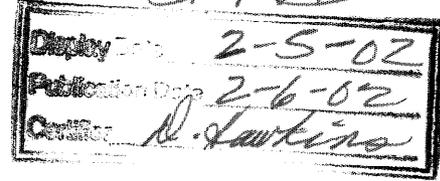


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0032]



Guidance for Industry; Implementation of Section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, Pub. L. No. 107-76, § 755 (2001) Regarding Common or Usual Names for 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 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, Pub. L. No. 1076-76, § 755 (2001) regarding Common or Usual Names for Catfish." Section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, provides that FDA may not spend any of its 2002 appropriation to allow admission of fish or fish products labeled in whole or in part with the term "catfish" unless the fish are from the *Ictaluridae* family. This guidance discusses how FDA plans to exercise enforcement discretion with regard to certain fish whose common or usual name contains the term "catfish."

DATES: Submit written or electronic comments at any time.

ADDRESSES: 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. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the guidance may be sent.

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Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, 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

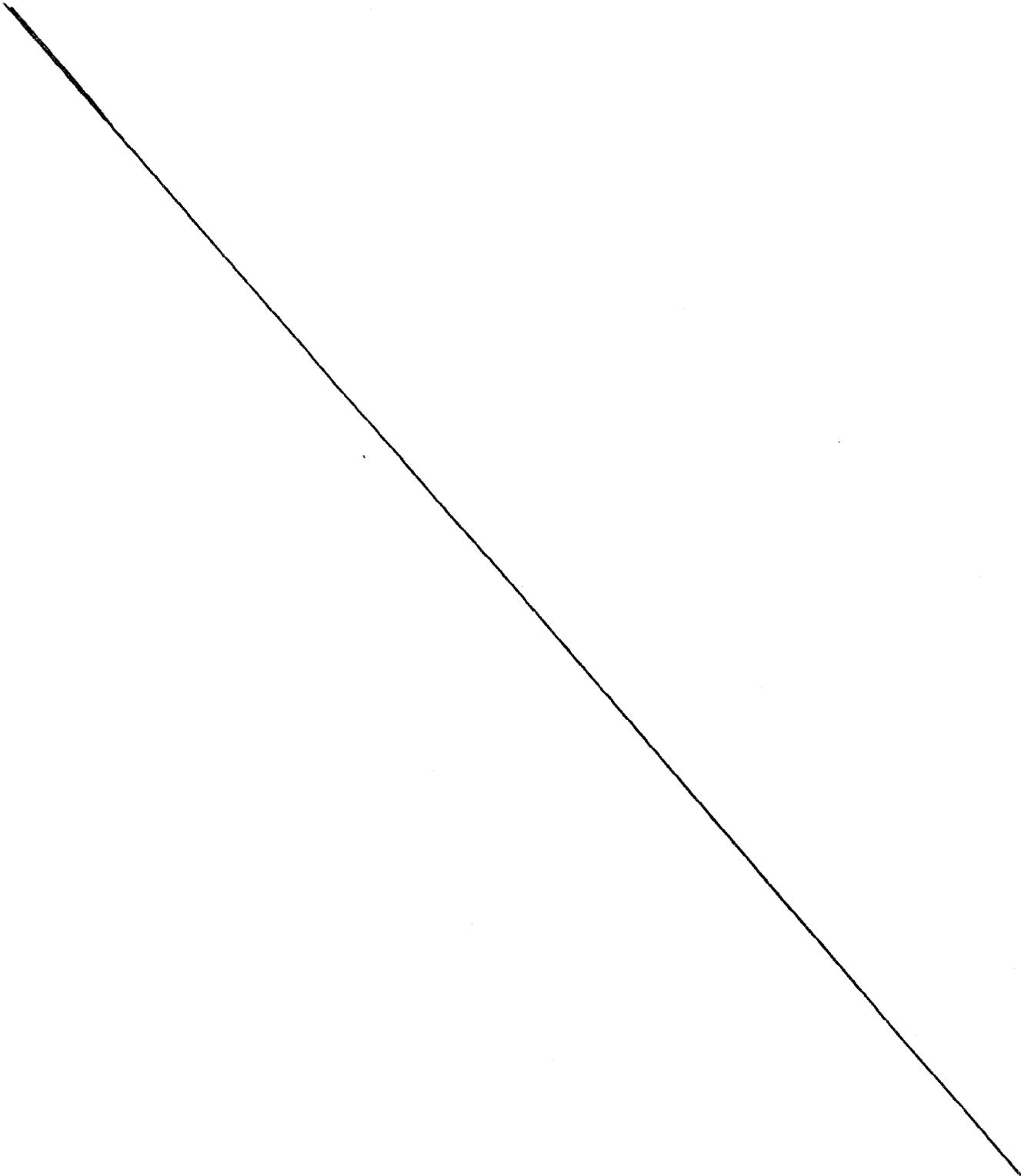
FDA is announcing the availability of guidance for industry implementing section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002 (Public Law 107-76, § 755 (2001)), which provides that FDA may not spend any of its 2002 appropriation to allow admission of fish or fish products labeled in whole or in part with the term “catfish” unless the fish are from the *Ictaluridae* family. This guidance discusses how FDA plans to exercise enforcement discretion with regard to certain fish whose common or usual name contains the term “catfish”.

This guidance is a level 1 guidance issued consistent with FDA’s regulation on good guidance practices (GGPs) (§ 10.115 (21 CFR 10.115)) relating to the development, issuance, and use of guidance documents. 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. FDA’s 2002 appropriation law was enacted on November 28, 2001, and section 755 is now in effect and must be implemented immediately. There is a need for guidance to help effect such implementation. Thus, FDA is making the guidance effective immediately.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments on the guidance. Two copies of any comments are to be

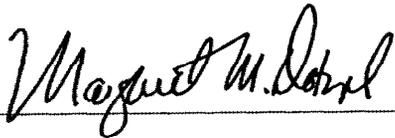
submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

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

Dated: January 18, 2002



Margaret M. Dotzel
Associate Commissioner for Policy

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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