/www.fda.gov/cber/guidelines.htm or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 1, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

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) 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 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 prior notice submissions that do not provide information about the identity of the manufacturing facility of food no longer in its natural state, articles of food imported or offered for import by express courier, prior notice submission time frames, and lastly, gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes.

DATES: This guidance is final and effective on November 8, 2004. 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 (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 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 section 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 part 1, subpart I, 1.276 through 1.285)). The original CPG was published December 2003, and was revised June 2004 to include additional guidance regarding food imported or offered for import for noncommercial purposes with a noncommercial shipper. In August 2004, the CPG was revised to provide additional guidance regarding food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale. We (FDA) also revised the CPG in August to extend until November 1, 2004,[1] our enforcement discretion policy concerning certain violations related to the registration number of the manufacturing facility and the shipper, the airway bill number or bill of lading number, and the name and address of the ultimate consignee.

A. Identity of the Manufacturer

FDA is revising the CPG to provide additional guidance regarding prior notice submissions that do not provide information to identify the manufacturing facility of an article of food (i.e., the specific facility that manufactured the food). This information is required for food that is no longer in its natural state. FDA and CBP intend to exercise broad enforcement discretion when this information is required but is not provided, under the following circumstances:

(1) If, after a good faith effort, the person submitting prior notice does not know the registration number of the facility that manufactured the food and the facility is required to be registered, that person instead provides the name and full address of the facility that manufactured the food.

(2) If, after a good faith effort, the person submitting prior notice does not know either the registration number or the name and full address of the facility that manufactured the food, that person instead provides the name and full address of the headquarters of the facility that manufactured the food.

(3) If, after a good faith effort, the person submitting prior notice does not know either the information described in (1) about the facility that manufactured the food, or in (2) about the headquarters of the facility that manufactured the food, that person instead provides the name and full address of the invoicing firm.

FDA is taking these steps to provide additional flexibility in filing prior notice to various kinds of importers while the final prior notice rule is under development. However, if the facility that manufactured the food is a foreign facility that is required to be registered and either its registration number is not provided or the name and address of a different facility (i.e., the manufacturing facility's headquarters or the invoicing firm) is provided, then it will be more difficult and/or may take more time for FDA and CBP to verify the identity of the manufacturing facility and its registration status and to determine whether the article of food is subject to being held under section 801(l) of the Federal Food, Drug, and Cosmetic Act (the act). As a result, if an article of food is imported or offered for import with the manufacturer's name and full address, or the name and address of the manufacturing facility's headquarters or the invoicing firm, instead of the manufacturer's name and registration number, and if FDA has concerns that the food may pose a serious health threat, then the food may be delayed at the port of arrival until the verification is completed. Moreover, as with other types of prior notice violations, FDA may consider the failure to provide required information about the manufacturer as a factor in determining whether and where to examine the article of food. Under all circumstances,

[1] This date was extended to November 7, 2004.

FDA and CBP intend to reject prior notice submissions unless the prior notice includes a valid registration number or an appropriate reason code selected from among those provided in the Prior Notice System Interface (PNSI) and the Automated Broker Interface of the Automated Commercial System (ABI/ACS). Rejected submissions are not confirmed for FDA review.

This change to our enforcement discretion policy pertains to all prior notice submissions, including but not limited to the following: (1) Food carried by or otherwise accompanying an individual that is not for personal use; (2) food arriving by international mail that is not food imported or offered for import for noncommercial purposes with a noncommercial shipper; and (3) food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption or resale.

Please note that the enforcement discretion policy for identity of manufacturer does not apply to the requirement to provide the registration number assigned to the shipper's facility that is associated with the article of food, if applicable (see 21 CFR 1.281(a)(9) and (b)(8)).

B. Express Courier

FDA also is revising the CPG to provide additional guidance regarding food imported or offered for import by an express courier. The term ''express courier'' is being used as the term ''express consignment operator or carrier'' is defined by CBP at 19 CFR 128.1(a) and includes, for example, Federal Express and United Parcel Service. If prior notice is inadequate because it does not include the required anticipated arrival information and/or planned shipment information, FDA and CBP should typically consider not taking any regulatory action if the article of food is imported or offered for import via an express courier, the person submitting prior notice is not the express courier, prior notice is submitted via the PNSI, and the prior notice includes the shipment's tracking number instead of the required anticipated arrival information and/or planned shipment information. CBP and the Transportation Security Administration have advised express couriers to not reveal to the public certain arrival information. FDA and CBP believe that the tracking number instead of the planned shipment information may provide a means of more accurately determining the arrival information and intend to explore this option while developing the final rule.

C. Time Frame

FDA is revising the CPG to allow prior notice to be submitted more than 5, but less than 10 days before the anticipated date of arrival of the food at the anticipated port of arrival (see 21 CFR 1.279(b)). FDA will typically consider not taking any regulatory action if there is a prior notice violation because the prior notice was submitted more than 5 calendar days before the anticipated date of arrival, provided that the following occurs: (1) The prior notice was submitted less than 10 calendar days before the anticipated date of arrival; and (2) the prior notice was submitted through the PNSI.

FDA is taking these steps to provide additional flexibility in submitting prior notice while the final prior notice rule is under development. FDA and CBP believe that 10 days before the anticipated date of arrival of the food is sufficient time for a carrier to assure that prior notice has been confirmed for FDA review before loading the food. FDA also believes that this extended period will not impact its ability to receive, review, and respond to prior notice submissions of food, although a time period greater than 10 days may be problematic. FDA has limited this guidance to prior notice submissions by PNSI because of the way the ABI/ACS is programmed; when prior notice is submitted through ABI/ACS, the prior notice confirmation number cannot be provided more than 5 calendar days before the anticipated date of arrival.

FDA recognizes that if any information in the prior notice submitted via PNSI changes except the anticipated arrival information, the estimated quantity, or the planned shipment information, after FDA has confirmed the prior notice submission for review, the prior notice should be cancelled and must be resubmitted.

D. Gift Pack Purchased or Otherwise Acquired by An Individual and Imported or Offered for Import for Nonbusiness Purposes

Another change to the CPG relates to gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes. FDA and CBP staff should typically consider not taking regulatory action if there is a prior notice violation because a single prior notice is submitted for a gift pack and the identity of the facility that packed the gift pack is submitted instead of the identity of the manufacturer, provided that the gift pack is purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes. The policy applies irrespective of where the individual who purchased or otherwise acquired the gift pack lives, irrespective of the type of carrier, and irrespective of whether it involves a commercial or noncommercial shipper. The CPG provides information to FDA and CBP staff about what constitutes a nonbusiness purpose, the identity of a gift pack by FDA product code and examples of gift packs.

E. Policies Contained in the Previous Version of the CPG

Please note that beginning November 8, 2004, FDA and CBP staff should typically consider taking enforcement action including refusal and/or assessment of Civil Monetary Penalties when the prior notice is inadequate, except the circumstances described in the revised CPG. FDA's enforcement discretion policies in the version of the CPG issued in August 2004 concerning certain violations related to the registration number of the shipper, the airway bill number or bill of lading number, and the name and address of the ultimate consignee will end on November 7, 2004, with the exception of the airway bill number or bill of lading number for prior notice submissions by individuals who are not the express courier (see section I.B of this document). Therefore, beginning November 8, 2004, FDA and CBP staff should typically consider taking enforcement action including refusal and/or assessment of Civil Monetary Penalties when the prior notice is inadequate because the registration number for the shipper is required but is not provided; the airway bill number or bill of lading number is not provided or is invalid (except as noted in section I.B of this document); or the name and address of the ultimate consignee is inaccurate because it contains the name and address of the express consignment operator or consolidator instead of the ultimate consignee.

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 section 110.310 is being implemented on November 8, 2004, without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. This document revises policies that are due to take effect on November 8, 2004, so it is urgent that the agencies explain their new enforcement policies before that date.

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 the revised CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: October 28, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–24872 Filed 11–4–04; 8:57 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0562]

Revised Compliance Policy Guide Sec. 110.300—Registration of Food Facilities 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. 110.300 entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (registration CPG). The revised CPG provides written guidance to FDA's staff on enforcement of section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which requires, beginning on December 12, 2003, registration with FDA for all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

DATES: This revised CPG 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 revised CPG 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 revised CPG may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised CPG.

Submit written comments on the revised 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

Food for human consumption: Judith Gushee, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 301–436–2417.

Food for animal consumption: Isabel Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 301–827–0175.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of revised CPG Sec. 110.300 entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (registration CPG). This revised CPG outlines for FDA staff the agency's policy on enforcement of section 305 of the Bioterrorism Act and its implementing regulation ((68 FR 58894, October 10, 2003); (codified at 21 CFR part 1, subpart H, 1.225 through 1.243)). The Bioterrorism Act and subpart H require that, beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must be registered with FDA.

I. Background

On December 19, 2003, FDA issued CPG Sec. 110.300 (the December CPG). The December CPG states that for domestic firms, FDA would initially plan to focus the agency's efforts on educating and otherwise informing the industry on how to comply with the registration of food facilities interim final rule, and that thereafter FDA would enforce the registration provision as appropriate in each situation. We set out in the Regulatory Action Guidance section our enforcement approach.

For foreign facilities, the December CPG referred to the policies set out in CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (the prior notice CPG).

II. Revised CPG Sec. 110.300

FDA is making only one substantive change in the registration CPG. Specifically, the revised CPG provides that, on November 8, 2004, FDA is fully implementing the agency's enforcement policy for domestic food facilities, which was set out in the Regulatory Action Guidance section of the December CPG. For foreign facilities, the registration CPG continues to state that generally, the registration requirement for the facilities of foreign manufacturers and shippers will be enforced in accordance with the policies set out in the prior notice CPG. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for the revision to the prior notice CPG, which is being issued under § 10.115(g)(2) (21 CFR 10.115(g)(2)) as level 1 guidance that is effective November 8, 2004.

FDA is also issuing the revised registration CPG as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115). Revised CPG Sec. 110.300 is being implemented immediately without prior public comment, under § 10.115(g)(2), because FDA has determined that prior public participation is not feasible or appropriate. Revision of FDA's prior notice enforcement policy directly affects the agency's enforcement of the registration requirement for foreign manufacturers and shippers. Given this relationship, it is appropriate that FDA coordinate announcement and implementation of the agency's revised enforcement policy for food facilities registration with the agency's comparable actions for the prior notice of imported food requirement.

III. 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 comments 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 guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.