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The Honorable Sherrod Brown
House of Representatives
Washington, D.C. 20515-3513

AUG 19 2003

Dear Mr. Brown:

Thank you for your letter of May 15, 2003, regarding a proposed rule 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 (Bioterrorism Act). You expressed concern that the proposed rule applies to food shipments that are in transit and are not intended for domestic markets. Your letter indicated that the World Shipping Council (WSC) and the American Association of Port Authorities (AAPA) have asserted that this is an "unjustifiable and unworkable" requirement.

FDA appreciates your comments regarding the proposed rule. Similar concerns were raised during the public comment period. We will carefully consider this issue as we develop the final regulation.

The prior notice provision of the Bioterrorism Act expressly applies to "an article of food that is being imported or offered for import into the United States." In our proposed rule, we stated that this means it applies to all food that is brought across the U.S. border except food carried in a traveler's personal baggage for personal use. We further stated that "FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is 'imported or offered for import' and thus must comply with the prior notice requirements."

Your letter indicates that the WSC and the AAPA also claimed that the documentation required by the proposed rule is unnecessary as the information is provided to the Bureau of Customs and Border Protection's (Customs) Automated Manifest System 24 hours before the cargo is loaded on the vessel in a foreign port. This is not entirely accurate. While it is true that much of the information we have proposed to be required may already be provided to Customs as part of its entry process, the Bioterrorism Act specifies what information must be provided to FDA. For example, the Bioterrorism Act specifies that the prior notice shall identify the grower of the article if known, the manufacturer of the article, and the country from which the article originates. As we understand it, such information is not part of

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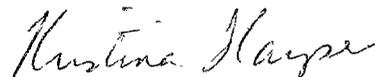
the Customs manifest system. Further, the Customs system does not currently receive advance notice of shipments arriving by air or by land. The Bioterrorism Act requires that prior notice be given to FDA for all shipments being imported or offered for import.

You may be interested to know that FDA and Customs have announced that we will work jointly to streamline the implementation of the prior notice requirements of the Bioterrorism Act by allowing food importers to provide the required information to both agencies using an integrated process. Since the Bioterrorism Act was enacted last year, FDA and Customs have worked together to find ways to modify Customs' Automated Commercial System which is currently used for the 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.

The comment period on this proposed rule closed on April 4, 2003. 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 to the Agency for us to consider. The Agency has received numerous comments on this proposal and is considering them as we develop the final regulation to implement this provision of the Bioterrorism Act. We have forwarded your correspondence to our Dockets Management Branch for inclusion in the docket for this matter.

Thank you again for your letter. We appreciate your continued interest in FDA's food safety and security activities. 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



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FOR IMMEDIATE RELEASE
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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 terrorists 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.

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