FDA/CDER
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Improving Drug Supply Chain Integrity

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Counterfeiting, contamination, drug diversion, cargo theft, importation of unapproved or otherwise substandard drugs… these are just a few of the threats that can compromise the integrity of the U.S. drug supply chain and result in exposing U.S. consumers to unsafe, and/or ineffective drugs.

Drug Supply Chain Security Act Implementation: The Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act), which President Obama signed into law on November 27, 2013, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S. This system will be developed and implemented over the next ten years, during which time drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA.

Ten years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will enable verification of the legitimacy of a drug product identifier down to the package level, better detection and notification of illegitimate products in the drug supply chain, and facilitate more efficient recalls of drug products. Failure to comply with the requirements of the law can result in penalties. Key provisions of the law include requirements for:

- *Product identification:* Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.

- *Product tracing:* Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.

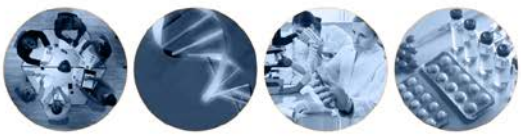
- *Product verification:* Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.

- *Detection and response:* Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous.

- *Notification:* Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.

- *Wholesaler licensing:* Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.

- *Third-party logistics provider licensing:* Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.



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FDA is developing a schedule for implementing the law's requirements. This includes, but is not limited to, developing standards, guidances, regulations, and pilot programs, and conducting public meetings. Information on the Drug Supply Chain Security Act is available on our website and in FDA Voice.

Protecting the integrity of the drug supply chain is a priority for FDA. These initiatives further our mission to ensure that the drugs which Americans rely on are safe, effective, and of high quality…

Secure Supply Chain Pilot Program: Another initiative to improve the integrity of the U.S. drug supply chain is the Secure Supply Chain Pilot Program (SSCPP), which FDA will be running from February 2014 through February 2016. The SSCPP will enable qualified firms to expedite the importation of active pharmaceutical ingredients and finished drug products into the U.S. The goal of the program is to enable FDA to focus its imports surveillance resources on preventing the entry of high-risk drugs that are the most likely to compromise the quality and safety of the U.S. drug supply. Participating firms will also demonstrate a commitment to securing their drug supply chains as participants in the Customs-Trade Partnership Against Terrorism (C-TPAT). The SSCPP is a voluntary program open to 100 qualified applicants. Each firm accepted to participate in the program will be allowed to have up to five drugs subject to expedited import entry review.

FDASIA: The FDA Safety and Innovation Act (FDASIA) includes a set of provisions, contained in Title VII of the statute, which give FDA authorities to address drug supply chain integrity challenges. FDA has been actively working to implement these authorities:

- FDA issued a proposed rule to enable FDA to administratively detain drugs encountered during an inspection that an officer or employee conducting an inspection has reason to believe are adulterated or misbranded.
- FDA issued a draft guidance defining conduct the agency constitutes delaying, denying, limiting or refusing inspection, resulting in a drug being deemed adulterated.
- In 2013, FDA advocated for higher penalties for adulterated and counterfeit drugs before the U.S. Sentencing Commission – and succeeded.
- FDA held a public meeting on July 12, 2013, to discuss how the agency might implement other parts of FDASIA to protect the drug supply chain.
- FDA issued a draft guidance specifying the unique facility identifier (UFI) system for drug establishment registration.

PLAIR (Pre-Launch Importation Requests): FDA issued a draft guidance to industry outlining the Agency's policy on the importation of unapproved finished drug products in anticipation of approval and market launch of a pending new drug application (NDA), abbreviated new drug application (ANDA) or biologics licensing application (BLA) regulated by CDER. If FDA grants the PLAIR, the Agency will detain the unapproved drug when it is offered for import for a period of up to 6 months pending a decision on the new drug application. If and when CDER approves the new drug application, FDA's Office of Regulatory Affairs will make the admissibility decision for the drug import.

Protecting the integrity of the drug supply chain is a priority for FDA. These initiatives further our mission to ensure that the drugs which Americans rely on are safe, effective, and of high-quality.

Thanks for tuning in…
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CDER Small Business Assistance

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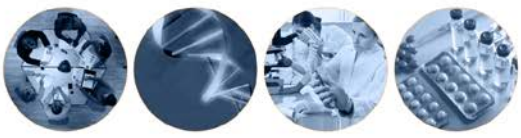

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