

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0137]

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Certifier R. LEDESMA

**Regulatory Procedures Manual; Chapter 9, Imports, Subchapter: Guidance
Concerning Recommending Customs' Seizure and Destruction of Imported Human
and Animal Food That Has Not Been Reconditioned; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft procedural guidance entitled "Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned." This draft guidance will provide FDA field offices with procedures for recommending seizure and destruction of foods that pose a significant risk to public health.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*], to ensure adequate consideration of the comments in the preparation of the final guidance. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph McCallion, Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6553, FAX 301-594-3787, email: jmccalli@ora.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 1999, the Secretaries of Health and Human Services and Treasury began development of new operational procedures to protect consumers from unsafe imported food. A plan, announced in December 1999, was developed by FDA and the U.S. Customs Service (Customs) to prevent distribution of unsafe imported food by destroying food products that pose a significant risk to public health. This initiative optimizes the statutory authorities and resources available to FDA and Customs.

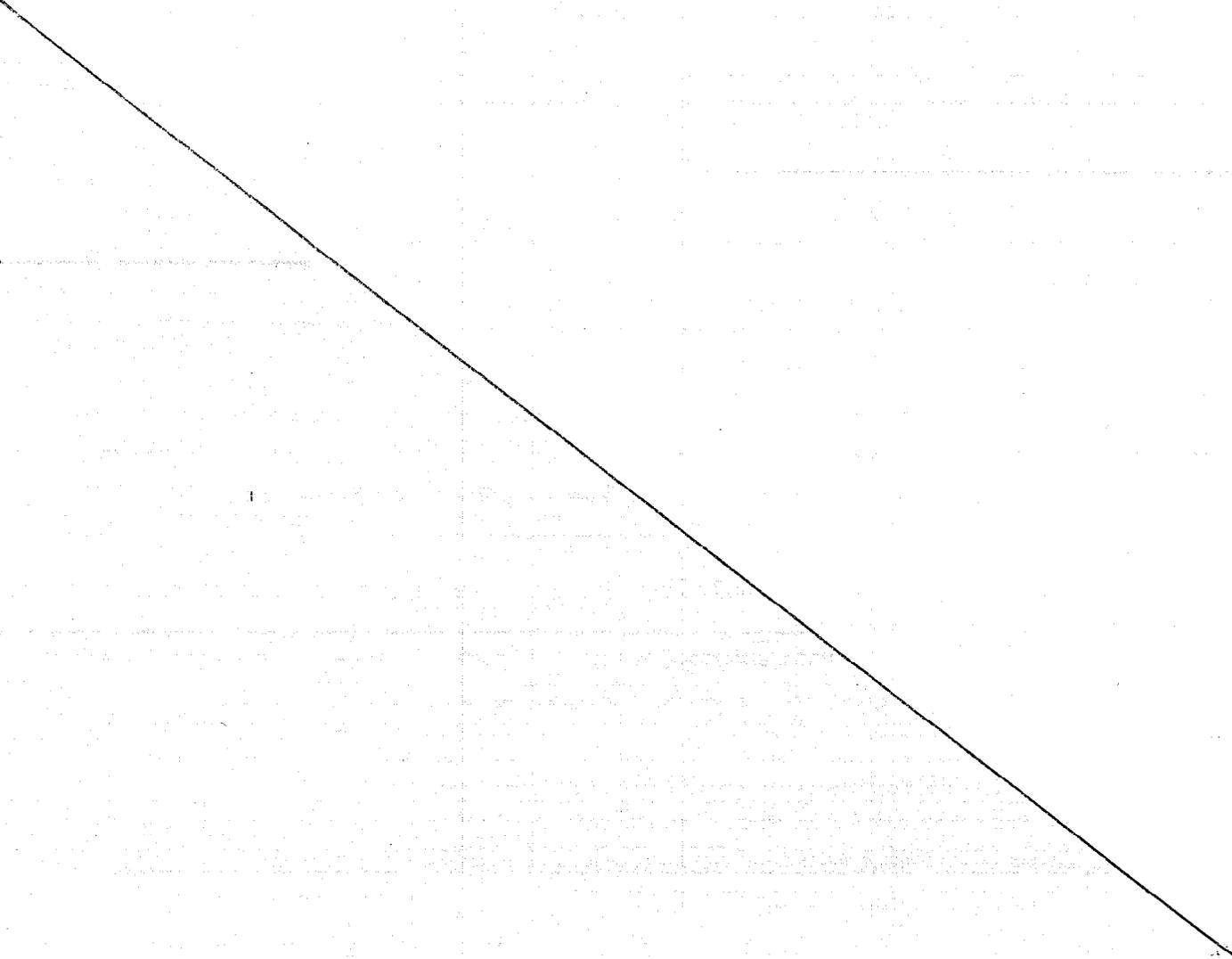
Food products refused entry into the United States may be offered subsequently for re-importation by importers who choose to circumvent the import regulatory system or by importers who are unaware of the previous refusal. FDA and Customs have worked together on numerous cases to seize and destroy unsafe imported products regulated by FDA. This draft guidance serves to delineate FDA's responsibilities for collecting information, analyzing public health risk, recommending seizure, and coordinating destruction of the violative imported food by Customs. The purpose of this guidance is to ensure that imported food that poses a significant risk to public health is not distributed or exported and subsequently re-entered into U.S. commerce.

The draft guidance entitled "Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned" is level 1 guidance that is being distributed for comment in accordance with FDA's regulation on good guidance practices (21 CFR 10.115) relating to the development, issuance, and use of guidance documents. The draft guidance represents the agency's current thinking on this topic. 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance 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/](http://www.cfsan.fda.gov/~dms/guidance.html)

[~dms/guidance.html](http://www.cfsan.fda.gov/~dms/guidance.html).

Dated: 4/5/02
April 5, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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