

Food and Drug Administration
Rockville MD 20857

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The Honorable Thomas H. Allen
House of Representatives
Washington, D.C. 20515-1901

AUG 19 2003

Dear Mr. Allen:

Thank you for your letter of June 2, 2003, regarding a proposed regulation published by the Food and Drug Administration (FDA or the Agency). As you know, the proposed rule is necessary to implement Section 307, Prior Notice of Imported Food Shipments, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. You expressed concern that the proposed rule could create a backlog of food shipments at the border and impede free trade.

FDA appreciates your comments on this matter. As you noted in your letter, many comments similar to yours were submitted to FDA during the public comment period which closed on April 4, 2003. FDA is considering these comments as we develop the final regulation. FDA conducted extensive outreach, both domestically and abroad, during the public comment period to ensure that affected parties were aware of the proposed requirements and could provide meaningful comment for the Agency to consider before finalizing the regulation.

Consistent with the statute, the proposed rule would require prior notice of all food imported or offered for import into the United States beginning December 12, 2003. FDA and the Bureau of Customs and Border Protection (Customs) have announced that we will work jointly to streamline the implementation of the prior notice requirement by allowing food importers to provide the required information to both agencies using an integrated process. We have enclosed a press release that provides additional details about this. Since the law was enacted last year, FDA and Customs have worked together to modify Customs' Automated Commercial System. As a result of this collaboration, importers, in most circumstances, will be able to provide the required information to FDA using this existing system, making it easier for them to comply with the new law.

Thank you again for your letter. We appreciate your interest in FDA's food security and food safety activities. We have forwarded your correspondence to our Dockets Management

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Branch for inclusion in the docket for these matters. If we may be of further assistance, please let us know.

Sincerely,



Amit K. Sachdev
Associate Commissioner
for Legislation

Enclosure

cc: Dockets Management Branch (HFA-305)
Docket No.: 02N-0278



U.S. Food and Drug Administration

Department of
Health and
Human Services

FDA News

FOR IMMEDIATE RELEASE
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Media Inquiries: 301-436-2335
Consumer Inquiries: 888-INFO-FDA

FDA and Bureau of Customs and Border Protection Announce Steps to Streamline Collection of Information on Food Imports

Washington, D.C. May 27, 2003 -- The U.S. Food and Drug Administration (FDA) and the Bureau of Customs and Border Protection (CBP) announced today that they will streamline the implementation of the prior notice requirements of the Bioterrorism Act ("the Act") by allowing food importers to provide required information on food imports to both agencies using an integrated process. Under the Act, importers will soon be required to provide "prior notice" about the content of their food imports to FDA, starting no later than December 12, 2003. Since the Act was passed last year, FDA and CBP have worked together to find ways to modify CBP's Automated Commercial System, currently used to obtain import information required by Customs. As a result of this collaboration, importers, in most circumstances, will be able to provide the required information to FDA using this existing system, making it easier for them to comply with the new law.

Nearly 20% of all imports into the U.S. are food and food products. Congress passed the Bioterrorism Act as part of its ongoing effort to combat terrorism - in this instance, by reducing the ability of international terrorists to carry out terrorist attacks in the U.S. by contaminating imported foods. The Act requires that FDA receive prior notice before food is imported or offered for import into the United States. The advance notice of import shipments will allow FDA and CBP to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies.

"FDA is dedicated to its mission as one of the nation's frontline defenses against terrorism. Collaborating closely with CBP is one of the essential steps we are taking to improve the security of our the food supply against new threats, while minimizing the impact on imported foods," said Commissioner of Food and Drugs, Mark B. McClellan, M.D., Ph.D.

Created on March 1, 2003 as part of the new Department of Homeland Security, Customs and Border Protection combines all of the agencies with primary responsibility for the borders, including all 18,000 customs, immigration, and agriculture inspectors at more than 300 ports of entry into the United States.

"The men and women of Customs and Border Protection are the guardians of our nation's borders," said CBP Commissioner Robert C. Bonner. "Our primary mission is keeping and terrorist weapons from entering the U.S. That is why we are partnering with the FDA to protect our nation against the potential of terrorists contaminating our imported food supply. And we are also partnering with the FDA to develop a system that will be less burdensome on the trade while at the same time fulfilling the mandates of the Bioterrorism Act."

FDA is reviewing the comments submitted on the proposed rule, published on February 3, 2003, and is preparing a final rule. The Act requires prior notice for imported food shipments beginning December 12, 2003. FDA anticipates publishing a final rule in early October.

Food Safety and Terrorism