Dated: July 14, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16447 Filed 7–17–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0265]

Compliance Policy Guide Sec. 540.575 Fish—Fresh and Frozen—Adulteration Involving Decomposition (CPG 7108.05); Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 540.575 Fish—Fresh and Frozen—Adulteration Involving Decomposition (CPG 7108.05) (CPG Sec. 540.575). This action is being taken because the guidance in CPG Sec. 540.575 relating to decomposition in fresh and frozen fish is not current.

DATES: The withdrawal is effective July 18, 2008.

ADDRESSES: Submit written requests for single copies of CPG Sec. 540.575 to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861.

A copy of CPG Sec. 540.575 may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert D. Samuels, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740–3835, 301–436–2300.

SUPPLEMENTARY INFORMATION: FDA is withdrawing CPG Sec. 540.575 because the CPG does not provide FDA staff with current agency regulatory action guidance relating to decomposition in fresh and frozen fish.

FDA has developed a draft CPG Sec. 540.370 Fish and Fishery Products—Decomposition (draft CPG Sec. 540.370) to provide guidance for FDA staff relating to decomposition in fresh and frozen fish as well as other fishery products. Draft CPG Sec. 540.370, when final, will provide FDA staff with current regulatory action guidance. Draft CPG Sec. 540.370 is available for comment, as indicated in the notice published elsewhere in this issue of the **Federal Register**.

Dated: June 30, 2008.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–16456 Filed 7–17–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0264]

Draft Compliance Policy Guide Sec. 540.370 Fish and Fishery Products — Decomposition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft Compliance Policy Guide Sec. 540.370 Fish and Fishery Products — Decomposition (the draft CPG). The draft CPG, when final, will provide FDA staff with current regulatory action guidance relating to decomposition in fish and fishery products.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit written or electronic comments on the draft CPG by September 16, 2008.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. Submit written comments on the draft CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Robert D. Samuels, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2300.

SUPPLEMENTARY INFORMATION:

I. Background

The draft CPG is intended to provide guidance to FDA staff for taking enforcement actions when fish and fishery products are adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 USC. 342(a)(3)), in that they consist in whole or in part of a decomposed substance. The draft CPG provides regulatory action guidance relating to FDA's direct reference enforcement policy on decomposition in fish and fishery products. The draft describes a two-class, pass/fail evaluating approach for detecting the presence of decomposition by sensory or chemical analysis.

The draft CPG, when final, will replace the following withdrawn and revoked CPGs relating to decomposition in fish and shrimp:

1. CPG Sec. 540.575 — Fish - Fresh and Frozen — Adulteration Involving Decomposition (CPG 7108.05). See the notice of withdrawal published elsewhere in this issue of the **Federal Register**.

2. CPG Sec. 560.650 Canned and Cooked/Frozen Shrimp — Adulterated by Decomposition (CPG 7119.13), revoked on July 5, 1995 (60 FR 35038).

3. CPG Sec. 540.400 Shrimp - Fresh or Frozen, Raw, Headless, Peeled or Breaded - Adulteration Involving Decomposition (CPG 7108.11), revoked December 24, 1996 (61 FR 67837).

The draft CPG applies a more consistent sampling and sample evaluation process to a broader spectrum of fishery products. Some of the revoked CPGs provided regulatory action guidance criteria that were based on a three-class organoleptic evaluation methodology for which gradations of decomposition had to be distinguished and more advanced decomposed portions were weighted more heavily than other decomposed portions in formulating a regulatory position. FDA expects that the two-class, pass/fail organoleptic methodology is easier to implement and provides more consistency in results.

The draft CPG is being issued as Level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent FDA's current thinking regarding enforcement criteria relating to the adulteration of fish and fishery products due to the presence of