ADDRESSES: You may submit either electronic or written comments 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–2020–N–1313 for ''Electronic Submissions; Data Standards; Support for Standard for the Exchange of Nonclinical Data.'' 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.'' The Agency 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 laws. 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.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: CBER is announcing support for the current version of CDISC SEND and an update to the FDA Data Standards Catalog for the submission of nonclinical data in NDAs, ANDAs, BLAs, and certain INDs. This update does not apply to: (1) Noncommercial INDs for a product that is not intended for commercial distribution (research and investigator-sponsored INDs); (2) INDs and BLAs for devices that are regulated by CBER as biological products under section 351 of the PHS Act (42 U.S.C. 262); and (3) submissions for blood and blood components, including Source Plasma. In section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(a)), Congress granted explicit statutory authorization to FDA to specify in guidance the format for the electronic submissions required under that section.

In the **Federal Register** of December 18, 2014 (79 FR 75568), FDA announced a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data.'' The guidance is available on FDA's Study Data Standards Resources web page at *https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources.* The guidance implemented the electronic submission requirements of section 745A(a) of the FD&C Act for study data contained in NDAs, ANDAs, BLAs, applications under subsection (a) or (k) of section 351 of the PHS Act, and certain INDs. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016. The guidance states that a **Federal Register** notice will specify the transition date for all new standards (with the month and day for the transition date corresponding to March 15).

The transition date for support of CDISC SEND is March 15, 2021, for CBER. Although SEND is now supported by CBER and sponsors or applicants are encouraged to begin using it, the SEND standard will only be required in studies that start 24 months after the transition date of March 15, 2021. The Catalog will list March 15, 2023, as the ''date requirement begins'' for CBER. When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15095 Filed 7–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3004]

Use of The Seafood List To Determine Acceptable Seafood Names; Compliance Policy Guide; 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 a final guidance for FDA staff entitled ''Compliance Policy Guide Sec. 540.750

Use of *The Seafood List* to Determine Acceptable Seafood Names'' (the CPG). The CPG provides guidance for FDA staff regarding use of *The Seafood List* to determine whether a seafood name is acceptable.

DATES: The announcement of the guidance is published in the **Federal Register** on July 14, 2020.

ADDRESSES: You may submit either electronic or written comments on FDA 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–2016–D–3004 for ''Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names.'' 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 (21 CFR 10.115(g)(5).

Submit written requests for single copies of the CPG to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Bldg. 32, Rm. 4337, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

FOR FURTHER INFORMATION CONTACT: Spring C. Randolph, Center for Food Safety and Applied Nutrition (HFC–325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1421.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for FDA staff entitled ''Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names.'' The CPG updates the previously issued ''CPG Sec. 540–750—Common or Usual Names for Seafood in Interstate Commerce.'' We are issuing this CPG consistent with our good guidance practices regulation (21 CFR 10.115). The CPG represents our current thinking on acceptable names for seafood in interstate commerce. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of November 18, 2016 (81 FR 81785), we made available a draft CPG entitled ''Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names'' and gave interested parties an opportunity to submit comments by January 17, 2017, for us to consider before beginning work on the final version of the guidance. We received no comments on the draft guidance. However, we made editorial changes. The editorial changes include adding ''vernacular name'' to the categories of names found in *The Seafood List* and revising the term ''Districts'' to ''Field Offices'' to reflect an FDA organizational change. The CPG announced in this notice finalizes the draft CPG dated November 2016.

II. Electronic Access

Persons with access to the internet may obtain the CPG from FDA's Office of Regulatory Affairs CPG history page at *https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15146 Filed 7–13–20; 8:45 am]

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