

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01D-0583]

#### Food Security Preventive Guidances; Availability

**AGENCY:** Food and Drug Administration, HHS

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of two revised, final guidance documents related to food security entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance," and "Importers and Filers: Food Security Preventive Measures Guidance." The revised, final guidance document entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" is designed as an aid to operators of food establishments (for example, firms that produce, process, store, repack, re-label, distribute, or transport food or food ingredients). It identifies the kinds of preventive measures that operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal or terrorist actions. The revised, final guidance document entitled "Importers and Filers: Food Security Preventive Measures Guidance" is designed as an aid to operators of food importing establishments, storage warehouses, and filers. It identifies the kinds of preventive measures that they may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal or terrorist actions.

**DATES:** You may submit written or electronic comments on either guidance document at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" or "Importers and Filers: Food Security Preventive Measures Guidance" to John Kvenberg, Office of Compliance, Center for Food Safety and Applied Nutrition (HFS-600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the guidance documents to Dockets Management Branch (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 documents.

**FOR FURTHER INFORMATION CONTACT:** John Kvenberg, Center for Food Safety and Applied Nutrition (HFS-600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2359, e-mail: [jkvenberg@cfsan.fda.gov](mailto:jkvenberg@cfsan.fda.gov) or Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS-400), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2300, e-mail: [dkraemer@cfsan.fda.gov](mailto:dkraemer@cfsan.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Operators of food establishments, food importing establishments, and filers are encouraged to review their current security procedures and controls in light of the potential for tampering or other malicious, criminal or terrorist actions and make appropriate improvements.

The revised, final guidance document entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" aids operators of food establishments (i.e., firms that produce, process, store, repack, re-label, distribute, or transport food or food ingredients). It is relevant to all sectors of the food system, including farms, aquaculture facilities, fishing vessels, producers, transportation operations, processing facilities, packing facilities, and warehouses. It is not intended as guidance for retail food store or food service establishments.

The revised, final guidance document entitled "Importers and Filers: Food Security Preventive Measures Guidance" aids operators of food importing establishments, storage warehouses, and filers.

Both guidance documents identify the kinds of preventive measures that operators can take to minimize the risk that food under their control will be subject to tampering or to criminal or terrorist actions. They take the operator through each segment of the farm-to-table system that is within their control, in order to minimize the risk of tampering or of criminal or terrorist action at each segment. Implementation of these measures requires commitment from both management and employees to be successful and, therefore, both should participate in their development and review.

Both guidance documents are level 1 guidances issued consistent with FDA's good guidance practices regulation (GGPs) (§ 10.115 (21 CFR 10.115)) relating to the development, issuance, and use of guidance documents.

On January 9, 2002, FDA announced the availability of two guidance documents in the **Federal Register** (67 FR 1224). At that time, the two documents were entitled "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance," and "Importers and Filers: Food Security Preventive Measures Guidance." The agency solicited public comment, but indicated that the two guidance documents would be implemented immediately in accordance with § 10.115(g)(2). The two guidance documents were prompted by the tragedies of September 11, 2001, and the resulting scrutiny of, and interest in, food safety and security that followed.

FDA received 11 written comments and 5 electronic comments on the 2 guidance documents. The agency reviewed and evaluated these comments and modified the guidance where appropriate. A number of the comments urged FDA to issue guidance that was specifically tailored for the retail food store and food service sector. FDA agrees with the request. Accordingly, the draft guidance directed toward retail food stores and food service establishments is provided in "Retail Food Store and Food Service Establishments: Food Security Preventive Measures Guidance," the availability of which is being announced elsewhere in this issue of the **Federal Register**. In that same notice, FDA is also announcing the availability of a draft guidance entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance." The original two guidance documents are now being made available as revised, final guidance. They no longer apply to retail food stores or food service establishments.

The two final guidance documents represent the agency's current thinking on appropriate measures that can be taken by food establishments, importing establishments and filers to minimize the risk that food under their control will be subject to tampering or other malicious, criminal or terrorist actions. They do not create or confer any rights for, or on, any person and do not operate to bind FDA or the public.

##### II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the

guidance documents at any time. Two copies of any mailed comments should be submitted, 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Copies of these guidance documents also are available on the Internet at <http://www.cfsan.fda.gov/guidance.html>.

Dated: March 14, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03D-0092]

#### Food and Cosmetic Security Guidances; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document related to food security entitled "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance" and a draft guidance document related to cosmetics security entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance." The draft guidance document entitled "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance" is designed as an aid to operators of retail food stores and food service establishments (i.e., for example, bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for homebound persons, mobile food carts, restaurants, and vending machine operators). It identifies the kinds of preventive measures that operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal

or terrorist actions. The draft guidance document entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" is designed as an aid to operators of cosmetics establishments (i.e., firms that process, store, repack, relabel, distribute, or transport cosmetics or cosmetics ingredients). It identifies the kinds of preventive measures that operators may take to minimize the risk that cosmetics under their control will be subject to tampering or other malicious, criminal or terrorist actions.

**DATES:** Submit written or electronic comments on the draft guidance documents by May 20, 2003, to ensure their adequate consideration in the preparation of revised guidances, if warranted. However, you may submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance," or "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" to John Kvenberg, Center for Food Safety and Applied Nutrition, (HFS-600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance documents to the Dockets Management Branch (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 draft guidance documents.

**FOR FURTHER INFORMATION CONTACT:** John Kvenberg, Center for Food Safety and Applied Nutrition (HFS-600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2359, e-mail: [jkvenberg@cfsan.fda.gov](mailto:jkvenberg@cfsan.fda.gov) or Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS-400), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2300, e-mail: [dkraemer@cfsan.fda.gov](mailto:dkraemer@cfsan.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Operators of retail food store, food service, and cosmetics establishments are encouraged to review their current security procedures and controls in light of the potential for tampering or other

malicious, criminal or terrorist actions and make appropriate improvements.

FDA announced the availability of two guidance documents related to food security in the **Federal Register** of January 6, 2002 (67 FR 1224). They were entitled "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance." The agency solicited public comment, but indicated that the two guidance documents would be implemented immediately in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)). The two guidance documents were prompted by the tragedies of September 11, 2001, and the resulting scrutiny of, and interest in, food safety and security that followed.

The agency reviewed and evaluated the comments it received (11 written and 5 electronic). A number of the comments urged the agency to issue guidance that was specifically tailored for the retail food store and food service sector. Accordingly, FDA is issuing this draft guidance document entitled "Retail Food Store and Food Service Establishments: Food Security Preventive Measures Guidance."

The draft guidance document entitled "Retail Food Store and Food Service Establishments: Food Security Preventive Measures Guidance" identifies the kinds of preventive measures that operators of retail food store and food service establishments (i.e., bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for homebound persons, mobile food carts, restaurants, and vending machine operators) can take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal or terrorist actions.

FDA is also requesting comment on whether the agency's package of food security guidance documents should be expanded to include coverage of cosmetics, in addition to foods. To facilitate such comments, FDA also is announcing the availability of a draft guidance document entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance." The draft guidance document entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" identifies the kinds of preventive measures that operators of cosmetics establishments can take to