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Dear Sir,

My name is Kazuaki Kawashima who attended on Food Security and Recall Workshops on July 25,2002.

I am sorry that I suddenly sent this letter to you.

I am really worried about the following letters.

I have some questions about the following papers about Section 305(Registration of Food Facilities), Section306 (Establishment and Maintenance of Records), Section307 (Prior Notice of Imported Food Shipments), and Section 303(Administrative).

What do we have to do now about those things now?

Do we have to register before Dec.12.2003?

Do you have any application forms about those things?

If we do this, could you please tell me how to do this in details?

I am really sorry to trouble you, please tell me about those questions.

Thank you,

Sincerely,



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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

Food and Drug Administration

July 17, 2002

Dear Colleague, FDA Foods Community:

The events of September 11, 2001, reinforced the need to enhance the security of the United States food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") (PL107-188), which President Bush signed into law on June 12, 2002.¹ The Act is divided into the following five titles:

- Title I - National Preparedness for Bioterrorism and Other Public Health Emergencies;
- Title II - Enhancing Controls on Dangerous Biological Agents and Toxins;
- Title III - Protecting Safety and Security of Food and Drug Supply;
- Title IV - Drinking Water Security and Safety; and
- Title V - Additional Provisions.

The purpose of this letter is: (1) to give you an overview of the four provisions in Title III, Subtitle A (Protection of the Food Supply), which require the Food and Drug Administration (FDA) to issue regulations in an expedited time period; (2) to inform you how the Department and FDA will be proceeding; and (3) to solicit comment on areas of concern to you and suggestions for how best to communicate those concerns to us.

A. Provisions Requiring Regulations

Attachment A provides an informal summary of the provisions in Title III, Subtitle A of the Bioterrorism Act. As noted, the Secretary, through the FDA, is required to propose and issue final regulations for the following four provisions:

- X Section 305 (Registration of Food Facilities) - requires the owner, operator, or agent in charge of a domestic or foreign facility to register with the FDA no later than December 12, 2003. Facilities are defined as any factory, warehouse, or establishment, including importers. The Secretary, through FDA, is required to issue final regulations addressing the registration requirements no later than December 12, 2003; however, food facilities

¹You may obtain a full copy of the Act at <http://thomas.loc.gov>, and searching with Bill number H.R. 3448.

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must register with FDA by this date even if FDA has not issued final regulations. The Bioterrorism Act exempts farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer; and fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3(k)) from the requirement to register. Also, foreign facilities subject to the registration requirement are limited to those that manufacture, process, pack, or hold food, only if food from such facility is exported to the United States without further processing or packaging outside the United States.

- X Section 306 (Establishment and Maintenance of Records) - requires the Secretary, through FDA, to issue final regulations by December 12, 2003, to establish requirements for the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food, (i.e., one up, one down). Such records are to allow FDA to address credible threats of serious adverse health consequences or death to humans or animals. Entities subject to these provisions are those that manufacture, process, pack, transport, distribute, receive, hold or import food. Farms and restaurants are exempt from these requirements.

- X Section 307 (Prior Notice of Imported Food Shipments) - requires that prior notice of food shipments be given to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry. The Secretary, through FDA, must issue final regulations by December 12, 2003. While we fully expect regulations to be issued by this date, if such regulations are not issued, the statute still requires importers to provide no less than 8 hours and no more than 5 days notice to FDA until the regulation takes effect.

- X Section 303 (Administrative Detention) - authorizes the Secretary, through FDA, to order the detention of food if an officer or qualified employee finds credible evidence or information indicating an article presents a threat of serious adverse health consequences or death to humans or animals. The Act requires the Secretary, through FDA, to issue final regulations to expedite court actions on perishable foods. No time frame is specified.

Unless exempted, these provisions apply to all facilities for all types of food products regulated by FDA, including dietary supplements.

B. FDA's Regulation Development Plans

While the statute establishes ambitious deadlines for each of the above provisions, I want to underscore that the Secretary has made it clear that he expects FDA to meet them. Our goal is to

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publish proposed regulations by the end of this calendar year, and we plan to offer at least a 60-day comment period.

We also are committed to receiving and considering the input from stakeholders as we develop the proposed and final regulations. Before issuing these proposed rules, FDA will seek to identify stakeholders' concerns and potential options for addressing them. During the comment period, we plan to hold several public meetings at various locations across the country to explain the proposed regulatory requirements, answer questions, and receive additional comment.

We also have opened public dockets for each regulation and are ready to receive input from you now. Comments would be most helpful if you not only identify any concerns you may have, but also provide both your recommended solution and any supporting data, if applicable. Also, to the extent feasible, we would appreciate receiving any initial comments you may have by August 30, 2002. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. We request that you submit two copies of any written comments, except that individuals may submit one copy. Please ensure that you include in your submission the docket number that applies to your comment from the list below:

- | | |
|-------------------------------|---------------------|
| • Section 305 (Registration) | Docket No. 02N-0276 |
| • Section 306 (Recordkeeping) | Docket No. 02N-0277 |
| • Section 307 (Prior Notice) | Docket No. 02N-0278 |
| • Section 303 (Detention) | Docket No. 02N-0275 |

If you would like to review comments FDA has received, you may do so at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Within the FDA, Ms. Linda Skladany, FDA's Senior Associate Commissioner for External Relations, will serve as the focal point for our outreach efforts. The Center for Food Safety and Applied Nutrition (CFSAN) will take the lead for the regulations development process. Mr. L. Robert Lake, CFSAN's Director of the Office of Regulations and Policy, will serve as senior manager of this effort. Ms. Leslye M. Fraser, CFSAN's Associate Director for Regulations, will serve as the overall lead for the regulations workgroups. Additional contact information is contained in Attachment B.

Lastly, many of the remaining provisions in Title III, Subtitle A of the Bioterrorism Act are effective now. Consistent with our good guidance practice (GGP) regulations, 21 CFR 10.115, FDA plans to issue guidance documents for several of these provisions prior to implementing them broadly. Please note that if FDA deems it necessary to use this new statutory authority to protect the public health prior to issuing written guidance, it will do so on a case-by-case basis after consulting with senior officials in the affected District and within Headquarters.

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I hope that you have found this information helpful. Again, the Secretary, Dr. Crawford and I are committed to meeting the statutory deadlines required to implement the provisions of the Bioterrorism Act intended to further protect the safety of the food supply.

Sincerely,

Joseph A. Levitt
Director
Center for Food Safety
and Applied Nutrition

Attachments

cc: Dr. Lester Crawford
Deputy Commissioner