CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

August 20, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Comments on Proposed Regulations to Implement Section 305 (Registration) of the Bioterrorism Act, Docket No. 02N-0276

The Food and Drug Administration (FDA) is soliciting input from stakeholders as it develops proposed regulations implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). On behalf of the Center for Science in the Public Interest (CSPI), we are writing to express our views on the appropriate regulatory provisions necessary to protect the U.S. food supply from intentional contamination and adulteration.

CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

Under section 305 of the Act, the FDA is to promulgate regulations requiring the owner, operator, or agent in charge of a domestic or foreign facility engaged in the manufacturing, processing, or handling of food for consumption in the United States to register with the FDA no later than December 12, 2003. The Act describes the information to be provided by the registrant, including the name and address of each facility, all trade names under which the registrant conducts business, and the general food category of foods made, processed, packed or

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held.

In proposing regulations to implement this provision, FDA should include in the registration requirement the following components.

Coverage

The regulation should clarify that the definition of "food" includes the raw ingredients and components of food, as well as finished or processed food products.

Form of Registration

The registration notice adopted by FDA should be in the form of a certificate or card that those subject to the registration requirement must submit to FDA and which can be displayed at the place of business. The registration form should be available both in written format and electronically for submission to the agency. This will help assure that information is standardized in FDA databases and also enable inspectors to determine immediately upon visiting a facility whether it is in compliance with registration requirements.

Triggers for notification

Once facilities are registered, the Act requires them to notify the Secretary in a timely manner of changes to the registration information. FDA should define "changes" to require notification when the facility goes out of business, there is a change in facility ownership, if the nature of the business changes, or there are other alterations to a facility's status. Other triggers to mandatory notification include where the registrant alters its supplier of raw ingredients, its shipper, or the kinds of products it manufactures, processes, packs or holds, including switching from production of human food products to animal food products.

Facilities that have gone out of business or cannot demonstrate ongoing business activities consistent with the filed registration should be removed immediately from the

registration list.

Timing of Notification of Changes

The Act requires registrants to notify the Secretary in a "timely manner" of changes to registration. FDA should specifically identify what constitutes "timely" notification. At a minimum, notification should be required within 30 calendar days of the changes. FDA should consider imposing a 15-day notification requirement where a facility goes out of business.

Termination of Registration

Although a failure to register is a prohibited act under section 301 of the Federal Food, Drug and Cosmetic Act, section 305 of the Bioterrorism Act does not specify the consequences for a failure to comply with registration requirements as ultimately promulgated by FDA. The FDA should establish a procedure whereby a facility's registration may be terminated if FDA personnel determine through records or inspection that the facility has gone out of business or has failed to report changes in the nature of its business with the designated time period.

Optional Registration Requirements

Although the Act specifies the minimal information required for registration, FDA should also request optional information about the nature of the facility's operation. Such optional information should include:

- identification of each different product manufactured, processed, packed or held by the facility, the average quantities of such product made, processed, packed or held, and each name and label under which the products are marketed;[1]

[1] Adoption of a product identification requirement as part of the registration also is consistent with section 306 of the Bioterrorism Act (recordkeeping) since that provision authorizes FDA to adopt regulations imposing recordkeeping requirements for the purpose of tracing foods forward and backward through the distribution chain.

- whether the facility operates on a seasonal basis, and if so, the months of operation; and
- whether the products made, processed, packed or held change depending on the season, and if so, the nature of the change.

Registration Database

The Act also requires the Secretary to maintain an up-to-date list of registered facilities. This database should include not only the information specified in the Act, but additional data concerning any actions that have been taken with respect to registered facilities, including registration or recordkeeping violations, as well as warning and other letters, enforcement actions, and detentions of product by that particular company. Although the information is protected from public disclosure pursuant to the 5 U.S.C. § 552, such information should be available to all Customs officials, USDA offices, and FDA offices and field locations via computer access.

Thank for the opportunity to provide comments on the proposed regulations.

Respectfully submitted,

Karen L. Egbert

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Dear Sir or Madam:

Enclosed please find the original and two copies of CSPI's comments on implementation of Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act. Please file these comments under Docket No. 02N-0276. Thank you very much.

Sincerely,

Karen Egbert

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