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Food & Drug

E-ALERT

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FDA Launches "Secure Supply Chain" Pilot Program To Improve Safety of Imported Drugs and Drug Ingredients

Voluntary Program May Foreshadow Permanent or Mandatory Program

On January 15, 2009, the Food and Drug Administration (FDA) announced the launch of a voluntary "Secure Supply Chain" pilot program to improve the safety of finished drug products and active pharmaceutical ingredients (API) produced outside the United States for the United States market. Secure supply chain involves the use of systems and technology to track and document the movement of a drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. Secure supply chain programs are intended to reduce the incidence of drug counterfeiting, diversion, and adulteration.

The stated goal of the pilot program is to "determine the practicality of developing a secure supply chain program." FDA indicated that such a program, if implemented, would allow FDA to "focus its resources on foreign-produced drugs that fall outside the program" and may pose the risk of being adulterated, misbranded, or unapproved. The program would also help to "expedite the entry of products" meeting the program's criteria into the United States.

Requirements

FDA will select about 100 companies from applicants for the two-year pilot program. Each applicant may designate up to five drugs for selection in the pilot program. Applicants must meet a series of criteria to ensure that they maintain control over the merchandise from the time of manufacture until delivery in the United States. The criteria are laid out in the Federal Register notice:

- The applicant must be either the holder of the New Drug Application or Abbreviated New Drug Application (NDA/ANDA), or the foreign manufacturer of the imported finished drug product or API.
- The ultimate consignee[1] identified on the new "Secure Supply Chain Pilot Program Application," Form FDA-3676, must be in compliance for the past three years with FDA registration, drug listing, and current good manufacturing practices (cGMP) requirements.
- If the imported merchandise is a finished drug product, the ultimate consignee must be identified in the NDA/ANDA.
- If the imported merchandise is an API, then it must be used in the production of an FDA-approved drug product.

[1] In this context, "ultimate consignee" means the U.S. party to whom the overseas manufacturer or shipper sold the imported merchandise.

- The foreign manufacturer of the imported merchandise must be in compliance with relevant drug manufacturing requirements.
- The applicant must be currently certified or have an application pending with the Customs-Trade Partnership Against Terrorism (CTPAT) program as a Tier II-certified supply chain.[2]
- The applicant must have plans for correcting deficiencies identified by FDA and for recalling or correcting finished drug products or APIs that do not meet FDA requirements.
- Applicants must comply with relevant recordkeeping provisions, including records documenting the imported merchandise's movement through the supply chain.
- The customs broker identified in the application must qualify for paperless entry filing with FDA's Operational and Administrative System for Import Support (OASIS).

Potential Benefits

FDA plans to "substantially increase" the rate at which merchandise imported under the pilot program is given a "may proceed" designation after electronic screening without human entry review, meaning that merchandise imported under the pilot program should clear the customs/import process faster.

Further, if the program is made permanent, participants will likely be advantaged by shaping the form of the permanent program and by having already-compliant supply chains. FDA also could elect to make the program mandatory in the future and require all imported merchandise of finished drug products or APIs to pass through a certified secure supply chain. It seems less likely that FDA will make the program permanent or mandatory before the expiration of the two-year pilot program.

Timing and Selection Criteria

FDA must wait for the U.S. Office of Management and Budget (OMB) to approve the new Form FDA-3676 before FDA may formally accept applications. Once OMB approves the form, FDA will publish another notice in the Federal Register and then process applications for participation in the pilot program in the order received, on a first-come, first served basis. FDA will complete the selection process and begin the pilot program 180 days after the second Federal Register notice.

The current Federal Register notice provides only limited guidance on what criteria FDA will use to select from among qualifying applications, which may mean that FDA will simply select the first 100 qualified applicants into the program. FDA noted that "pilot program participants must be in full compliance with all requirements of the [Federal Food, Drug, and Cosmetic Act (FDCA)] relating to drug products," and that FDA may terminate a participant's inclusion in the program if the participant receives a Warning Letter or otherwise is found to have violated any drug-related requirements of the FDCA. FDA also reserved the right to modify the number of participants it selects for participation in the program.

Context and Comments

The pilot program comes as FDA makes additional "risk-based" attempts to increase the safety of imports of foreign-made merchandise, including issuing draft guidance on good importer practices, opening offices in China and India, and signing collaborative

[2] The CTPAT program, operated by DHS' Customs and Border Patrol, is a voluntary program that allows importers with certified supply chains to enjoy fewer customs inspections. After joining the CTPAT program as a Tier I member, a company may be awarded Tier II status after CBP verifies additional supply chain security criteria.

agreements with FDA's regulatory counterparts as part of its "Beyond Our Borders" initiative and the interagency "Action Plan for Import Safety."

Interested parties may submit comments on the pilot program by March 16, 2009 to http://www.regulations.gov or to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

If you have any questions concerning the material discussed in this client alert, or would like assistance in preparing an application to participate in the Secure Supply Chain pilot program, please contact the following members of our food & drug practice group:

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