Discussion Topics for FDA's Public Workshop:
Proposed Pilot Project(s) under the Drug Supply Chain Security Act
April 5-6, 2016

For the purposes of this public workshop only, FDA is providing the following information to help facilitate discussions.

The Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act which was enacted November 27, 2013, requires FDA to establish pilot project(s) to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers. These pilot project(s) will build upon efforts to enhance the safety and security of the pharmaceutical distribution supply chain, including any pilot project previously conducted, and will deliver meaningful information and learning as inputs to future FDA Guidance for Industry and other clarifying documents in order to implement the law.

Purpose of Workshop

- To provide an opportunity for interested persons to share information and discuss key issues and opportunities concerning the proposed design objectives of pilot projects that will explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.
- To obtain information and input from pharmaceutical distribution supply chain members about issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the pharmaceutical distribution supply chain, and identifying the system attributes that are necessary to implement the requirements under section 582.
- To learn more about the practices, processes, and systems that supply chain stakeholders currently use or plan to use to meet the requirements under section 582, specifically the product tracing and verification requirements.

Discussion

To ensure an efficient and effective workshop, participants should be familiar with the requirements established by the DSCSA (Public Law 113-54, Title II) and provisions under section 582(j) that describe pilot projects and project design. Participants should review all applicable definitions in the DSCSA including, but not limited to, the definitions for transaction information (TI), transaction history (TH), and transaction statement (TS), product identifier, suspect product, and illegitimate product. FDA expects workshop participants to work collaboratively with all stakeholders and engage in productive discussions.

The discussion topics will include, but are not limited to:

- the design and goals of pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain
- challenges associated with pilot projects, including consideration of the size and role of supply chain entities
- identifying the system attributes needed to accomplish the DSCSA's requirements

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- the ability of trading partners to accomplish the DSCSA's product tracing requirements, with a focus on utilization of the product identifier
- the ability of trading partners to accomplish the DSCSA's requirements to verify product to identify suspect and illegitimate products
- the ability of trading partners to utilize the electronic, interoperable system of product-tracing information across the pharmaceutical distribution supply chain
- to better understand the following evaluation factors:
    - baseline measures: current practices and operations from the point of view of the pre-pilot process.
    - projections and insights: how the experience and observations might apply to other trading partner types or sizes or product types, in addition to the pilot project outcomes and differing results of similar pilot projects.
    - scalability implications: how controlled, small scale versions of projected operations would change when increased to larger scale

Resources

FDA's Drug Supply Chain Security Act webpage:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

Title II of the Drug Quality and Security Act; The Drug Supply Chain Security Act:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm

Comments

Comments related to these discussion topics can be submitted electronically to the docket established for this public workshop at http://www.regulations.gov . The docket number is FDA-2016-N-0407. Written comments can also be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number. Written or electronic comments should be submitted to the docket by April 21, 2016 for Agency consideration.