<u>Discussion Topics for FDA's DSCSA Public Meeting</u>
<u>Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act</u>
Meeting # 3 – February 28, 2018

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 is the third in a series of meetings providing FDA and supply chain stakeholders the opportunity to discuss issues related to the enhanced prescription drug distribution security provisions of the DSCSA and collaborate on implementation strategies. The discussion topics for this meeting include enhanced security needs, identification of topics for which the development of guardrails is appropriate, verification of the product identifier, and protection of confidential commercial information and trade secrets.

> *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 facilitate:

- 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: (1) enhanced security needs, (2) identification of topics for which establishing guardrails is appropriate, (3) verification of the product identifier, and (4) protection of confidential commercial information and trade secrets. FDA recommends that stakeholders who are coming to the meeting be prepared to discuss their views, expertise, and experiences with respect to these topics, how the topics relate to their vision for the 2023 system, and what information they need from FDA on each topic. Additional information about each topic is provided below to help prepare participants for the discussions at the public meeting. The information may also be helpful to stakeholders intending to submit comments on these topics to the public docket.

Enhanced Security Needs

For discussion purposes, the following are enhanced security needs to improve the ability of the supply chain to identify and help prevent the distribution of suspect or illegitimate product (not in any particular order.)

1. Fully electronic and interoperable

2. Secures data and system(s) against falsification, malicious attacks, and breaches

3. Ensures the protection of confidential commercial information and trade secrets

4. Enables authorized trading partners to capture, maintain, and exchange data accurately and efficiently for each transaction

5. Enables the prompt response of the transaction information and transaction statement for product upon request by the FDA (or other appropriate Federal or State official) in the event of a recall or for purposes of investigating a suspect product or an illegitimate product

6. Facilitates prompt gathering of the information necessary to produce the transaction information for each transaction going back to the manufacturer, when requested by the FDA (or other appropriate Federal or State official) in the event of a recall or for purposes of investigating a suspect or illegitimate product

7. Enables authorized trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns

8. Signals that a product has been determined to be illegitimate (e.g., red flags)

9. Enables scalability for integration by any size business

10. Prevents trading partners who are not "authorized" from accessing and using the system

Guardrails

Stakeholders have asked FDA to provide "guardrails" to assist with the development of an electronic, interoperable system by 2023. To facilitate the discussion on "guardrails," FDA will describe its understanding of what issues may be appropriate for the development of guardrails and will seek input from meeting participants to identify guardrails for FDA consideration. Examples of potential issues that have been suggested by stakeholders include inference and governance. At the public meeting, we intend to expand the discussion on potential guardrails and will ask participants to prioritize the topics/issues for which guardrails are needed based on the level of importance and need by supply chain stakeholders.