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; Draft 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SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for FDA staff entitled "Compliance Policy Guide Sec. 540.750 Use of The Seafood List to Determine Acceptable Seafood Names" (the draft Compliance Policy Guide (CPG)). The draft CPG, when finalized, will provide guidance for FDA staff regarding use of The Seafood List to determine whether a seafood name is acceptable.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft CPG before we begin work on the final version of the CPG, submit either electronic or written comments on the draft CPG by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft CPG to the Food and Feed Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft 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 the draft CPG entitled "Compliance Policy Guide Sec. 540.750 Use of The Seafood List to Determine Acceptable Seafood Names." The draft CPG, if finalized, will update the previously issued "CPG Sec. 540.750--Common or Usual Names for Seafood in Interstate Commerce." The draft CPG is intended to provide guidance for FDA staff regarding use of The Seafood List to

determine whether a seafood name is acceptable. The draft CPG explains when we may consider a seafood product to be misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343). The draft CPG also contains information that may be useful to the regulated industry and to the public.

We are issuing this draft CPG consistent with our good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent 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.

II. Electronic Access

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

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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