

Dms

Display Date 12.11.03 @ 8:45pm

Publication Date 12.15.03

Certifier G. Penley

BILLING CODE 4160 - 01 - P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0554]

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 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'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, beginning on December 12, 2003, prior notice for all food imported or offered for import into the United States.

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

cf0341

2003D-0554

NAD 1

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 (HFA-305), Food and Drug Administration, 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: Joe McCallion, Office of Regulatory Affairs, Food and Drug Administration, 301-443-6553 or Ted Poplawski, Office of Regulatory Affairs, Food and Drug Administration, 301-443-6553.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of CPG Sec. 110.310 entitled “Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” This guidance is issued jointly with CBP 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, beginning on December 12, 2003, prior notice to FDA of all food imported or offered for import into

the United States. (68 FR 58974 (Oct. 10, 2003) (to be codified at 21 CFR 1.276 - 1.285)).

FDA is issuing this document as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The 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 are effective December 12, 2003, making it urgent that the agencies explain how they intend to enforce those requirements.

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.

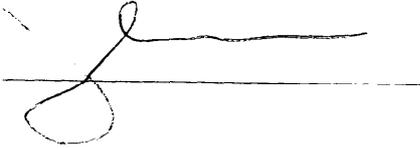
III. Electronic Access

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

December 10, 2003

4

Dated:

A handwritten signature in black ink, consisting of a large loop on the left and a horizontal line extending to the right, crossing the horizontal line of the 'Dated:' label.

John M. Taylor, III
Associate Commissioner for Regulatory Affairs
Food and Drug Administration

Dated: _____

Jayson P. Ahern
Assistant Commissioner, Office of Field Operations
U.S. Customs and Border Protection

CERTIFICATE OF TRUE
COPY OF THE ORIGINAL

Glenn Lundy