

INFORMED COMPLIANCE NOTICE CONCERNING PHASE 2 ENFORCEMENT OF THE BIOTERRORISM ACT

On October 10, 2003, the Food and Drug Administration (FDA) published in the Federal Register, two interim final rules implementing the Prior Notice and Registration requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, popularly known as the Bioterrorism Act or the BTA.

Under the requirements of the BTA, the FDA must receive Prior Notice (PN) for all food imported or offered for import into the United States. Also, foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with the FDA. Any imported food products that are not in compliance with the PN requirements of the BTA may be held at either the port of arrival or at a secure facility until such time that they are either brought into compliance with the BTA or exported from the U.S. Although these requirements technically entered into force on December 12, 2003, FDA and CBP have agreed to a phase-in period for these requirements lasting 8 months. The specific phases of this discretionary enforcement period are described in the FDA Compliance Policy Guide which can be found at <http://www.cfsan.fda.gov/~pn/cpgpn.html>.

Phase 2 of the discretionary enforcement plan will be implemented on March 12, 2004 and will run through May 12, 2004. During this time, FDA will provide information to CBP regarding those entities that have failed to file PN data as required. CBP will be issuing informed compliance notices to those entities that the FDA has identified as non-compliant. Phase 2 enforcement also includes the ability for CBP to issue monetary penalties to egregious violators for non-compliance with the PN filing requirement. During this phase in period CBP and the FDA are committed to pursuing informed compliance prior to the issuance of any BTA related penalty action. CBP will not be issuing any BTA related penalties until the later part of Phase 2. CBP will provide public notice via another web posting of the commencement of any potential penalty issuance period and will provide basic guidance about the types and amounts of potential penalty actions.

If you have questions about CBP activity related to Phase 2 enforcement of the BTA can be directed to the Other Government Agency Branch at (202) 927-0300.