Healthcare Distribution Alliance

HEALTH DELIVERED

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Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket; Request for Information and Comments

Dear Dr. Verbois and Ms. Kundi:

The Healthcare Distribution Alliance[1] (HDA) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments to the agency's reopened docket, *Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act* (RFI).[2]

HDA previously submitted comments to this RFI docket in February of this year.[3] We submit these additional comments in response to the agency's recent announcements regarding waivers and exemptions beyond the stabilization period. ***Given that FDA has encouraged trading partners to submit requests by August 1, our concerns are urgent as the scope of a granted waiver or exemption will impact wholesale distributor and dispenser operations and ability to fulfill compliance obligations.*** We urge FDA to consider the following when evaluating any waiver or exemption request:

- **A product-specific waiver or exemption, if granted, should be based on the National Drug Code (NDC), not lot or batch number within an NDC.** Further, if an NDC is subject to a waiver or exemption, all products assigned that NDC should be removed from tracing and saleable returns requirements during the term of the waiver/exemption to avoid burdening downstream trading partners.

- **A product-specific waiver or exemption should be initiated by the NDC owner, typically the manufacturer, as it is the party who can explain the rationale for the request and the plan to come into compliance**. However, if FDA does grant a product-specific waiver or exemption based upon a request by someone other than the NDC owner, that waiver or exemption should apply to all transactions of that NDC (that is, for

[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] 89 Fed. Reg. 49884 (June 12, 2024).
[3] HDA, Letter to FDA (Feb. 14, 2024), available at https://www.regulations.gov/comment/FDA-2023-N-4806-0010.

all products assigned that NDC, regardless of whether handled by the waiver/exemption requester).

- **Wholesale distributors cannot implement an FDA-granted exemption or waiver that would require maintenance of both lot-level and serialized data DSCSA compliance systems**; creating such dual systems would necessitate rebuilding information systems and require significant time, expense, and resources.

- **As part of its evaluation of a waiver/exemption request, FDA should consider readily available alternatives (to granting the waiver/exemption) that do not burden downstream trading partners.**

- **FDA should consider carefully the challenges presented by products in the supply chain as a granted waiver or exemption expires.**

Further explanations of these issues are provided below.

I. POST-STABILIZATION WAIVERS AND EXEMPTIONS

HDA appreciates the agency's update to its *Waivers and Exemptions Beyond the Stabilization Period* information page.[4] HDA had asked FDA to clarify its expectations beyond the Stabilization Period and this update provides additional information for the Agency to consider. We are hopeful the announcement of the end of stabilization will incentivize action and data exchange for those suppliers who continue to lag behind the rest of the industry.

We appreciate FDA's recommendation that a trading partner submit a request for a waiver or exemption by August 1, 2024, if it does not believe it will be in full compliance by November 27, 2024. Further, we appreciate the agency's recommendation that requesters should identify the steps they have taken to implement § 582 requirements, why they need more time, and what steps they will take to achieve full implementation.

To that end, FDA has stated in the *Waivers, Exceptions, and Exemptions from the Requirements of Section 582* (*WEE Final Guidance*) that when it evaluates a waiver, exception, or exemption (WEE) request, it will consider effects upon downstream trading partners and may provide appropriate relief. The agency will also consider how products subject to a WEE might continue to move in the supply chain. It is imperative that the agency include these factors in its evaluations of post-Stabilization Period waiver and exemption requests. The scope and conditions of a waiver or exemption granted to one trading partner could impact wholesale distributors; some conditions may not be implementable at all, or only with costly changes to information systems. We address these urgent practical and operational impacts to waivers and exemptions below.

1. A product-specific waiver or exemption, if granted, should be based on the NDC, not lot or batch number within an NDC.

We understand that most of our members' experiences with granted WEEs have been on a product-by-product basis, with manufacturers identifying the NDCs that are the subject of the FDA-granted WEE and are therefore, outside DSCSA requirements. Operationally, wholesale

[4] Waivers and Exemptions Beyond the Stabilization Period (June 12, 2024), *available at* https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/waivers-and-exemptions-beyond-stabilization-period.

distributors typically place a "flag" in their system which removes that NDC from all internal DSCSA systems and processes.

It is our understanding that some stakeholders have suggested that the scope of a waiver or exemption could be narrowed to specific lots and batches within an NDC. However, our members report that their DSCSA systems and operational processes cannot differentiate by lot number within an NDC. Our wholesale distributor members report that they will be unable to implement a granted waiver or exemption for a single batch or lot number without costly and time-consuming changes to existing information technology. Therefore, we urge FDA to continue to grant waivers and exemptions only on an NDC basis.

2. **A product-specific waiver or exemption should be initiated by the NDC owner, typically the manufacturer, as it is the party who can explain the rationale for the request and the plan to come into compliance**.

Under the DSCSA, wholesale distributors must provide accurate, complete, and timely serialized product tracing data to their customers. Given the interdependency of the supply chain, the compliance of all other downstream trading partners depends upon the ability of the manufacturer or repackager (collectively, "manufacturer") at the outset to meet this statutory obligation for all covered products for all transactions.

Wholesale distributors should not be expected to seek a waiver or exemption from their own compliance obligations because their suppliers cannot provide accurate, complete, and timely data for all NDCs for all transactions. For each product, the manufacturer is in the best position to be able to explain the reasons for its delay and when and how it will come into compliance. The manufacturer is also in the best position to notify all affected trading partners. However, this also means that a wholesale distributor does not "control its fate" and is left to the readiness of its suppliers.

We ask the following of the agency:

- Where a party other than the manufacturer that owns the NDC submits a waiver or exemption request, which cites as the reason a manufacturer's inability to provide accurate, complete, and timely serialized product tracing data for its NDC(s), the agency should immediately notify and involve that manufacturer.
- Any NDC-specific waiver or exemption that FDA grants, regardless of the requester, should cover all transactions of that product with all trading partners. We believe it could be very confusing for dispensers for example, if one wholesale distributor has obtained relief from § 582 requirements for an NDC and another wholesale distributor, who is purchasing and reselling the same NDC, has not.
- If the agency grants the waiver or exemption requested by someone other than the NDC owner, the agency will need to instruct the NDC owner to inform all trading partners. We suggest the agency also consider ways for trading partners to view a list of all NDCs subject to a waiver or exemption.
- Finally, if an NDC is subject to a granted waiver or exemption, which excuses the supplier from providing accurate, complete, and timely serialized data to its wholesale distributor customer, it would be helpful for FDA to make clear that wholesale distributors are also excused from providing, receiving, or maintaining any product tracing data for products assigned that NDC.

3. Wholesale distributors cannot implement an FDA-granted exemption or waiver that would require maintenance of both lot-level and serialized data DSCSA compliance systems.

FDA explains in the *WEE Final Guidance* that, when granting a WEE, the agency may also provide "corresponding relief" for DSCSA requirements of downstream trading partners. For example, in the small dispenser exemption, the agency may have sought to accomplish this goal by allowing other trading partners to "continue to rely on current methods for providing, capturing, and maintaining" lot-level transaction data. While we appreciate the agency's commitment to consideration of how waivers and exemptions impact downstream customers, we are concerned with any assumption that continuing current methods of compliance will be a feasible and less burdensome alternative for all trading partners.

The DSCSA mandates that trading partners move from lot-level data exchange (typically provided in an Advance Ship Notice or ASN) to secure, electronic, and interoperable exchange of package-level product tracing data.[5] FDA has recommended the EPCIS standard for this exchange of serialized product tracing data.[6] Trading partners must transition to providing, receiving, and maintaining serialized product tracing data before the end of the Stabilization Period.

We have described previously to FDA that our wholesale distributor members cannot simultaneously receive from suppliers (for purposes of DSCSA compliance) serialized data in EPCIS event files from some suppliers while others continue current practice of providing lot-level data in an ASN.[7] Our wholesale distributor members spent significant resources and years of work to build their DSCSA technology systems to meet their 2023 obligations. These systems were not designed to concurrently maintain and employ dual compliance methods for accepting transaction data. Put simply, once wholesale distributors transition by November 27, 2024, from receipt of lot-level data in an ASN to receipt of serialized data in EPCIS event files for DSCSA compliance, they cannot continue to accept or rely on the ASN as their DSCSA compliance document.

4. In evaluating a waiver/exemption request, FDA should consider readily available alternatives (to granting the request) that do not burden downstream trading partners.

If a trading partner transacts a sealed container, it must provide to its customer the product identifiers for each package in the sealed container. Yet, we understand that some manufacturers continue to not provide accurate product tracing data that includes the product identifiers for each package in the transaction when those packages are within an already sealed container.[8]

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[5] § 582(g)(1).
[6] *See* DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Final Guidance for Industry.
[7] HDA, Letter to FDA (June 2, 2023), *available at* https://www.hda.org/getmedia/d989d7c7-3961-4df0-bff4-7c92621866f4/HDA-Recommended-Phased-Approach-Letter-6-2-23.pdf.
[8] We describe here what is commonly referred to as "aggregation" which the agency has recognized promotes efficiency though it is not expressly required in the DSCSA. We believe this is unhelpful semantics. Section 582(g)(1)(B) requires product identifiers for each package in a transaction. If the manufacturer did not capture product identifiers during packaging and aggregate them to higher levels of packaging, it must generate the package-level data via some other means.

In these instances, we believe that there are readily available alternatives that place compliance obligations on the responsible party and are less burdensome to downstream trading partners. For example, a manufacturer can open its sealed containers, scan the products within, and generate the required data for each package in a transaction as the law requires; alternatively, they can send the products to a repackager who can undertake this re-work.

5. FDA should consider carefully the challenges presented by products in the supply chain as a granted waiver or exemption expires.

The *WEE Final Guidance* recognizes that products subject to a WEE will continue to move in the supply chain and that FDA may address the issue if it grants the request. FDA has, with other compliance deadlines, extended that policy for all transactions until a product's expiration.[9] We recommend continuing this approach for post-Stabilization Period waivers and exemptions.

We note that this policy, however, still poses some challenges. For example, for a single NDC, some products may enter the supply chain after November 27, 2024, under a waiver or exemption with no product tracing data, other products, including packages in sealed cases, will have lawfully entered the supply chain prior to November 27, 2024, with only lot-level data, and, eventually, other products will enter the supply chain with serialized product tracing data. Regulators and auditors will need to understand that this condition is present in the supply chain, and it will take time for products with serialized product tracing data to replace all others. Trading partners will have to develop procedures and rules appropriate for their business needs to manage the sale, return, and resale of such products. The issue will persist until only products with serialized product tracing data are circulating in the supply chain and all others are consumed or expire.

To ease this challenge, HDA notes that placing certain timing conditions in a waiver or exemption could address at least some of the confusion associated with products in the supply chain that are not supported by serialized data. For example, the agency could specify a timetable, with the manufacturer's transitioning to providing accurate, complete, and timely serialized product tracing data well ***before*** the WEE expires, ideally several weeks or months. We believe that requiring a manufacturer to phase in serialized data exchange while it has the benefit of the waiver or exemption provides an "on-ramp" can help a successful and orderly operational transition.

II. SMALL DISPENSER EXEMPTION

We appreciate the small dispenser exemption and believe it will be helpful for some of our members' downstream trading partners. We recognize that FDA intended the exemption to also ease burdens for the suppliers to small dispensers. However, from an operational standpoint, our members report that their challenges to providing accurate and complete serialized product tracing data to their customers are not due to customer size but primarily because some suppliers are not currently meeting

[9] *See, e.g.*, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies*, "In addition, FDA does not intend to take action to enforce the requirement under section 582(g)(1)(B) of the FD&C Act with respect to product that is introduced in a transaction into commerce by the product's manufacturer or repackager before November 27, 2024, and for subsequent transactions of such product through the product's expiry"; *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier*, "Trading partners may engage in transactions involving grandfathered product per the conditions of the grandfathering policy until product expiry, regardless of when the transaction occurs."

their statutory obligations. For business, efficiency, and patient safety reasons, we believe our members intend to continue towards full compliance for all customers for all products and all transactions as soon as they are able.

We have raised before[10] and reiterate the critical importance of FDA-led education for the dispenser community and their state regulatory authorities.

Conclusion

We thank FDA for this opportunity to provide comments on the RFI and the WEE process. If you have any questions, please contact me at kshankle@hda.org.

Sincerely,

/s/ Kala Shankle

Kala Shankle
Vice President, Regulatory Affairs

[10] HDA, Letter to FDA (Feb. 14, 2024), *available at* https://www.regulations.gov/comment/FDA-2023-N-4806-0010.