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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-0367]

Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-Forming Fish and Fishery Products--Decomposition and Histamine; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft Compliance Policy Guide entitled "Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products--Decomposition and Histamine" that published in the *Federal Register* of December 27, 2021. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested parties to develop and submit data, other information, and comments before FDA begins work on the final guidance.

DATES: FDA is reopening the comment period for the draft Compliance Policy Guide announced in the *Federal Register* on December 27, 2021 (86 FR 73295). Submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], to ensure that we consider your comments before we begin work on the final guidance.

ADDRESSES: You may submit comments on any guidance 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 "Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products--Decomposition and Histamine." 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.

FOR FURTHER INFORMATION CONTACT: Steven Bloodgood, Division of Seafood Safety (HFS-325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-5316, email: Steven.Bloodgood@fda.hhs.gov; or Jessica Larkin, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of December 27, 2021 (86 FR 73295), we published a notice announcing the availability of a draft Compliance Policy Guide (CPG) entitled "Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products--Decomposition and Histamine (CPG 7108.24)." This draft CPG would update and replace existing guidance for FDA staff on adulteration associated with decomposition and histamine identified during surveillance sampling and testing of fish and fishery products susceptible to histamine formation. We gave interested parties until February 25, 2022, to submit comments before we began work on the final guidance.

FDA has received a request for a 30-day extension for this comment period to allow additional time for interested parties to develop and submit data, other information, and comments for this draft Compliance Policy Guide before we begin work on the final version of the guidance. We have considered this request and are reopening the comment period for 30 days. FDA believes that this additional 30 days will allow adequate time for any interested parties to submit data, other information, and comments before we begin work on the final guidance.

Dated: March 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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