VENABLE® LLP

Client Alerts

August 2013

Quickly Take Your Medicine: FDA's Secure Supply Chain Pilot Program Presents Opportunity for Expedited Imports of API and Finished Drug Products

AUTHORS

David G. Adams
Lindsay B. Meyer
Matthew R. Rabinowitz

RELATED PRACTICES

International Trade and Customs

RELATED INDUSTRIES

Drugs, Medical Devices and Biologics

ARCHIVES

2013 2009 2005
2012 2008 2004
2011 2007 2003
2010 2006

Taking a page from an established Customs program, importers of active pharmaceutical ingredients (APIs) and finished drug products may now have the opportunity to become eligible for expedited entry into the United States. **Could this help your business?** If so, consider the U.S. Food and Drug Administration's (FDA) **August 20, 2013 notice** of a new Secure Supply Chain Pilot Program (SSCPP), which will enable qualified importers to receive a "May Proceed" without human entry review or examination for APIs and finished drug products offered for import into the United States. Given the fact that more than 80% of APIs and 40% of finished drugs are currently imported into the U.S., this new program may significantly improve the approval time for those few qualified importers and products under this Pilot Program.

The FDA is initially limiting the SSCPP voluntary program to only 100 qualified applicants. Each firm accepted to participate in the program will be allowed **up to five drugs** that will be subject to expedited import entry review. In order to participate in the pilot program, the importing company must meet certain criteria, which include, but are not limited to, the following:

- The applicant must be either: (a) the sponsor of the New Drug Application (NDA) or the Abbreviated New Drug Application (ANDA), or (b) the foreign manufacturer of the imported finished drug product or API;
- Foreign drug manufacturers and U.S. establishments receiving drugs must comply with good manufacturing practices as well as applicable registration and listing requirements;
- The applicant must have a plan in place for promptly correcting concerns that the FDA identifies regarding its secure supply chain or specific importations;
- The importer of record must have a validated secure supply chain protocol per the U.S. Customs and Border Protection's Customs-Trade Partnership Against Terrorism (C-TPAT) program as either C-TPAT Tier II or Tier III; and
- Primary and secondary contacts identified in the SSCPP application must be able to answer questions and resolve issues raised by the FDA, and applicants must maintain records of the product's movement through the secure supply chain for the duration of their participation in the program.

This initiative marks a clear collaborative effort between the FDA and U.S. Customs and Border Protection (CBP) leveraging existing C-TPAT membership. The well-established C-TPAT program has been in place since November 2001 and currently boasts more than 10,000 members, representing, by value, more than 50% of imports into the United States. In contrast, with new membership capped at 100 companies, this initial foray by the FDA will be available to only a minute percentage of the potential importing community. Therefore, if you are contemplating participation, don't delay in readying your application.

The Pilot Program will run from February 2014 through February 2016. ***Notably, the FDA will accept applications for participation from September 16, 2013, through December 31, 2013. Applications will be processed on a first-come, first-served basis.***

Could expedited clearance of your imported APIs and finished drug products help your bottom line? If so, please contact Venable's **Drugs, Medical Devices, and Biologics Practice Group** or **International Trade and Customs Practice Group** with any questions or for assistance in applying to this Pilot Program.