

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0200]

Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to receive information and comments on standards for the interoperable exchange of information associated with transactions involving human prescription drugs in a finished dosage form (prescription drugs) to comply with new requirements in the Drug Supply Chain Security Act (DSCSA). We are seeking information from drug manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies) and other drug supply chain stakeholders and interested parties, including standards organizations, State and Federal Agencies, and solution providers. In particular, stakeholders and other interested parties are requested to comment about the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of product in which a change of ownership occurs. This action is related to FDA's implementation of the DSCSA.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments 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 found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Connie T. Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301-796-3130.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the DSCSA (Title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA, which adds section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), directs the Secretary of Health and Human Services (the Secretary) to establish standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale drug distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders.

FDA has been engaged in efforts to improve the security of the drug supply chain for many years to protect U.S. patients from unsafe, ineffective, and poor quality drugs. Since the formation of the first FDA Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multilayered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit and diverted drugs. The ability to track and trace finished prescription drugs plays a significant role in providing transparency and accountability in the drug supply chain. Under section 505D of the FD&C Act (21 U.S.C. 355e), FDA has been

evaluating existing and emerging standards, system attributes and needs, and adoption of track and trace and authentication systems and technology. The system that will be established under DSCSA will enhance FDA's ability to help protect U.S. consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful by improving detection and removal of potentially dangerous drugs from the drug supply chain.

FDA is announcing the establishment of a public docket to provide an opportunity for interested persons to share information, current practices, research, and ideas on the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data.

## II. Definitions

The following definitions for transaction information, transaction history, and transaction statement as defined under the DSCSA are provided to assist stakeholders in developing comments or responses. In addition, FDA is interested in learning about practices, processes, and systems that supply chain stakeholders currently use to exchange information, such as product information, information related to the sale or change of ownership of prescription drugs, or communications about drugs in distribution. For other definitions, please refer to section 202 of DSCSA.

Under DSCSA, "transaction information" means (A) the proprietary or established name or names of the product; (B) the strength and dosage form of the product; (C) the National Drug Code number of the product; (D) the container size; (E) the number of containers; (F) the lot number of the product; (G) the date of the transaction; (H) the date of shipment, if more than 24

hours after the date of transaction); (I) the business name and address of the person from whom ownership is being transferred; and (J) the business name and address of the person to whom ownership is being transferred. “Transaction history” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. “Transaction statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction--(A) is authorized as required under the DSCSA; (B) received the product from a person that is authorized as required under the DSCSA; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582 [of the DSCSA]; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 582 [of the DSCSA]; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.

### III. Request for Comments and Information

FDA is requesting comments and supporting information on the following: (1) Current practices and ideas that may be used for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of product in which a change of ownership occurs (i.e., transaction); (2) the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data; and (3) current practices and ideas that may be used for the exchange of information between members of the pharmaceutical distribution supply chain and FDA to provide, receive, and terminate notifications, respond to requests for verification of product, and

respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product.

To facilitate this discussion, FDA has included several questions in the following paragraphs. These questions, which are not meant to be exhaustive, are provided to stimulate public comments that will help FDA establish initial standards for the interoperable exchange of information for tracing of prescription drugs in paper or electronic format. The public is encouraged to address these and/or other related issues.

Questions related to (1) current practices and suggestions for the interoperable exchange of transaction information, transaction history, and transaction statements and (2) the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of prescription drugs and to facilitate the exchange of lot level data:

1. What types of information about transactions do you exchange? What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange this information? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?
2. What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

3. Do the practices, processes, or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?
4. If you are currently using paper means to exchange transaction information or history, when do you plan to move to an electronic format?
5. Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history? How can these challenges be addressed?
6. Are there practices, processes, or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA?
7. Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form? How can these challenges be addressed?
8. Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?
9. Are there other technologies, systems, or solutions available now that would enable the interoperable exchange of transaction information, transaction history, or transaction statements?

Questions related to (3) current practices and suggestions for the exchange of information between supply chain stakeholders or with FDA to provide, receive, and terminate notifications, respond to requests for verification of suspect product, and respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product:

10. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders and FDA with respect to providing, receiving, and terminating a notification that an illegitimate product is found in distribution? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.
11. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders or with FDA to respond to requests to verify the lot number, expiration date, and other indices of identity assigned to a product by the manufacturer or repackager (i.e., requests for verification of suspect product)? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.
12. Are there current practices, processes, or systems that could be used for providing information in response to requests from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

Question related to capturing information that has not necessarily been addressed by the previous questions:

13. Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions? Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA.

### III. Submission of Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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