Bioterrorism Act Regulations: FDA Enforcement Phase III Begins Today

U.S. Customs and Border Protection (CBP) has announced that beginning on June 4, 2004 at 6:00 a.m. EST the third phase of enforcement of FDA’s regulations requiring registration of food facilities and prior notice of food shipments imported into the U.S. will be implemented. Phase III, originally scheduled to begin May 13, 2004, was pushed back for further monitoring of software changes in CBP’s system (see NGJ International Trade Update dated May 19, 2004 - http://www.ngjensen.com/itu/20040519.asp).

CBP advises that the delay of Phase III implementation does not automatically mean that the scheduled date for full enforcement will also be pushed back. CBP is advising parties to “assume that the Phase IV enforcement will begin on time on (August 13, 2004).

Beginning today, failure to submit prior notice of all food for human or animal consumption to be imported or offered for import into the United States, will result in the merchandise being refused entry. Under the Bioterrorism Act, FDA requires prior notice to be received two hours prior to arrival for food shipped via truck, four hours for rail and air, and eight hours for food arriving on a vessel.

Based on the foregoing, we strongly recommend affected parties review their documentation procedures and ensure they are providing accurate, timely prior notice information for those shipments.

The FDA’s Compliance Policy Guide, which sets forth full details of the agency’s intended enforcement actions and schedules, is available online at the following address: http://www.cfsan.fda.gov/~pn/cpgpn.html.

If you have questions, please call your NGJ account representative or nearest NGJ office, or contact us via e-mail at techservices@ngjensen.com.