

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0195]

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Certifier N. Hawkins

**Guidance for Industry on Necessity of the Use of Food Product Categories
in Registration of Food Facilities; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Necessity of the Use of Food Product Categories in Registration of Food Facilities." FDA has developed this guidance in response to section 305(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which states that FDA may require registrants to submit the general food categories of food manufactured, processed, packed, or held at the facility, if FDA determines "through guidance" that such information is necessary. This guidance contains FDA's finding that information about food categories is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

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 Office of Regulations and Policy (HFS-24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office

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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 on the guidance to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled “Necessity of the Use of Food Product Categories in Registration of Food Facilities.” FDA is issuing this guidance as a followup to the publication of its proposed regulation to implement the Bioterrorism Act’s requirement that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with FDA by December 12, 2003. (See 68 FR 5378, February 3, 2003.) The final rule, which FDA plans to publish in the Federal Register by October 10, 2003, will implement section 305 of the Bioterrorism Act. Section 305 of the Bioterrorism Act requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations. Section 305 of the Bioterrorism Act also states that FDA may require registrants to submit the general food categories (as identified in § 170.3 (21 CFR 170.3)) of food manufactured, processed, packed, or held at the facility, if FDA determines through guidance

that such information is necessary. This guidance contains FDA's finding that inclusion of food product categories in a facility's registration is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

FDA believes that information about a facility's food product categories is a key element to allow for rapid communications between FDA and facilities directly affected by an actual or potential bioterrorist attack or other food-related emergency. Information about the categories of food a facility handles will assist FDA in conducting investigations and surveillance operations in response to a food-related emergency. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. For example, if FDA receives information indicating that soft drinks could be affected by a bioterrorist incident or other food-related emergency, FDA would be able to alert soft drink manufacturers/processors¹, packers, and holders about the incident. Additionally, the food categories in conjunction with the prior notification requirements that have been proposed for 21 CFR part 1, subpart I (68 FR 5428, February 3, 2003), would aid FDA in verifying that imported products are correctly identified by where and when they were produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice for a shipment of nuts purporting to have been produced at that facility, FDA can inspect the shipment for verification based on the discrepancy. FDA, therefore, proposed in § 1.232(e) of the proposed rule to include the food product categories listed in § 170.3 as a mandatory field on the registration form. (See 68 FR 5378 at

¹ In the proposed rule, FDA noted that the meanings of the terms "manufacture" and "process" overlap and proposed to define both activities together as "manufacturing/processing." (See 68 FR 5378 at 5382, February 3, 2003.)

5419, February 3, 2003.) Since § 170.3 does not list all the categories of food that are manufactured/processed, packed, or held for consumption in the United States, FDA proposed to include additional food categories as an optional field on the registration form.

This guidance represents FDA's finding on the need for food product category information as part of the registration of food facilities under the Bioterrorism Act. Section 305 of the Bioterrorism Act directs FDA to require information about the food categories listed in § 170.3, if the agency determines "through guidance" that such information is a necessary component of registration. Because of Congress's explicit statutory authorization to establish a binding requirement based on a finding in guidance, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document's nonbinding effect. (See § 10.115(d) and (i) (21 CFR 10.115(d) and (i)).)

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited, and the agency's guidances also ordinarily include the following standard paragraph:

This guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for

implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

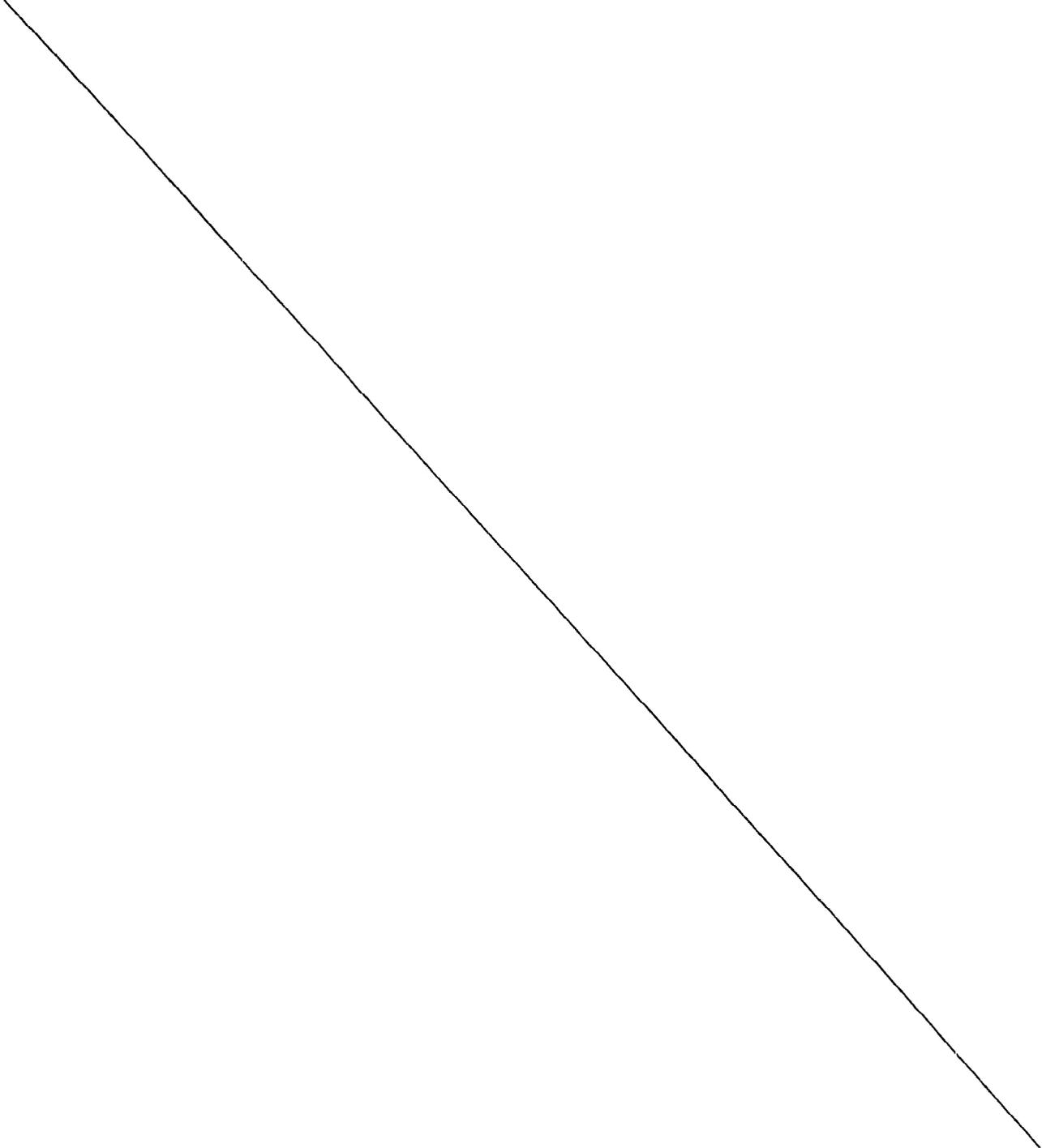
Although this guidance has no binding effect, it contains a finding that serves as the predicate for a binding regulation that would impose a new requirement on industry. If the provisions of the proposed rule (68 FR 5378) regarding food categories are finalized as proposed, the final rule would require registrants to indicate in their registration which of the food categories listed in § 170.3 they manufacture/process, pack, or hold. In that event, facilities would be unable to use an alternative approach to including those food categories in registration because no alternative approach would satisfy the requirements of the applicable statute and regulations. Therefore, FDA is not including the standard guidance paragraph in the guidance because it does not apply.

FDA is issuing this guidance document as a level 1 guidance. Consistent with FDA's GGP regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. FDA is under a strict statutory deadline in which to complete the final rule associated with this guidance. Moreover, the public has already had an opportunity to comment on the necessity of food product categories in the proposed rule.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit a single paper copy of electronic comments to <http://www.fda.gov/dockets/ecomments> 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.



III. Electronic Access

An electronic version of this guidance is available on the Internet at <http://www.cfsan.fda.gov/guidance.html>.

Dated: 7/7/03
July 7, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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