

to substantiate the effectiveness of pathogenic STEC reduction drugs.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic.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.

## III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These 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). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

## IV. Comments

Interested persons may submit either electronic comments regarding this document 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>.

## V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: February 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0595]

### Environmental Protection Agency and Food and Drug Administration Advice About Eating Fish; Closure of the Public Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; closure of the public comment period.

**SUMMARY:** On June 11, 2014, the Food and Drug Administration (FDA), in coordination with the U.S. Environmental Protection Agency (EPA), (the Agencies), released for public comment draft fish consumption advice entitled “Fish: What Pregnant Women and Parents Should Know.” The draft advice would update the Agencies’ consumption advice and recommend that women who are pregnant (or might become pregnant) or nursing and anyone who prepares food for young children eat certain amounts and types of fish in order to improve health and developmental outcomes while minimizing risk from methylmercury in fish. The draft advice is consistent with recommendations in the *Dietary Guidelines for Americans 2010*, which are issued every 5 years by the U.S. Departments of Agriculture and Health and Human Services. FDA and EPA are now announcing the closure of the public comment period.

**DATES:** The comment period will close on March 26, 2015.

**ADDRESSES:** Comments may continue to be submitted until March 26, 2015. 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. FDA will share with EPA all comments submitted to the FDA docket.

#### FOR FURTHER INFORMATION CONTACT:

FDA: William Jones, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1422, email: [William.Jones@fda.hhs.gov](mailto:William.Jones@fda.hhs.gov); EPA: Jeffrey Bigler, MS–4305T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460, 202–566–0389, email: [bigler.jeff@epa.gov](mailto:bigler.jeff@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 11, 2014 (79 FR 33559), FDA, in coordination with EPA, announced the availability of the draft

updated fish advice, entitled “Fish: What Pregnant Women and Parents Should Know,” for public comment (the notice). The draft advice is available electronically at <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm>. The notice stated that the comment period would be open until 30 days after the last transcript became available from either the FDA Risk Communication Advisory Committee (RCAC) meeting to be held on the draft advice or any other public meeting that the Agencies chose to hold on the draft advice (79 FR 33559). The notice also stated that the date for closure of public comment will be published in a future notice in the **Federal Register** (id.).

The RCAC meeting was held on November 3 and 4, 2014, and the transcript of the meeting became available on December 2, 2014. The meeting addressed the draft updated fish advice in great detail and included presentations by the Agencies on both the substance and the presentation of the draft advice, and included presentations by invited experts in risk communications. The meeting also provided members of the public with an opportunity to express their views to the RCAC and to members of the Agencies who were in attendance. A number of organizations and private citizens availed themselves of this opportunity. For these reasons, FDA and EPA have concluded that the thoroughness of this public meeting, in addition to the public comments received and still to be received, remove the need for additional public meetings and are hereby closing the public comment period on March 26, 2015. The transcript from the RCAC meeting is available electronically at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM425352.pdf> and <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM425353.pdf>.

Dated: February 18, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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