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]

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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

decomposition. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

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*.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs home page. It may be accessed at *http://www.fda.gov/ora* under ''Compliance Reference.''

Dated: June 30, 2008.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–16453 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–N–0038]

Animal Models for the Treatment of Acute Radiation Syndrome; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, and the National Institutes of Health, National Institute of Allergy and Infectious Diseases, are announcing a public workshop entitled ''Animal Models for the Treatment of Acute Radiation Syndrome (ARS).'' The purpose of the public workshop is to discuss issues that should be considered when developing animal models to assist in developing and demonstrating the efficacy of products intended for treatment of ARS.

Date and Time: The public workshop will be held on September 17, 2008, from 8:30 a.m. to 5:30 p.m., and on September 18, 2008, from 8:30 a.m. to 1 p.m.

Location: The public workshop will be held at the Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079; e-mail: *CBERTraining@fda.hhs.gov* (Subject line: Animal Models for ARS Workshop).

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 25, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m. If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: There are no approved medical products with an indication for treatment of ARS. The public workshop will provide the opportunity to explore current research involving animal models for the development of treatments for ARS, and to determine what areas need further research. There will be feature presentations by experts from government, academia, and medicine. The first day of the workshop will include presentations on the effects of radiation and the management of patients with ARS, and a discussion of the application of the animal rule to therapies for ARS. Both days of the workshop will examine the challenges faced when using animal models to mimic radiation exposure scenarios and will include panel discussions that will focus on various animal models and their application to the different syndromes of ARS.

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 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16461 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–N–0038]

Rapid Methods for Detecting Mycoplasma Contamination in the Manufacture of Vaccines, Including Pandemic Influenza Vaccines, and Other Biological Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Rapid Methods for Detecting Mycoplasma Contamination in the Manufacture of Vaccines, Including Pandemic Influenza Vaccines, and Other Biological Products.'' The purpose of the public workshop is to provide a forum on recent scientific and technical achievements in the development of rapid methods for mycoplasma testing during the manufacture of vaccines and other biological products. Such discussion may help to assess how these methods compare with currently used methods. Expedited manufacture may be of particular importance to public health during an influenza pandemic.

Date and Time: The public workshop will be held on September 22, 2008, from 8:30 a.m. to 5 p.m., and September 23, 2008, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, e-mail: *CBERTraining@fda.hhs.gov* (Subject line: Mycoplasma Workshop).