document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 9, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–15898 Filed 7–17–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0397]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit written or electronic comments on the collection of information by September 16, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2 (d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	1	1	1	10	10

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 14, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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

BILLING CODE 4160–01–S

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]

BILLING CODE 4160–01–S

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