

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 121

[Docket No. FDA-2013-N-1563]

Appendix 4 To 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; Extension of 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 appeared in the **Federal Register** of December 24, 2013 (78 FR 78064), entitled “Appendix 4 to 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” (draft RA Appendix) to June 30, 2014. We are taking this action to keep the comment period for the draft RA Appendix consistent with the comment period for the proposed rule.

DATES: FDA is extending the comment period on the draft RA Appendix. Submit either electronic or written comments on the proposed rule and the information collection by June 30, 2014.

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: Ryan Newkirk, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2428.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 24, 2013, we published a document entitled “Appendix 4 to 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 draft RA Appendix) with a 100-day comment period on the provisions of the proposed rule.

FDA has received requests for an extension of the comment period on the

proposed rule entitled “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration” (78 FR 78014). This document directly relates to the proposal. The requests conveyed concern that the current 100-day comment period does not allow time to thoroughly analyze the proposal, due to the inherent complexity and unique nature of food defense issues. FDA has considered the requests and is granting an extension of the comment period to June 30, 2014, for the draft RA Appendix to allow interested persons additional time to submit comments. Elsewhere in this issue of the **Federal Register**, we are also extending the comment period for the proposed rule “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.” To clarify, FDA is requesting comment on all issues raised by the document.

II. 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: March 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-06469 Filed 3-24-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 121

[Docket No. FDA-2013-N-1425]

RIN 0910-AG63

Focused Mitigation Strategies To Protect Food Against Intentional Adulteration; 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 December 24, 2013 (78 FR 78014), entitled “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration” and its information collection provisions. We are taking this action in response to requests for an extension to allow interested persons an opportunity to fully review and analyze the approaches FDA has proposed for the rule and its potential impact as well as to consider the complexity and if the proposal has the flexibility to address the many types of food operations that will be affected.

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 June 30, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-1425 and/or Regulatory Information Number (RIN) 0910-AG63, 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-2013-N-1425, and RIN 0910-AG63 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: Ryan Newkirk, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2428.

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 December 24, 2013, we published a proposed rule entitled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" with a 100-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 100-day comment period does not allow time to thoroughly analyze the proposed rule since this is unlike any other proposal and due to the inherent complexity and unique nature of food defense issues. The requests also stated an extended comment period would allow interested persons an opportunity to fully review and analyze the approaches FDA has proposed for the rule and its potential impact as well as consider the complexity and if the proposal has the flexibility to address the many types of food operations that will be affected. FDA has considered the requests and is granting an extension of the comment period to June 30, 2014, for the "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" proposed rule to allow interested persons additional time to submit comments. We also are extending the comment period for the information collection provisions to June 30, 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 "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration."

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: March 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-06468 Filed 3-24-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2014-F-0295]

DSM Nutritional Products; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that DSM Nutritional Products has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 25-hydroxyvitamin D₃ in feed for swine.

DATES: Submit either electronic or written comments on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement by April 24, 2014.

ADDRESSES: Submit electronic comments to: <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2280) has been filed by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of 25-hydroxyvitamin D₃ in feed for swine.

The petitioner has requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(r). Interested persons may submit either electronic or written comments regarding this request for categorical exclusion to the Division of Dockets Management (see **DATES** and **ADDRESSES**). 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.

Dated: March 19, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014-06487 Filed 3-24-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA-2013-N-1529]

Medical Device Classification Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing classification and reclassification of medical devices to conform to the