Discussion Topics for FDA's DSCSA Public Meeting: The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security

December 8-9, 2020

As part of its efforts to help ensure that safe and effective prescription drugs are available to U.S. patients, FDA is working to further secure the pharmaceutical distribution 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 can trace certain human, finished, prescription drug products as they are distributed within the U.S. 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 gives FDA and supply chain stakeholders the opportunity to listen to participants of the DSCSA Pilot Project Program and other DSCSA related pilot activities, about the key findings and lessons learned of their pilot projects. Meeting participants will also have the chance to discuss issues related to the enhanced prescription drug distribution security provisions of the DSCSA and collaborate on implementation strategies.

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 at the time they are found
- Improved efficiency of recalls
- Transparency and accountability in the pharmaceutical distribution supply chain

Topics for discussion at the public meeting

The following topics will be discussed at the meeting will focus on enhanced product tracing and verification requirements that go into effect in 2023. FDA recommends that stakeholders who are coming to the meeting be prepared to discuss their views, expertise, and experiences with respect to these requirements, including system interoperability and how the 2023 requirements can support enhanced product tracing and verification in an automated, efficient and accurate way.

Key enhanced drug distribution security requirements and needs include:

- An electronic and interoperable system across the pharmaceutical distribution supply chain
- Secure data & system(s) against falsification, malicious attacks, & breaches
- Ensure protection of confidential commercial information & trade secrets
- Enable authorized trading partners to exchange & store data accurately and efficiently for each transaction
- Enable authorized trading partners to promptly respond to a request for product tracing information
- Enable prompt gathering of the information necessary to produce the transaction information for each transaction going back to the manufacturer when appropriately requested
- Enable authorized trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns
- Alerts that a product has been determined to be illegitimate
- Enable scalability for integration by any size business
- Ensure appropriate users have access to the data and system(s)

There will be sessions to discuss the following specific topics with an emphasis on automation, efficiency and accuracy:

- **Appropriate data and system access,** including determination of authorized trading partner status
- **Data, system, and process changes in 2023 for enhanced product tracing**, including incorporation and utilization of product identifier, facilitating the gathering of transaction information back to the manufacturer, and the impact of inference on enhanced product tracing
- **Data, system, and process changes in 2023 for enhanced verification**, including incorporation and utilization of the product identifier, and the impact of inference on enhanced verification