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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

Guidance for Industry; Implementation of the Federal Food, Drug, and Cosmetic Act Regarding the Use of the Term "Catfish;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry; Implementation of Section 403(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(t)) Regarding the Use of the Term 'Catfish.'" Section 10806 of the Farm Security and Rural Investment Act of 2002 amends the Federal Food, Drug, and Cosmetic Act (the act) to provide that a food shall be deemed to be misbranded "[i]f it purports to be or is represented as catfish, unless it is fish classified within the family *Ictaluridae*." This guidance assists importers and domestic distributors of fish previously called "catfish" in selecting a new common or usual name that is consistent with the act.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Submit written requests for single copies of this guidance to the Office of Seafood (HFS-400), Center for Food Safety and Applied Nutrition, Food and

Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

Include a self-adhesive address label to assist that office in processing your request, or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

FOR FURTHER INFORMATION CONTACT: Spring C. Randolph, Center for Food Safety and Applied Nutrition (HFS-415), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2303, FAX 301-436-2599.

SUPPLEMENTARY INFORMATION:

I. Background

On May 13, 2002, Public Law 107-171, entitled the Farm Security and Rural Investment Act of 2002 (FSRIA), became law. Section 10806 of the FSRIA amends the food misbranding provision in section 403 of the act (21 U.S.C. 343) to provide that a food shall be deemed to be misbranded “[i]f it purports to be or is represented as catfish, unless it is fish classified within the family *Ictaluridae*.” This amendment overrides prior guidance that lists fish other than those from the family *Ictaluridae* as fish bearing the acceptable name “catfish.”

The guidance document states that, consistent with the amendment to section 403 of the act, importers, domestic distributors, and sellers of fish in interstate commerce bearing the term “catfish,” that are not classified within the family *Ictaluridae*, may no longer use the term “catfish” on labeling, in whole or as part of their common or usual name. This guidance relates to all fish that are distributed in interstate commerce, including imports.

The document discusses how to apply FDA's common or usual name "general principles" regulation (21 CFR 102.5) in determining a name that can be used for the fish once known as "catfish," but for which that name can no longer be used.

This guidance represents the agency's current thinking on acceptable common or usual names for fish bearing the name "catfish" that are not from the family *Ictaluridae*. 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 is a level 1 guidance issued consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115 (21 CFR 10.115)). Consistent with GGPs, the agency is soliciting public 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. Section 403(t) of the act is now in effect and must be implemented immediately. Thus, FDA is making the guidance effective immediately.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: November 15, 2002.



Margaret M. Dotzel,
Assistant Commissioner for Policy.

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