–13; 8:45 am]

BILLING CODE 4910–13–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 Period for Information Collection Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for information collection provisions.

SUMMARY: The Food and Drug Administration (FDA or ''we'') is extending the comment period for the information collection related to the proposed rule on ''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. In the preamble to the proposed rule, FDA requested comments on the information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments on the information collection provisions associated with the rule.

DATES: The comment period for the proposed rule published January 16, 2013 (78 FR 3646), is extended. Submit either electronic or written comments by May 16, 2013.

ADDRESSES: To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.''

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Picard Dr., 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), FDA 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 Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Comments on the provisions of the rule and on the information collection provisions will inform FDA's rulemaking to modernize the regulation for ''Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food'' and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to establish and implement hazard analysis and risk-based preventive controls for human food.

OMB and FDA have received two requests for a 90-day extension of the comment period for the information collection provisions of the proposed rule. The requests conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the information collection provisions submitted to OMB under the Paperwork Reduction Act of 1995.

We have considered the requests and are extending the comment period for the information collection for 90 days, until May 16, 2013. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. A 90-day extension also will make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule.

II. Request for Comments

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.''

Dated: February 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03732 Filed 2–15–13; 8:45 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 Period for Information Collection Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for information collection provisions.

SUMMARY: The Food and Drug Administration (FDA or ''we'') is extending the comment period for the information collection provisions of the proposed rule on ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' that appeared in the **Federal Register** of January 16, 2013. In the preamble to the proposed rule, FDA requested comments on the information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments on the information collection provisions associated with the rule.

DATES: The comment period for the proposed rule published January 16, 2013 (78 FR 3504), is extended. Submit

either electronic or written comments by May 16, 2013.

ADDRESSES: To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.''

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Picard Dr., 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), FDA 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). Comments on the provisions of the rule and on the information collection provisions will inform FDA's rulemaking to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce for human consumption to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce.

We have received a request for a 90-day extension of the comment period for the information collection provisions of the proposed rule. The request conveyed concern that the current 30-day comment period does not allow sufficient time to provide meaningful input on the information collection provisions submitted to OMB under the Paperwork Reduction Act of 1995.

We have considered the request and are extending the comment period for the information collection for 90 days, until May 16, 2013. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. A 90-day extension also will make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule.

II. Request for Comments

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.''

Dated: February 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03778 Filed 2–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2009–N–0458]

RIN 0910–AG29

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

AGENCY: Food and Drug Administration, HHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) published a proposed rule in the **Federal Register** of April 1, 2010, along with a companion direct final rule. The proposed rule proposed to amend the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. The Agency received significant adverse comment and withdrew the direct final rule. The Agency is issuing this supplemental notice of proposed rulemaking re-proposing the amendments reflecting comments received.

DATES: Submit either electronic or written comments on the proposed rule by April 22, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 21, 2013, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0458 and/or RIN number 0910–AG29, 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–2009–N–0458 and Regulatory Information Number (RIN) 0910–AG29 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: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Rm. 1651, Silver Spring, MD 20993, 301–796–6563.

SUPPLEMENTARY INFORMATION: