FDA Verification Systems for DSCSA Guidance – October 29, 2018 Summary

On October 25, 2018, the FDA posted on the Federal Register draft guidance *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* to share the FDA's interpretation of the DSCSA requirements for verification systems/processes in suspect/illegitimate product scenarios and saleable returns verification, along with recommendations for cleared product notifications.

Background

This guidance is designed to help all industry stakeholders involved in verification processes to understand the information and business process expectations from the FDA given DSCSA requirements and in certain situations describe FDA recommendations for managing such verification. The FDA had previously published guidance relating to investigation and management of suspect products and notification of illegitimate products across the supply chain so this guidance is in part an extension of that guidance but is not designed to address all verification provisions under DSCSA.

Key Summary Implications

This summary is meant to highlight certain key points of the guidance and act as an outline for understanding the guidance. Much of this guidance is a reinforcement of the statements in DSCSA whereby stakeholders need to have verification systems and processes in place to manage the determination, quarantine and investigation/disposition of suspect and illegitimate product. This guidance does not focus on specific technologies or information architectures but instead highlights the FDA's expectations as to the capabilities of such systems and processes implemented.

Certain statements in this guidance were made with respect to DSCSA saleable returns verification. DSCSA saleable returns verification of product identifiers, which will become a major challenge facing manufacturers, repackagers and wholesale distributors starting in November 2019 when the verification of 10s of millions of drug products annually will begin to be required, was slightly touched upon in this guidance. While the guidance provided little specificity around systems and technologies for saleable returns verification, the guidance did highlight that such saleable returns for which the product identifier cannot be verified should be treated as suspect product. This possibility was discussed at length in the HDA Verification Router Service (VRS) task force, of which TraceLink is a member, as well as in TraceLink's Product Information Manager – Product Verification solution innovation group. Given the volume of verification requests which will be generated by saleable returns in the supply chain, we strongly encourage all stakeholders to ensure that:

- The information exchanged and the interpretation of that information under such verification processes are well understood by all affected stakeholders to minimize errors
- The systems being leveraged for verification, particularly of saleable returns which may be of high volume or frequency, support both the required verification checking as well as the ability to exchange other related information to help guide appropriate understanding of the results

Guidance Details – Verification Systems under DSCSA

NOTE: we have slightly reordered the sections describing the various verification systems in the guidance

System for Processing Saleable Returns

Manufacturers, wholesale distributors, and repackagers must have systems in place that will allow them to process saleable return products that they intend to further distribute. These systems must allow the trading partners to verify the product identifier (the four data elements making up the DSCSA product identifier) on each sealed homogeneous case of saleable returned product or on each package of saleable returned product if such product is not in a sealed homogeneous case.

A saleable returned product may not be further distributed until the product identifier is verified and if the product identifier is not successfully verified, the product should be handled as a suspect product.

System for Responding to Requests for Verification

Manufacturers and repackagers must have systems in place to respond to requests for verification from trading partners within 24 hours of receipt of such a request. Such systems must allow the manufacturer or repackager to notify the trading partner making the request whether the product identifier that is the subject of the request corresponds to the product identifier affixed or imprinted by that manufacturer or repackager. Note that this guidance does not address any potential business or operational requirements arising across the supply chain from such requests for verification.

Such systems should allow the manufacturer or repackager to respond to the request within the required timeframe with a clear statement as to whether the product identifier has been verified or not, and be integrated with the overall system used by such companies to identify suspect product and illegitimate product.

If the product identifier in the query does not correspond to the product identifier affixed or imprinted by the manufacturer or repackager, the product must be treated by the manufacturer or repackager as a suspect product (as applicable) and if the responding entity has reason to believe that the product is illegitimate, it must indicate that in its response to the request for verification from a trading partner and inform them as to why they believe the product may be illegitimate.

Systems to Determine That a Product is Suspect

Trading partners must have systems in place to help determine if a particular product is a suspect product. These systems should be well-designed to detect and assess a potentially suspect product under the previously published definitions of suspect product and under a company's own due diligence processes. The FDA may make a request for verification to a trading partner if the FDA has determined that the trading partner may have such product within its possession or control. Systems implemented

should support such requests and the resultant processes/procedures documented under DSCSA. Processes for managing illegitimate product notifications must be followed by all trading partners.

System for Suspect Product Quarantine and Investigation

Upon determining that a product is suspect or upon receiving a request for verification from the FDA, a trading partner is required to quarantine and investigate the product to determine if it is an illegitimate product. Trading partners must have systems in place to enable such quarantines and investigations.

Quarantining may be accomplished through physical separation and/or electronic means where applicable and such implemented systems should be robust enough to ensure that suspect product is not inadvertently distributed and responsibilities for clearing quarantined product are well understood.

Investigations of suspect product must include validation of any applicable transaction history and transaction information, including active communication and coordination with the manufacturer and/or repackager or other trading partners as are appropriate, coupled with appropriate laboratory techniques and testing where necessary to determine if such a product is an illegitimate product.

After each investigation of a suspect product, a review of the verification system and its components should be undertaken to determine lessons learned and if improvements are possible and warranted.

System for Cleared Product Notification Regarding Suspect Products

Trading partners must promptly notify the Secretary, if applicable, if they determine after an investigation that the suspect product is not an illegitimate product. The FDA expects such "cleared product notifications" to be submitted to the FDA only if the suspect product is the subject of an FDA request for verification. Other cleared product notifications should not be submitted to the FDA. Trading partners must have systems in place for such cleared product notifications.

A cleared product notification submitted to the FDA should contain several pieces of information, including a subject line "Cleared Product Notification", data on product in question (proprietary or established name, strength and dosage form, NDC, lot number, expiration date, serial number (for product covered under the product identifier requirements), container size and number of containers), reason why the product was determined to be suspect and a summary of the investigation, date the product was cleared, name and official position of the individual of the trading partner who cleared the suspect product (including their signature), and the distribution or disposition of the product.

The cleared product notification should be submitted to drugnotifications@fda.hhs.gov, including the above information, the date of the FDA request for verification to which the cleared product notification applies, and the name of the FDA office and/or employee who made the request for verification. If a trading partner determines, after investigation, that a suspect product is not an illegitimate product and

is not the subject of an FDA request for verification, the trading partner should not submit a cleared product notification to the FDA but should retain the notification in their investigation records.

Records of suspect product investigations, including all cleared product notifications, must be maintained for a period of at least 6 years after the conclusion of the investigation.

System for Illegitimate Product Quarantine and Disposition

Trading partners must meet certain requirements for the quarantine and disposition of illegitimate product, including coordination with trading partners as applicable. In making an illegitimate product determination, trading partners are required to coordinate with the manufacturer.

Processes required including ensuring that illegitimate products are kept physical separate from other products intended for distribution, ensuring that any systems for quarantining are robust enough to ensure that an illegitimate product is not inadvertently distributed, ensuring that there are appropriate written procedures/SOPs for disposition of illegitimate product, ensuring that any contractors hired to dispose the product are appropriately audited, and ensuring that the process for retention of samples to examine such illegitimate product are well designed as outlined in the guidance. Records of the disposition of an illegitimate product must be maintained by trading partners for not less than 6 years after the conclusion of the disposition.

System for Illegitimate/High Risk of Illegitimacy Product Notifications

Trading partners must have systems in place for notifying the FDA and immediate trading partners of an illegitimate product and, for manufacturers, product with a high risk of illegitimacy. The Suspect Product and Notification guidance previously published sets forth the processes and procedures for such notifications.