

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2007-D-0487] (formerly Docket No. 2007D-0260)

Draft Compliance Policy Guide; "Sec. 110.310 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 draft Compliance Policy Guide (CPG) entitled "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." The draft CPG 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 food imported or offered for import into the United States. The final rule entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" is published elsewhere in this issue of the **Federal Register**.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit written or electronic comments concerning the draft CPG by December 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861.

Submit written comments on the draft CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866-521-2297.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft CPG entitled "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." This guidance is issued with CBP concurrence and explains to FDA and CBP staff the 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 1.276 through 1.285). The final regulation requiring that FDA receive prior notice of the importation of food is published elsewhere in this issue of the **Federal Register** and will take effect on May 6, 2009.

FDA is issuing this CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized,

will 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. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic copies or two paper 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 draft CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

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

Dated: October 10, 2008.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

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