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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-~~F~~-0072]

Guidance for Industry: Fish and Fisheries Products Hazards and Controls Guidance Third Edition June 2001: Letter to Seafood Processors that Purchase Grouper, Amberjack, and Related Predatory Reef Species Captured in the Northern Gulf of Mexico

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001: Letter to Seafood Processors that Purchase Grouper, Amberjack and Related Predatory Reef Species Captured in the Northern Gulf of Mexico." The guidance sets forth the agency's recommendations for ensuring the safety of grouper, amberjack, and related predatory reef species captured in the northern Gulf of Mexico with respect to ciguatera fish poisoning (CFP). The guidance is in response to recent cases of CFP that have occurred in the United States.

DATES: This guidance is final [*insert date of publication in the* **Federal Register**]. Submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written comments on the guidance 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:/*

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/*www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 301–436–2651. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Byron Truglio, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1420.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled "Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001: Letter to Seafood Processors that Purchase Grouper, Amberjack and Related Predatory Reef Species Captured in the Northern Gulf of Mexico." The purpose of the document is to revise guidance provided to industry for processing potentially ciguatoxic fish species captured in the northern Gulf of Mexico which are subject to the provisions of the Hazard Analysis and Critical Control Point regulation for seafood (21 CFR part 123) (the seafood HACCP regulation). This guidance is in response to recent CFP outbreaks that have been traced to fish captured in an area in the United States where ciguatera was previously extremely rare. CFP is caused by consumption of fish that have eaten toxic marine algae directly or that have eaten other toxin-contaminated fish. CFP can result in gastrointestinal, cardiovascular, and neurological symptoms. In severe cases, recurring neurological symptoms can persist for months to years.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g) (2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the recent cases of CFP. The guidance represents the agency's current thinking on CFP from fish in the Northern Gulf of Mexico. 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. This guidance modifies our previous guidance on this subject (See "Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001" *http://www.cfsan.fda.gov/guidance.html*). The recommendations in this guidance only pertain to grouper, amberjack, and related predatory reef species associated with CFP that have been captured in the Northern Gulf of Mexico. This guidance does not pertain to other species of fish that have not been associated with CFP.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. 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. The guidance and 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 Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: 1/31/08

January 31, 2008.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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