Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 6, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 3, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10999 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0138]

Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry on the implementation of the mandatory food recall provisions of the FDA Food Safety Modernization Act (FSMA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

DATES: Although you may comment on any guidance at any time, to ensure that the Agency considers your comments on this draft guidance before it completes a final version of the guidance, submit electronic or written comments on the draft guidance by July 6, 2015.

ADDRESSES: Submit written requests for single copies of the guidance to the Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance 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: Cecilia M. Wolyniak, Food and Drug Administration, WO32 Rm. 4352 HFC–210, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8209.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the Federal Food, Drug and Cosmetic Act (FD&C Act), as added by section 206 of FSMA, gives FDA the authority to order a responsible party to recall an article of food where FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

FDA is announcing the availability of a draft guidance for industry entitled ''Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry.'' The draft guidance provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance does not refer to any information collection provisions found in FDA regulations. Collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that the Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls is not subject to Paperwork Reduction Act of 1995.

III. Comments

Interested persons may submit either written comments regarding the guidance to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding the guidance to *http://www.regulations.gov.* 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11009 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2029]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Practices and Procedures; Formal Evidentiary Public Hearing

AGENCY: Food and Drug Administration, HHS.