

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0554]

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Certifier A. Corbin

Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) Sec. 110.310 entitled “Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” The original CPG, which was published in the **Federal Register** of December 15, 2003 (68 FR 69708), provides written guidance to FDA’s and Customs and Border Protection’s (CBP’s) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency’s implementing regulations, which require prior notice for all food imported or offered for import into the United States. The CPG has been revised to provide additional guidance to FDA and CBP staff regarding how to address food that is imported or offered for import for noncommercial purposes with a noncommercial **shipper**. The revised CPG also reflects a change in the date of Stage III enforcement guidance for the interim final rule from May 13, 2004, to June 4, 2004.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Domenic Veneziano, Office of Regulatory Affairs (HFC-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703-621-7809.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of revised CPG Sec. 110.310 entitled “Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” This revised guidance is issued with CBP concurrence and explains to FDA and CBP staff the new FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (68 FR 58974, October 10, 2003 (codified at 21 CFR 1.276 through 1.285)). FDA has revised the original CPG, which was published on December 15, 2003 (68 FR 69708), to

additional guidance regarding food imported or offered for import for noncommercial purposes with a noncommercial shipper. The CPG explains that a “non-commercial purpose” generally exists when the food is purchased or otherwise acquired by an individual for nonbusiness purposes and the shipper is the individual (i.e., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for nonbusiness purposes, i.e., not for sale, resale, barter, business use, or commercial use). With respect to these food imports, FDA intends to focus its efforts on education through March 2005 (or shortly thereafter, depending on the date of issuance of the final rule). Examples of foods imported or offered for import that may be covered by this noncommercial category include the following:

- Food in household goods, including military, civilian, governmental agency, and diplomatic transfers;
- Food purchased by a traveler and mailed or shipped to the traveler’s U.S. address by the traveler;
- Gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment. The revised CPG also corrects the date of Stage III enforcement guidance for the interim final rule from May 13, 2004, to June 4, 2004, per the Automated **Broker** Interface (ABI) Administrative Message 04–1406 issued by CBP on June 3, 2004.

FDA is issuing this document as level 1 guidance consistent with FDA’s good guidance practices regulation § 10.115 (21 CFR 10.115). The revised CPG Sec. 110.310 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. Under section 307 of the

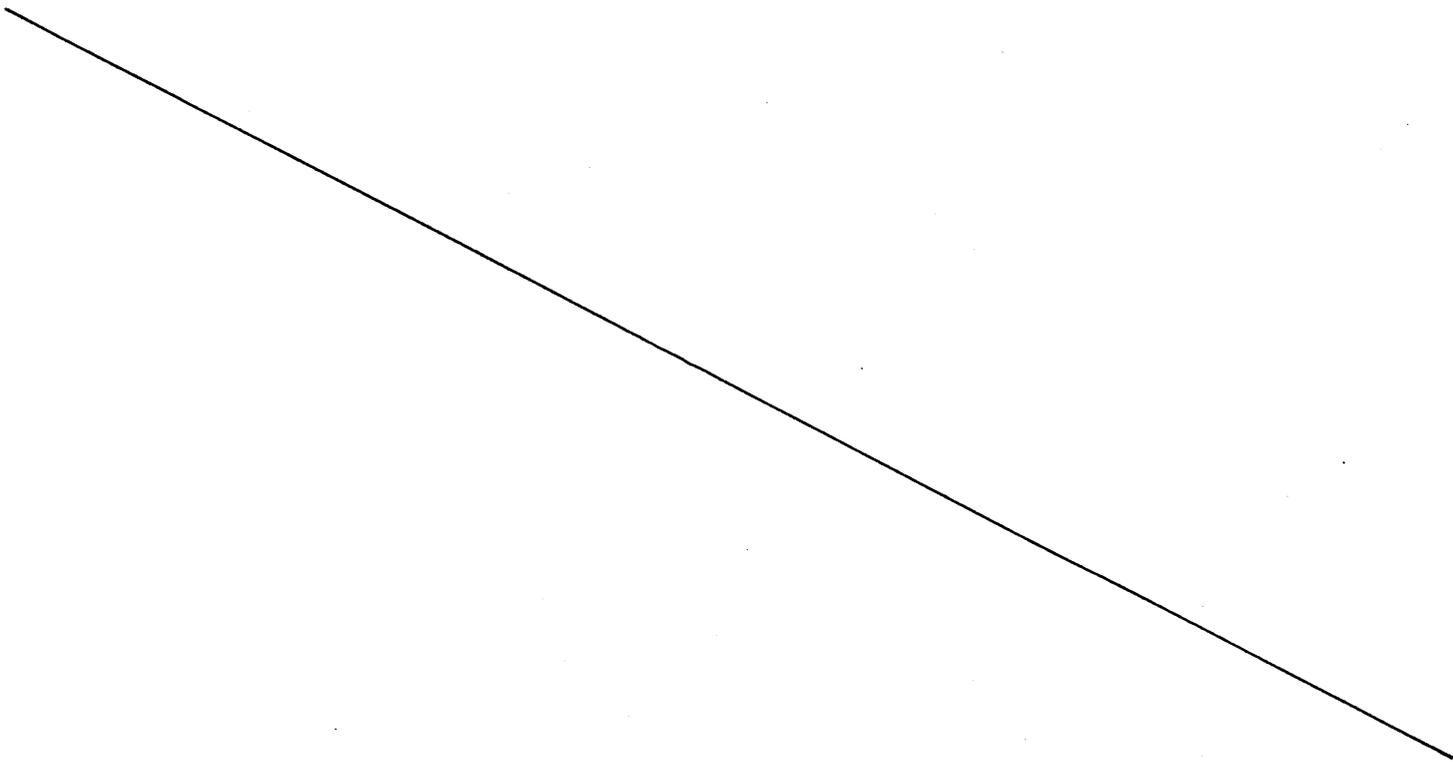
Bioterrorism Act, the prior notice requirements were effective December 12, 2003, making it urgent that the agencies explain how they intend to enforce those requirements. Moreover, as a result of the revision to the CPG, FDA's policies are generally less burdensome for food imported or offered for import for noncommercial purposes with a noncommercial shipper.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, 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. 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.

11. Electronic Access

An electronic version of this guidance is available on the Internet at <http://www.fda.gov/ora> under "Compliance References."



Dated: 6/24/04

June 24, 2004.



John M. Taylor,
Associate Commissioner for Regulatory Affairs.

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