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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier J. Colte

[Docket No. 2003D-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 guidance document related to food security entitled "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance" (food security guidance) and a guidance document related to cosmetics security entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" (cosmetics security guidance). The food security preventive Measures Guidance" is designed as an aid to operators of retail food stores and food service establishments (e.g., 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 cosmetics security guidance is designed as an aid to operators of cosmetics establishments (e.g., 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: You may submit written or electronic comments on the guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the 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 documents 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 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* 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*.

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 9, 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.

A number of the comments on the two guidance documents urged FDA to issue guidance that was specifically tailored for the retail food store and food service sector. In response to these comments, the agency announced in the **Federal Register** of March 21, 2003 (68 FR 13932), the availability of a draft guidance document entitled “Retail Food Store and Food Service Establishments: Food Security Preventive Measures Guidance.” This draft guidance document identified the kinds of preventive measures that operators of retail food store and food service establishments (e.g., 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.

In that same March 21, 2003, **Federal Register** notice, the agency also requested 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, the agency announced the availability of a draft guidance document entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" (68 FR 13932). This draft guidance identified the kinds of preventive measures that operators of cosmetics establishments can take to minimize the risk that cosmetics under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It takes the operator through each segment of the cosmetics production system that is within their control, in order to minimize the risk of tampering or other malicious, 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.

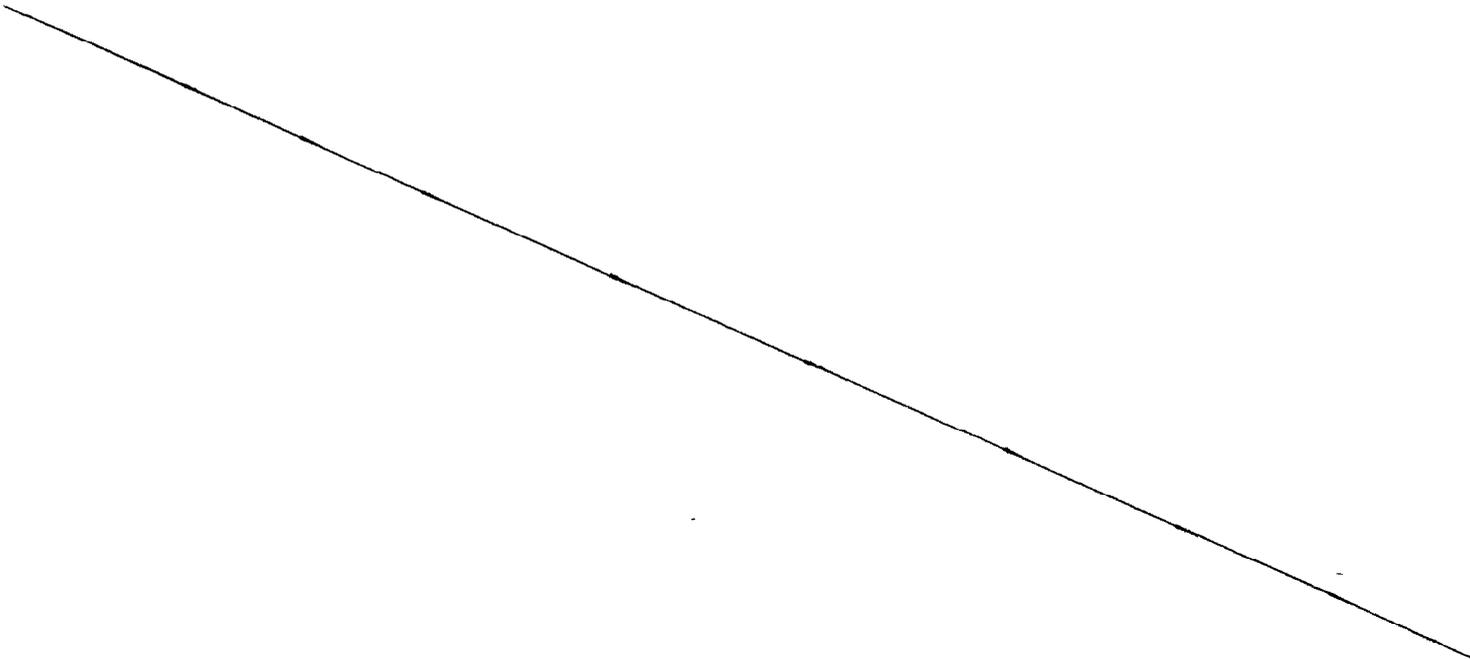
The agency solicited public comment on the draft guidance documents. FDA received three letters and three electronic responses, each containing one or more comments, from industry, consumer groups, and consumers in response to the draft guidance documents. The agency has reviewed and evaluated the comments and has determined that further modification of the guidance documents is unnecessary. The agency is therefore finalizing the draft guidances without revision.

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

The guidance documents represent the agency's current thinking on appropriate measures that retail food store, food service, and cosmetics establishments may take to minimize the risk that foods or cosmetics under their control will be subjected 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

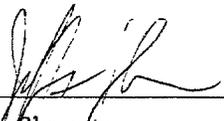
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these guidance documents. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance documents and received comments are available for public examination in the Division of Dockets Management 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>. The guidance documents also can be viewed at: <http://www.fda.gov/ohrms/dockets>.

Dated: 12/3/03
December 3, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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