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This level 1 draft guidance is being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 The draft guidance, when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

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may obtain the draft guidance at either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

Dated: February 17, 2015.

Leslie Kux,
Associate Commissioner for Policy.

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
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240–402–1422, email: 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.

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/Committees
MeetingMaterials/RiskCommunication
AdvisoryCommittee/UCM425352.pdf
and http://www.fda.gov/downloads/
AdvisoryCommittees/Committees
MeetingMaterials/RiskCommunication
AdvisoryCommittee/UCM425353.pdf.

Dated: February 18, 2015.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015–03691 Filed 2–23–15; 8:45 am]
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