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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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Comments may continue to be submitted until **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. 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; EPA: Jeffrey Bigler, MS-4305T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460, 202-566-0389, email: 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. 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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