

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003D-0554]

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Certifier L. CLAWSON  
DDM

**Revised 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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft revisions to 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 CPG provides written guidance to FDA and Customs and Border Protection (CBP) 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 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 specific situations covering routine shipments of food that are transported through the United States, arriving from and exiting to the same country, and regarding the Harmonized Tariff Schedule (HTS) code that is part of the planned shipment information.

**DATES:** The draft revisions to the CPG are found in section C, items 7 and 8. Submit written or electronic comments concerning the draft revisions to the

CPG by *[insert date 30 days after date of publication in the Federal Register]*.

You may submit written or electronic comments on the other sections of the CPG at any time.

**ADDRESSES:** Submit written requests for single copies of the revised 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 a draft revision to 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 (21 CFR part 1.276 through 1.285).

FDA is considering taking these steps while the prior notice final rule is under development to provide additional flexibility in filing prior notice when, due to the geography, the only practical transportation route available for the shipment is through the United States and when there is a prior notice violation because the prior notice does not include the 6-digit HTS code for the article of food.

FDA is issuing the revisions to the CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). The draft revisions to the CPG represent the agency's current thinking on its enforcement policy concerning prior notice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The draft revisions to the CPG are found in section C, items 7 and 8.

## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. Submit a single copy of electronic copies or two 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 revised CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## **III. Electronic Access**

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

Dated: 2/24/05  
February 24, 2005.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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