

DmB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 12-11-03
Publication Date 12-12-03
Certifier A. Corbin

[Docket Nos. 2002N-0276 and 2002N-0278]

Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of small entity compliance guides (SECGs) for the interim final rules on Registration of Food Facilities and Prior Notice of Imported Food issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Both interim final rules published in the **Federal Register** of October 10, 2003. These SECGs are intended to help small businesses better understand the registration and prior notice regulations.

DATES: Submit written or electronic comments on the SECGs at any time.

ADDRESSES: Submit written comments concerning these SECGs 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 SECGs to <http://www.fda.gov/dockets/ecomments>.

Submit requests for single copies of one or both SECGs to the Prior Notice help desk by telephone at 1-800-216-7331 (within the United States) or 301-575-0156 (outside the United States), by FAX: 301-210-0247, or by e-mail:

cf0387

NAD 1

furls@fda.gov. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these SECGs.

FOR FURTHER INFORMATION CONTACT: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6230.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894 and 68 FR 58974), FDA issued two interim final rules to implement sections 305 (Registration of Food Facilities) and 307 (Prior Notice of Imported Food) of the Bioterrorism Act. The registration interim final rule requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The prior notice interim final rule requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States beginning on December 12, 2003.

We examined the economic implications of these interim rules as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that they would have a significant economic impact on a substantial number of small entities.

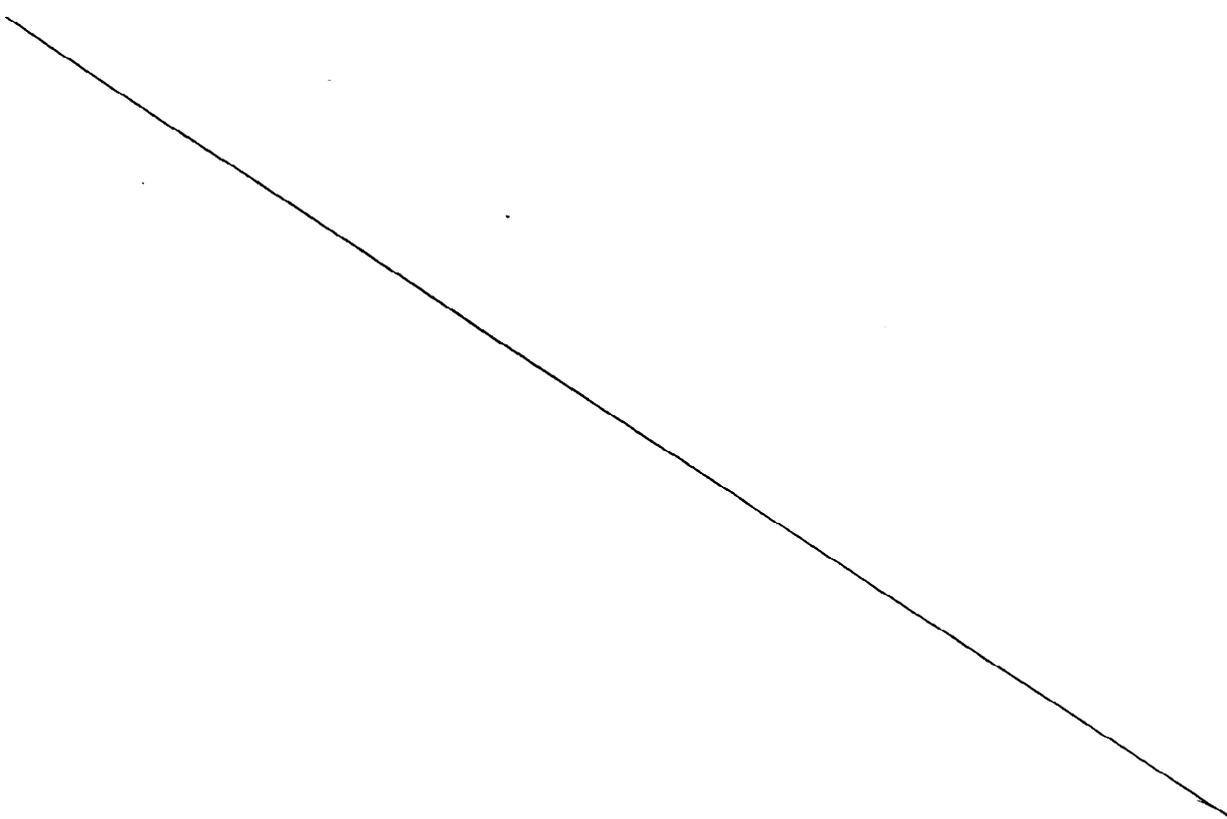
In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), we are making available these SECGs that explain the requirements of these regulations.

FDA is issuing these SECGs as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). These SECGs restate, in simplified format and language, FDA's current requirements for Registration

of Food Facilities and Prior Notice of Imported Food. As guidance, these documents are not binding on either FDA or the public. FDA notes, however, that the regulations that serve as the basis for these guidance documents establish requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulations at 21 CFR part 1, subparts H and I, in addition to reading these SECGs.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these SECGs. 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 applicable docket number(s) found in brackets in the heading of this document. 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

Persons with access to the Internet may obtain these SECGs at <http://www/cfsan.fda.gov/guidance.html>.

Dated: 12/3/02

December 3, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

