

2. Question #5: Additional evidence-based CDSME programs added to the list (reflective of approved programs included in the FY2019 Funding Opportunity Announcement).

3. Question #7: Information regarding funding source(s) requested to assess progress toward developing a sustainable program delivery infrastructure that is not solely reliant on ACL discretionary dollars.

- Participant Information Survey:

1. Participant I.D. modified to reduce risk of personally identifiable information exposure.

2. Question #10: Added question regarding veteran status to further describe program participants, as well

as to assist with partnerships with veteran-serving organizations.

3. Question #12: In tandem with Question #11, this item will allow for further assessment of caregiver status.

4. Question #14: Anxiety Disorder and Depression are listed separately (vs. being combined). Also included Yes/No response options for each chronic condition listed to improve data analyses and reporting.

5. Question #15: Response options have been delineated as sub-bullets (vs. being grouped into a single item) to align with the American Community Survey.

6. Question #16: Added question regarding social isolation, a construct

which has been demonstrated to have an association with health-related risks for older adults. This question will also be asked upon completion of the last program session.

7. Question #17: This question will be asked at baseline and upon completion of the last program session to measure change.

The proposed data collection tools may be found on the ACL website for review at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Program facilitators (Program Information Cover Sheet, Attendance Log).	1,350	Once per program33	445.5
Program participants (Participant Information Survey)	13,500	120	2,700
Data entry staff (Program Information Cover Sheet, Attendance Log, Participant Information Survey).	65	Once per program times 1,350 programs.	.17	229.5
Total	3,375

Dated: June 27, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019-14564 Filed 7-8-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0595]

Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of revised fish advice entitled “Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children.” The revised advice updates advice that FDA and the U.S. Environmental Protection Agency (EPA) jointly issued in January 2017. The advice is intended to help women who are or might become pregnant, breastfeeding mothers, and parents of children over 2 years make

informed choices about fish that are nutritious and safe to eat. We are revising the advice in accordance with a recent directive from Congress. FDA is seeking public comment on the development of educational materials on the updated fish advice for women who are or might become pregnant, breastfeeding mothers, and parents of young children.

DATES: Although you can comment on the fish advice at any time, to ensure that FDA considers your comments on the development of educational materials before it begins work on such materials, submit either electronic or written comments on the requested information by September 9, 2019.

ADDRESSES: You may submit comments as follows.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2014-N-0595 for “Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children.” Received comments will be placed in the docket and, except for those submitted as “Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William R. Jones, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1422, William.Jones@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2017 (82 FR 6571), FDA, in coordination with EPA, announced the availability of revised advice entitled “Advice About Eating Fish” (the “2017 advice”). The 2017 advice encourages women who are pregnant and breastfeeding to consume

8 to 12 ounces of a variety of fish per week, from choices that are lower in mercury. The 2017 advice presents recommendations for how often the target audience should consume different fish, using a color-coded chart of more than 60 different fish. The chart presents fish in categories of “Best Choices,” from which we recommend the target audience eat a variety of 2 to 3 servings a week; “Good Choices,” from which we recommend the target audience eat 1 serving a week; and “Choices to Avoid.”

On February 15, 2019, the Consolidated Appropriations Act, 2019 (Pub. L. 116-6) became law. Section 773 of Public Law 116-6 directs the Commissioner of Food and Drugs to, by July 1, 2019, and “following the review required under Executive Order 12866 (5 U.S.C. 601 note; relating to regulatory planning and review),” issue “advice revising the advice” provided in the notice of availability entitled “Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration, Revised Fish Advice, Availability” (82 FR 6571) in a manner that is “consistent with nutrition science recognized by FDA on the net effects of seafood consumption.” This notice announcing the availability of revised fish advice entitled “Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children” responds to that directive.

II. The Revised Fish Advice

The revised fish advice, like the 2017 advice, is intended to encourage fish consumption by emphasizing the benefits of eating fish and to help women who are or might become pregnant, breastfeeding mothers, and parents of children over 2 years make informed choices among types of fish. Specifically, the revised advice, now renamed as “Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children,” includes a statement that eating fish when pregnant or breastfeeding can provide health benefits and states that fish and other protein-rich foods have nutrients that can help children’s growth and development. The revisions also include a statement that, as part of a healthy eating pattern, eating fish may offer heart health benefits and lower the risk of obesity. The revised advice also makes clear that many types of fish are both nutritious and lower in mercury.

The revised advice also discusses nutritional value of fish, as outlined in the 2015–2020 Dietary Guidelines for Americans. Based on information in the

Dietary Guidelines, the revised advice states that fish are part of a healthy eating pattern and provide protein, healthy omega-3 fats (called docosahexaenoic acid and eicosapentaenoic acid), more vitamin B12 and vitamin D than any other type of food, iron, and other minerals like selenium, zinc, and iodine.

Finally, the revised advice continues to provide information to help women who are or might become pregnant, breastfeeding mothers, and parents of children over 2 years choose varieties of fish that are lower in mercury.

You may submit comments on the advice at any time.

III. Consolidated Appropriations Act, 2019

The fish advice provides information for use by consumers. It is not intended to have the force and effect of law, does not implement, interpret, or prescribe law or policy, and does not describe procedural or practice requirements. As required by section 773 of Public Law 116-6, the revised advice was reviewed by the Office of Management and Budget under Executive Order 12866.

The advice was revised in accordance with the directive in section 773 of Public Law 116-6 that the advice be updated “in a manner that is consistent with nutrition science recognized by FDA on the net effects of seafood consumption.” FDA considered the totality of the evidence, including nutrition science on the net effects of seafood consumption, when updating the fish advice. The overall changes we made include clarifying the target audience to make clear it applies to women who could become or are pregnant, women who are breastfeeding, and parents who are feeding children 2 years and older and adding highlights of key consumer messages, including that eating fish can provide health benefits when pregnant or breastfeeding, that many types of fish are both nutritious and lower in mercury, and that the consumption advice is based on mercury levels. Specifically, with respect to health benefits, the advice now highlights benefits related to risk of heart disease and obesity, benefits supporting children’s growth and development, and the substantive nutritional contributions to a healthy diet from protein, omega-3 fats, vitamin B12, vitamin D, iron, selenium, zinc, and iodine.

The primary focus of the revisions is to further align the advice with the 2015–2020 Dietary Guidelines for Americans, which establishes Federal, evidence-based policy on diet and health. The revised advice supports the

recommendations of the 2015–2020 Dietary Guidelines for Americans, developed for people 2 years and older, which reflects current science on nutrition to improve public health. The Dietary Guidelines for Americans focuses on dietary patterns and the effects of food and nutrient characteristics on health. FDA recognizes the nutrition science that is reflected in the guidelines, including nutrition science that was based on scientific analysis that considered evidence regarding the net effects of seafood consumption. In addition, the guidelines recommend eating fish as part of a healthy eating pattern because there are benefits in doing so.

The process to develop the 2020–2025 Dietary Guidelines is under way, and per the Agricultural Act of 2014, will include a comprehensive review of scientific evidence and development of guidance for infants and toddlers from birth to 24 months, as well as for women who are pregnant. Additionally, EPA is in the process of updating its Integrated Risk Information System (IRIS) Assessment for Methylmercury. FDA will consider the final products from these efforts, as appropriate, in any future updates to the fish advice.

IV. Request for Comments

FDA intends to develop educational materials such as simple factsheets, posters, infographics, and social media tool-kits on the updated fish advice for women who are or might become pregnant, breastfeeding mothers, and parents of young children. Specific materials will also be developed for health care professionals, health educators, nutritionists, and dietitians. These resources will be printable and could be used in physician's offices, public health clinics, and stores.

FDA is seeking public comment on:

(1) Additional target populations that should be considered who may benefit from this advice;

(2) Additional information that should be included in these educational resources; and

(3) Additional effective means of disseminating and broadening the reach of this information.

While FDA welcomes comment at any time, we would appreciate comments on these questions by September 9, 2019.

V. Electronic Access

Persons with access to the internet may obtain the advice at either <https://www.fda.gov/food/resources-you-food>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the advice.

Dated: July 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14524 Filed 7–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2281]

Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled “Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs.” This public meeting and request for comments is intended to support FDA guidance development as required by the Animal Drug and Animal Generic Drug User Fee Amendments of 2018. The topics to be discussed will inform the development of guidance to assist sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is seeking comments from stakeholders, including representatives of regulated industry, consumer groups, academia, veterinarians, and food producers.

DATES: The public meeting will be held on July 16, 2019, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by August 17, 2019.

ADDRESSES: The public meeting will be held at Johns Hopkins University—Montgomery County, Gilchrist Hall, 9601 Medical Center Dr., Rockville, MD 20850. Free parking is available on site.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of August 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

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- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2019–N–2281 for “Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9