Guidance for Industry

Necessity of the Use of Food Product Categories in Registration of Food Facilities

GUIDANCE

Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-2378.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
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TABLE OF CONTENTS

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I. INTRODUCTION

This guidance represents the Food and Drug Administration's (FDA's) conclusion on the necessity of food product categories in registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Section 305 of the Bioterrorism Act directs FDA to require information about the food categories listed in 21 C.F.R. 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 21 C.F.R 10.115(d)(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:

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[1] This guidance has been prepared by the Office of Regulations and Policy in the Center for Food Safety and Applied Nutrition of the U S. Food and Drug Administration.

> 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.

FDA is not including this standard language in this guidance because it is not an accurate description of the effect that the guidance has. Although the 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 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 21 C.F.R. 170.3 they manufacture/process,[2] pack, or hold. In that event, facilities would not be able 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 this guidance because it does not apply.

II. BACKGROUND

On February 3, 2003, FDA issued a 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 by October 10, 2003, will implement section 305 of the Bioterrorism Act. Section 305 requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations. Section 305 states that FDA may require registrants to submit the general

food categories (as identified in 21 C.F.R. 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.

III. DISCUSSION

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 impacted 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/processors, 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 by 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 finds that

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[2] 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

requiring food product category information as part of 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. Therefore, the agency proposed in Sec. 1.232(e) of the proposed rule to include the food product categories listed in 21 C.F.R. 170.3 as a mandatory field on the registration form. (See 68 FR 5378 at 5419; February 3, 2003). If the provisions of the proposed rule 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 21 C.F.R. 170.3 they manufacture/process, pack, or hold.

IV. ELECTRONIC ACCESS

Copies of this guidance are available on FDA's website at http://www.cfsan.fda.gov/guidance.html. Submit electronic comments to http://www.fda.gov/dockets/ecomments.