4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0588]

Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein (the CPG). The CPG provides guidance for our staff on our labeling requirements for processed and blended seafood products made primarily with fish protein.

DATES: Submit either electronic or written comments on FDA's CPGs at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the CPG.

Submit electronic comments on the CPG to http://www.regulations.gov. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFC-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of revised Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein. We are issuing the revisions to the CPG as Level 2 guidance under our good guidance practices regulation (21 CFR 10.115). Consistent with our good guidance practices regulation, we will accept comments on the CPG at any time. The CPG represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The CPG updates previously issued CPG Sec. 540.700 Processed and/or Blended Seafood Products, which provides guidance for our staff on labeling requirements for processed and blended seafood products made primarily with fish protein. The CPG has been revised for clarity and format, including the addition of Regulatory Action Guidance and Specimen Charges sections. The CPG contains information that may be useful to the regulated industry and to the public.

II. Comments

Interested persons may submit either written comments regarding the guidance to the Division of Dockets Management (see ADDRESSES) or electronic comments regarding the guidance to http://www.regulations.gov. It is only necessary to send one set of comments.

Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either 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: December 18, 2014.

Melinda K. Plaisir,

Associate Commissioner for Regulatory Affairs,

Office of Regulatory Affairs.

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