

derived from the generic drug applicant program fee would increase from 35 percent in GDUFA II to 36 percent in GDUFA III.

*E. Impact of GDUFA III Enhancements on User Fee Revenue*

To implement the proposed enhancements for GDUFA III, funding for a total of 128 new full-time equivalent staff is proposed for FY 2023.

#### IV. Public Meeting Information

##### A. Purpose and Scope of the Meeting

The meeting will include presentations by FDA and panels representing different stakeholder groups identified in the statute (such as patient and consumer advocacy groups and regulated industry). For members of the public who would like to make verbal comments on the proposed enhancements (see instructions below), there will be a public comment period at the end of the meeting. We will also provide an opportunity for individuals to submit written comments to the docket before and after the meeting.

##### B. Participating in the Public Meeting

**Registration:** Registration is optional to attend this virtual meeting. However, registering will allow FDA to provide you with email updates if any meeting details change. Persons interested in registering for this public meeting must register online by 11:59 p.m. Eastern Time on November 15, 2021, at <https://www.eventbrite.com/o/fda-34063199905>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

**Opportunity for Public Comment:** If you wish to present during the public comment session, please submit your request to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov) by 11:59 p.m. Eastern Time on November 8, 2021. Your email should contain which topic(s) you wish to address and include complete contact information, including name, title, affiliation, address, and email address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by November 9, 2021. If selected for presentation, any presentation materials must be emailed to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov) no later than November 11, 2021. No commercial or promotional material will be permitted to be presented or distributed during the virtual public meeting.

**Streaming Webcast of the Public Meeting:** The Zoom Webinar ID for this public meeting is 160 003 0426. The webcast link for this public meeting, which should allow you to enter the webinar directly, can be found here: <https://fda.zoomgov.com/j/1600030426?pwd=YThMd0sweXNQOVN0dVpYZHMrdVFSUT09>. If Zoom asks for a passcode, please use the following case-sensitive passcode: GDUFA3!

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments> and in this docket at <https://www.regulations.gov>. It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: October 22, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Advice About Eating Fish: For Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1-11 Years, 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 Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1-11 Years." The revised advice updates advice that FDA and the U.S. Environmental Protection Agency (EPA) jointly issued in January 2017 and subsequently revised in July 2019. The advice is intended to help those who might become or are pregnant or breastfeeding, and parents and caregivers of children 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.

**DATES:** The announcement of the revised advice is published in the **Federal Register** on October 29, 2021.

**ADDRESSES:** You may submit comments on the advice at any time. 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 Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1-11 Years." 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, 240-402-7500.

• **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.govinfo.gov/content/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, 240-402-7500.

Submit written requests for single copies of the advice to Division of Seafood Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., 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.

**FOR FURTHER INFORMATION CONTACT:** Emanuel Hignutt, Jr., Office of Food Safety (HFS-325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2469; or Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug

Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of July 9, 2019 (84 FR 32747), FDA, in coordination with EPA, announced 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 “2019 advice”). The 2019 advice responded to section 773 of the Consolidated Appropriations Act, 2019 (Pub. L. 116-6), which directed the Commissioner of Food and Drugs to, by July 1, 2019, and following the regulatory planning and review required under Executive Order 12866, issue advice revising the advice announced 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; January 19, 2017) in a manner that is consistent with nutrition science recognized by FDA on the net effects of seafood consumption. The 2019 advice encouraged fish consumption by emphasizing the benefits of eating fish and helping those who are or might become pregnant or are breastfeeding, and parents of children over 2 years make informed choices among types of fish. The 2019 advice made clear that many types of fish are both nutritious and lower in mercury. The 2019 advice also discussed the nutritional value of fish, as outlined in the 2015–2020 Dietary Guidelines for Americans.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) became law. Section 745 of Public Law 116-260 directs the Commissioner of Food and Drugs to, by September 30, 2021, and following the review required under Executive Order No. 12866, issue advice revising the advice announced 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 Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1–11 Years” responds to that directive.

On December 29, 2020, the Department of Health and Human Services and the U.S. Department of Agriculture released the Dietary

Guidelines for Americans, 2020–2025 (Ref. 1), which, for the first time, provides dietary patterns for children under age 2 years. It also provides additional nutrition information for caregivers of children and those who are pregnant or lactating on healthy eating patterns that can help promote health and reduce the risk for chronic disease. The updated edition of the Dietary Guidelines is supported by a robust review of the scientific evidence on seafood and health outcomes across the populations for which the FDA/EPA Fish Advice is targeted and also includes additional evidence that is now available on the role of seafood, as part of a healthy eating pattern, in potentially achieving specific health benefits.

##### **II. The Revised Fish Advice**

The revised fish advice, like the 2019 advice, is intended to encourage fish and shellfish consumption (collectively referred to in the advice as “fish”) by emphasizing the benefits of eating fish and to help those who might become or are pregnant or breastfeeding and parents and caregivers of children ages 1 through 11 years make informed choices among types of fish. Specifically, the revised advice, now renamed as “Advice About Eating Fish: For Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1–11 Years,” expands the lower range of the target audience of children from 2 years to 1 year. The revised advice further explains that a healthy eating pattern consists of choices across all food groups (vegetables, fruits, grains, dairy, and protein foods, which includes fish), eaten in recommended amounts, and within calorie needs, and that healthy eating patterns include foods that provide vitamins, minerals, and other health-promoting components and have no or little added sugars, saturated fat, and sodium. Specific to fish, the revised advice elaborates that moderate scientific evidence shows that eating patterns relatively higher in fish but also in vegetables, fruits, legumes, whole grains, low- or non-fat dairy, lean meats and poultry, nuts, and unsaturated vegetable oils, and lower in red and processed meats, sugar-sweetened foods and beverages, and refined grains are not only associated with lower risk of obesity but now also promotion of bone health and lower risk of colon and rectal cancers. The revised advice states that strong evidence shows that eating fish, as part of a healthy eating pattern, may have heart health benefits. The revised advice also makes clear that many types of fish are both nutritious and lower in mercury.

The revised advice also discusses the nutritional value of fish, as outlined in the Dietary Guidelines for Americans, 2020–2025 (Ref. 1). 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) and omega-6 fats, vitamins B12 and D, iron, and other key nutrients like selenium, zinc, iodine, and choline. In addition, the revised advice includes statements that fish provide omega-3 and omega-6 fats, iron, iodine, and choline, which are key nutrients during pregnancy, breastfeeding, and/or early childhood to support a child's brain development; choline also supports the development of the baby's spinal cord; and fish also provide iron and zinc to support children's immune systems. The revisions also include a statement that fish intake during pregnancy is recommended, as moderate evidence shows that it can help a baby's cognitive development.

The revised advice continues to provide information to help those who might become or are pregnant or breastfeeding, and parents and caregivers of children choose varieties of fish that are lower in mercury. The revised advice now includes a recommended serving size of about 1 ounce of "Best Choices," to be consumed twice a week, for children age 1 year.

Finally, the revised advice also provides information on how the recommendations of the Healthy U.S.-Style Dietary Patterns for children in the Dietary Guidelines for Americans could be met when those recommendations include more ounces of fish per week than the amounts in the FDA/EPA advice. The revised advice provides a list of the subset of "Best Choices" of fish identified in Tables 2–1 and A3–1, Footnote E of the Dietary Guidelines for Americans, 2020–2025 that are at or below the mean methylmercury concentration that supports exposures at or under the methylmercury Reference Dose, when the amounts recommended in the Healthy U.S.-Style Dietary Pattern in the Dietary Guidelines are greater than the amount of all "Best Choices" in the FDA/EPA advice.

### III. Consolidated Appropriations Act, 2021

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.

Consistent with section 745 of Public Law 116–260, the revised advice was reviewed by the Office of Management and Budget.

The advice was revised in accordance with the directive in section 745 of Public Law 116–260 that the advice be updated in a manner that is consistent with nutrition science recognized by FDA on the net effects of seafood consumption. The overall changes we made include revised evidence statements on fish consumption and health benefits, as outlined in the Dietary Guidelines for Americans, 2020–2025, including new information about when and how to introduce fish to infants, and terminology changes for inclusivity. Specifically, with respect to health benefits, the revised advice now highlights that there is moderate scientific evidence regarding favorable measures of cognitive development in young children associated with fish intake in pregnancy as well as lower risk of additional diet-related conditions associated with consuming fish as part of a total eating pattern.

The primary focus of the revisions is to align the revised advice with the Dietary Guidelines for Americans, 2020–2025, which establishes Federal, evidence-based policy on diet and health. The revised advice supports the recommendations of the Dietary Guidelines for Americans, 2020–2025, which reflects current science on nutrition to help promote health and reduce chronic disease. 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 Dietary Guidelines for Americans and the preceding Scientific Report of the 2020 Dietary Guidelines Advisory Committee (Ref. 2), including the nutrition science described therein that considered the net effects of seafood consumption on growth and development, as well as health. In addition, the Dietary Guidelines for Americans recommends eating fish as part of a healthy eating pattern because there are benefits in doing so.

EPA is in the process of updating its Integrated Risk Information System Assessment for Methylmercury. FDA will consider the final products from this effort, as appropriate, in any future updates to the fish advice.

### IV. Paperwork Reduction Act of 1995

This revised advice contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### 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.

### VI. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020–2025*, 9th Edition, December 2020. Available at <https://www.dietaryguidelines.gov>.
2. Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. Available at <https://www.dietaryguidelines.gov/2020-advisory-committee-report>.

Dated: October 26, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Request for Public Comment: 30-Day Notice for Extension of the Indian Health Service Loan Repayment Program (LRP)

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice and request for comments. Request for extension of approval.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (PRA), the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–0014, titled, "IHS Loan Repayment Program (LRP)." The IHS is requesting OMB to approve an