DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0367]

Sec. 540.525 Scombrotoxin (Histamine)-Forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24) Compliance Policy Guide; Guidance for Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for FDA staff entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24) Compliance Policy Guide.'' This compliance policy guide (CPG) is intended to provide FDA staff guidance on adulteration associated with decomposition and/or histamine identified during surveillance sampling and testing of fish and fishery products susceptible to histamine formation.

DATES: The announcement of the guidance is published in the **Federal Register** on November 4, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2021–D–0367 for ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24) Compliance Policy Guide.'' 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.'' We will review this copy, including the claimed confidential information, in our 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Division of Seafood Safety, Office of Dairy and Seafood Safety, Office of Microbiological Food Safety, Human Foods Program, 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: Steven Bloodgood, Division of Seafood Safety, Office of Dairy and Seafood Safety, Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5316; or Jessica Ritsick, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a CPG for FDA Staff entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24).'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

This CPG is intended to provide FDA staff guidance on adulteration associated with decomposition and/or histamine identified during surveillance sampling and testing of fish and fishery products susceptible to histamine formation. This finalized CPG supersedes FDA's existing CPG on this topic.

In the **Federal Register** of December 27, 2021 (86 FR 73295), we made

available a draft guidance for FDA staff entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24)'' and gave interested parties an opportunity to submit comments by February 25, 2022, for us to consider before beginning work on the final version of the guidance. In the **Federal Register** of March 15, 2022 (87 FR 14538), in response to a request from stakeholders, we reopened the comment period until April 14, 2022.

We received comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include the addition of a detailed explanation for our revisions to the histamine levels set forth in the guidance. The guidance announced in this notice finalizes the draft guidance dated December 2021.

II. Paperwork Reduction Act of 1995

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

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 22, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25315 Filed 11–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate and any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 3, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx—New.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under oversight of the HRSA, operates the U.S. procurement and transplantation system. The Secretary and/or HRSA may direct the collection of data in accordance with the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits data elements for collection to OMB for official federal approval.

Need and Proposed Use of the Information: HRSA and the OPTN Board of Directors use data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The regulatory authority in 42 CFR 121.11 of the OPTN Final Rule allows the Secretary of HHS to prescribe data collection. This regulatory authority requires OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, and members of the public for evaluation, research, patient information, and other purposes.

This is a request to expand the current OPTN data collection, approved under OMB No. 0915–0157. HRSA is submitting this new data collection, separate from OMB No. 0915–0157, since it includes new forms developed in response to an HHS Secretarial Data Directive that are not in use by OPTN. HRSA believes that separating these data collections will minimize confusion, increase clarity among OPTN members and stakeholders, and enable more direct feedback on the new forms. Both data collections include time-sensitive, life-critical data on transplant candidates and potential organ donor patients, the organ matching process, histocompatibility results, organ labeling and packaging, and pre-and post-transplantation data on recipients and donors. The OPTN collects these specific data elements from transplant centers.

HRSA and the OPTN use this information to: (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance, including the possible transmission of donor disease.

This new collection consists of three new data forms as directed by the HHS Secretary, which were developed to improve the OPTN organ matching and allocation process and OPTN member compliance with OPTN requirements:

- One new form will collect data from the point of referral of a patient to an organ procurement organization (OPO) for potential deceased organ donation. These data will provide a more objective source of information on procurement practices, the management of donor patients, and how these practices inform the supply of deceased donor organs available for transplant. These data may also help to improve monitoring of OPO performance and would facilitate quality assurance and performance improvement efforts to reduce the variation in the quality-of-care OPOs provide to donors and donor families.
- Two new forms will expand data collection from the point of patient registration, referral, and evaluation at transplant centers. These data will enable collection of data from the point of referral. Pre-waitlisting data will provide insight into who gets referred