HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Re: Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Guidance for Industry, Dkt. No. FDA-2020-D-2024

Dear Dr. Verbois and Dr. Jung:

The Healthcare Distribution Alliance[1] (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments regarding the agency's Guidance for Industry, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act (EDDS Final Guidance).[2] We appreciate the agency's leadership and timely release of this EDDS Final Guidance and its revision on January 18, 2024, as trading partners continue to work towards compliance with the Drug Supply Chain Security Act's (DSCSA) requirements for enhanced drug distribution security.

HDA supports the EDDS Final Guidance. In the interest of advancing compliance with the DSCSA's enhanced drug distribution security requirements, we ask for further clarification on parts of the Final Guidance and suggest the agency publish a revision to the guidance or a concise Questions & Answers (Q&A) document to facilitate such clarification.

1. **FDA should recognize in a revision to the guidance or Q&A that verification of product identifiers may utilize a variety of modalities.**

The EDDS Final Guidance appears to assume "interoperable" verification.[3]

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[1] HDA represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.
[2] 88 Fed. Reg. 60217 (Aug. 31, 2023).
[3] In this context, "verification" refers to the term defined in §581(28), that is, a determination of "whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the

> Each trading partner should have its own individual systems and processes for accessing and managing its products and associated data. Such individual systems and processes should permit secure, appropriate, and efficient sharing of electronic information (i.e., data) between trading partners; more specifically**,** individual systems and processes should allow for trading partners to exchange data with each other for product tracing ***and verification*** in an accurate, interoperable manner that also protects confidential commercial information and trade secrets.

EDDS Final Guidance at page 9 (emphasis supplied). Similarly, the discussion of verification at the conclusion of the EDDS Final Guidance states:

> Section 582(g)(1)(C) of the FD&C Act requires systems and processes for verification of product at the package level. … The trading partner's individual system and processes should permit FDA, other Federal and State officials, and other trading partners (requestors), as applicable and appropriate, ***to submit a verification request and receive the response in an electronic, interoperable, and standardized manner.***

EDDS Final Guidance at pages 16-17 (emphasis supplied).

HDA is concerned that the EDDS Final Guidance appears to assume that the process for initiating and responding to requests for verification of product identifiers should always be interoperable. If so, this position does not appear to fully align with the recently finalized Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs Guidance for Industry (Verification Systems Guidance). The Verification Systems Guidance describes the systems and processes trading partners should have to verify product identifiers where required but, unlike the EDDS Final Guidance,[4] does not specify that these verification systems and processes should be interoperable.

The Verification Systems Guidance appears to recognize the reality that trading partners will use a variety of systems and processes for the initiation of and response to verification requests. These systems and processes will likely always include manual and partially manual processes. The FDA's recently established DSCSA CDER NextGen portal assumes that a manufacturer or repackager responding to a verification request initiated by the agency would manually enter its response into the portal. Furthermore, a wholesale distributor may manually scan a saleable return product package to verify the package's product identifier against transaction data that the wholesale distributor interoperably received from the product's manufacturer or repackager in an Electronic Product Code Information Services (EPCIS) file.[5]

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standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager."

[4] The EDDS Final Guidance does cross-reference the (then draft) Verification Systems Guidance at page 16.

[5] This process is often referred to as "Direct-to-Replicate Verification" and is described in Chapter 4 of the Partnership for DSCSA Governance (PDG) Foundational Blueprint for 2023 Interoperability. Direct-to-Replicate Verification permits a wholesale distributor to verify the product identifier on a saleable return against a replicate of the data generated by and received from the manufacturer or repackager of the product. Wholesale distributors using this method will maintain up-to-date information received from manufacturers to assure that products are not subject to a recall, an illegitimate product notification, or some other action that would prevent them from being returned to inventory for resale. Though the EDDS Final Guidance suggests that a wholesale distributor's "individual systems and processes may be similar for general verification of the product identifier and verification of the product identifier for saleable returns," we note that the PDG Blueprint permits verification against replicate data only for saleable returns and not for other verification under other circumstances, such as in suspect and illegitimate product investigations.

The EDDS Final Guidance sets out a desirable goal: that a "trading partner's individual system and processes should permit FDA, other Federal and State officials, and other trading partners (requestors), as applicable and appropriate, to submit a verification request and receive the response in an electronic, interoperable, and standardized manner." As FDA is aware, verification of product identifiers can be accomplished interoperably through the Verification Router Service (VRS). The VRS is a useful and functional tool that permits an authorized trading partner to scan the identifier on a product package; the VRS then routes that query to the appropriate manufacturer's data repository, which then sends a response back to the initiating trading partner that the product identifier is, or is not, verified.

In addition to the VRS, we are aware of at least two other systems for potential verification of product identifiers: FDA's own CDER NextGen Portal, and the National Association of Boards of Pharmacy (NABP) Pulse digital platform. All are electronic, and we understand that NABP is working to make Pulse interoperable with the VRS. However, participation in the VRS and Pulse is wholly voluntary and FDA's NextGenPortal is not interoperable with these other verification systems. A trading partner or regulator who is not participating in the VRS (or Pulse) and that cannot verify against transaction data it received from the package's manufacturer or repackager would likely have to rely upon manual measures, such as contacting the manufacturer or repackager via phone or email to verify a package's product identifier.

We, therefore, ask that FDA recognize in a Q&A or in a revision to the guidance that verification of product identifiers may utilize a variety of systems and processes and that all would be compliant with the DSCSA so long as they return an accurate and timely verification response as required under the law. Further, we ask that the agency explain clearly in the Q&A or guidance revision that, before a wholesale distributor may further distribute a returned product, the wholesale distributor must verify that the product identifier imprinted upon or affixed to the package or homogenous case corresponds to the information assigned to the product that the wholesale distributor received from the manufacturer or repackager of such product.

2. FDA should clarify in a Q&A or revision to the EDDS Final Guidance the appropriate processes if trading partners cannot resolve an error or discrepancy in product tracing information within ten business days.

The draft EDDS guidance specified that any errors and discrepancies in product tracing information should be resolved within three business days. The EDDS Final Guidance extends this timeframe to ten business days.[6] HDA continues to believe that a time limit is unnecessary so long as the product remains quarantined. For instance, HDA understands from the VRS experience that resolutions can sometimes take longer than even ten business days. Trading partners continue to work together to resolve mismatches between a product and data, but, as the product will not be transacted unless and until the data error or discrepancy is resolved, a quarantined product poses no safety or security risk.

Further, it is unclear what should occur if ten business days pass and the trading partners cannot resolve the clerical error or data mismatch. Trading partners may not be able to resolve the error despite best efforts. We ask that FDA clarify that in such instances, trading partners should document that they cannot resolve the clerical error or discrepancy and that the product has been permanently removed from saleable inventory.

[6] EDDS Final Guidance at page 13.

3. **FDA should clarify in a Q&A or revision to the EDDS Final Guidance that data validation does not apply to all trading partners.**

The EDDS Final Guidance states:

> For the purpose of this guidance, "data architecture" refers to the type of data collected and the data validation policies, standards, and safeguards that govern how data is stored, managed, and used within and between organizations and respective organizations' individual systems.

EDDS Final Guidance at page 9.

To the extent "data validation policies, standards, and safeguards" are intended to include process validation, we ask the agency to clarify in a Q&A or revision to the EDDS Final Guidance that such requirements are limited to pharmaceutical manufacturers and repackagers. HDA addressed this issue in further detail in its January 2022 comments submitted following FDA's public meeting on the EDDS draft guidance (available here).

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We thank FDA for this opportunity to provide comments on the EDDS Final Guidance. If you have any questions, please contact me at kshankle@hda.org.

Sincerely,

/s/ Kala Shankle

Kala Shankle
Vice President, Regulatory Affairs