Discussion Topics for FDA's DSCSA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act
Meeting # 1 – August 23, 2017

As part of its efforts to ensure that safe and effective drugs are available to U.S. consumers, FDA is working to further secure the drug supply chain through implementation of the Drug Supply Chain Security Act (DSCSA). The DSCSA outlines critical steps to build an electronic, interoperable system by 2023 that is able to trace certain human, finished, prescription drug products as they are distributed within the United States. The new system will enhance FDA's ability to protect consumers from exposure to drugs that may be counterfeit, diverted, stolen, intentionally adulterated, the subject of a fraudulent transaction, or otherwise harmful. FDA and supply chain stakeholders play important roles in addressing the challenges of improving the security of the pharmaceutical distribution supply chain.

This public meeting is the first of a series of meetings at which FDA and supply chain stakeholders will have the opportunity to discuss issues related to the enhanced drug distribution security provisions of the DSCSA and collaborate on implementation strategies. This meeting will focus on exploring the vision for the electronic, interoperable system that is expected in 2023 and what is needed for enhanced drug distribution security. We intend to build on these discussions at subsequent public meetings in this series.

> *For the purposes only of this public meeting, FDA is providing the following information to help facilitate discussion.*

Enhanced Drug Distribution Goals

The DSCSA establishes requirements for the interoperable, electronic tracing of products at the package level that go into effect in November 2023. The 2023 system is expected to provide:

- Electronic exchange of information by trading partners at the package level
- Verification of product identifiers at the package level
- Prompt response to suspect and illegitimate products when found
- Improved efficiency of recalls
- Transparency and accountability in the drug supply chain

Topics for discussion at the public meeting

Two topics will be discussed at this meeting: (1) the vision for 2023; and (2) the enhanced drug distribution security needs related to tracing prescription drugs at the package level. Guiding questions for each topic are included below. To prepare for discussions at the public meeting, FDA encourages participants to use the following questions to help the form their perspective on these topics. Other stakeholders may consider these questions if they intend to submit comments to the public docket.

Vision for 2023

- How will the 2023 system and processes protect and enhance public health?

- In what ways can the system and processes be used to prevent, detect, and respond to suspect and illegitimate products?

- What are the roles of manufacturers, wholesalers, repackagers, dispensers, FDA, and others in the 2023 systems and processes?

- Are there opportunities for interoperability of the 2023 system that can be leveraged within the health care system? What are the benefits and the risks?

- Where does the 2023 system and processes fit within the global supply chain/marketplace?

Enhanced Drug Distribution Needs

- What do we need to do to improve the efficiency of the supply chain?
  (*e.g., are there improvements we can make related to product distribution, exchange of data, communications, and notification*)

- What do we need to do to increase the security of the drug distribution supply chain?
  (*e.g., improve efforts regarding verification products and authorized trading partners, prevention of the distribution of illegitimate product, investigation of suspect and illegitimate product, initiation and termination of notifications*)

- What do we need to do to ensure the security of the 2023 system?
  (*e.g., data security, authorized access)?*

Potential functions/properties of a system that provides enhanced drug distribution security:

- Provides appropriate access to data necessary for interoperability
- Secures data and systems against falsification, malicious attacks, and breaches
- Enables integration of any size businesses
- Fully electronic and interoperable
- Enables trading partners and Federal/State officials to access and use data in the system, as appropriate
- Enables trading partners to capture, maintain, and exchange data accurately and efficiently
- Enables trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns
- Verifies that a trading partner is an "authorized" trading partner
- Improves the ability of FDA and trading partners to prevent distribution of suspect or illegitimate product
- Captures the product identifier of a product for each transaction
- Provides the status of a product through the use of the product identifier (e.g., "dispensed" or "expired")
- Creates the distribution history of the product