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Re: Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs, Draft Guidance for Industry, 87 Fed. Reg. 13738 (March 10, 2022), Docket No. FDA–2018-D-3462

Dear Dr. Jung:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments regarding the agency's reissued Draft Guidance for Industry, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs, 87 Fed. Reg. 13738 (March 10, 2022) ("2022 Draft Guidance" or "Verification Draft Guidance"). The Verification Draft Guidance, first released as a draft in 2018 (referred to here as the "2018 Draft Guidance"), has undergone revisions so significant that FDA has elected to again issue it in draft form and solicit additional comments on the many changes prior to finalization. We greatly appreciate this ongoing dialogue with the agency on implementation of the Drug Supply Chain Security Act (DSCSA). The result of this beneficial exchange between the agency and stakeholders is better guidance that comports with the DSCSA, ubstantially aids in protecting patients and the supply chain, and is operationally feasible.

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA recognizes and appreciates the many instances in the 2022 Draft Guidance where FDA addressed the concerns we raised in comments to the 2018 Draft Guidance.[1] In the interest of time and economy and given the urgent competing priorities of 2023 readiness and the recently proposed National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers[2] ("Licensure Proposed Rule"), our comments focus specifically on the aspects of the 2022 Draft Guidance likely to be most impactful to wholesale distributors. Where we are silent, the lack of comment should not be construed as support (or neutrality) as to any part of the 2022 Draft Guidance, or any change to it from the 2018 Draft Guidance.

We present most of our views in a chart format, as a separate attachment, with two exceptions,

- System for Quarantine of Suspect and Illegitimate Product, Section III.B. and Section III.D., and,
- Verification of Production Identifier, Section III.F. and Section III.G.

Our comments on these parts of the 2022 Draft Guidance are too detailed for the abbreviated chart format and so are presented below.

1. Sections III.B. and III.D. – System for Quarantine of Suspect and Illegitimate Product

a. Much of the expanded explanation of quarantine is helpful

The 2022 Draft Guidance expands upon the concept of "electronic quarantine." Section III.B.1., Lines 281-298, addresses suspect product quarantine and Section III.D.1., Lines 470-486, addresses quarantine for illegitimate product. These sections represent a significant expansion from the 2018 Draft Guidance and we support much of what is proposed in the 2022 Draft Guidance, including the following:

- We appreciate that FDA has recognized that quarantine is not limited to physical separation but, consistent with the DSCSA, can mean "other procedures" which include electronic means.
- We support Lines 292-293 and 480-481 which provide that the system for quarantine should be "robust enough" to ensure that suspect and illegitimate products, respectively, are not inadvertently distributed.
- We note that the Licensure Proposed Rule, mentioned above, includes considerable discussion of physical and, where appropriate, electronic segregation of prescription drugs.[3] We encourage the Agency to consider aligning the Draft Guidance's approach to these topics with that of the Licensure Proposed Rule.

The 2022 Draft Guidance frequently uses the term "system" for quarantine (*e.g.,* Lines 285-286 ("an electronic system or process"), Lines 288-289 ("the trading partner's system should designate the suspect product as quarantined"), and Lines 292-480 ("system for quarantine")). We believe it is more accurate to refer to "systems." The DSCSA itself refers to "systems" for verification (*see, e.g.*, § 582(b)(4), (c)(4)), which, of course, include procedures for quarantining suspect and illegitimate

[1] Cover Letter and Comment of the Healthcare Distribution Alliance (Dec. 20, 2018), Dkt. No. FDA-2018-D-3452, https://www.regulations.gov/comment/FDA-2018-D-3462-0004.
[2] 87 Fed. Reg. 6708 (February 4, 2022).
[3] *See, e.g.*, proposed § 205.26(c)(5)(ii)(A), 87 Fed. Reg. 6708, 6752 (Feb. 4. 2022) ("Any prescription drug that appears to be unfit for distribution must be stored in a secure area clearly defined for such use and physically segregated from saleable drugs, or electronically segregated, if appropriate, until the wholesale distributor determines by thorough examination that such drugs are fit for human use or nonsaleable.")

products. A trading partner's verification systems involve numerous components and elements, both physical and electronic, and human and machine. We suggest changing "system" to "systems" in the final guidance to reflect this operational reality and reduce the expectation that any trading partner will have a single system that will handle all verification-related activities.

b. It is not possible to electronically quarantine what a trading partner does not have

We are concerned with Lines 282-283 and 472-473 which both state that a trading partner should rely upon an "electronic quarantine" "when a trading partner lacks physical possession of a product." What FDA suggests is not possible given the current inventory management, quality assurance, and DSCSA systems of HDA's wholesale distributor members. HDA members report that these systems and processes do not permit "electronic quarantine" of a product the wholesale distributor does not physically have in its possession. Indeed, operationally, a wholesale distributor cannot electronically quarantine a product it does not have any more than it could physically do so. Quarantine is limited, exclusively, to product a wholesale distributor has in its physical possession.

Moreover, the DSCSA is clear that quarantine is only done for suspect and illegitimate product when the product in question is in the "possession or control" of the trading partner. For example, a wholesale distributor must:

- "quarantine such [suspect] product within the ***possession or control*** of the wholesale distributor from product intended for distribution until such product is cleared or dispositioned"; and,
- "quarantine such [illegitimate] product within the ***possession or control*** of the wholesale distributor from product intended for distribution until such product is dispositioned."

Section 582(c)(4)(A)(1)(i), § 582(c)(4)(B)(1)(i) (emphasis supplied).

Operationally, systems are not designed to and do not permit a wholesale distributor to quarantine what it does not have. Moreover, the DSCSA does not require wholesale distributors to do so.[4]

Trading partners wish to be able to use electronic quarantine – conceptually, a "status" update in their systems indicating that a product is not saleable – in lieu of always using physical quarantine. We are pleased that the 2022 Draft Guidance seems to permit this. However, the final guidance should not suggest that electronic quarantine is limited only to when a trading partner does not have the product in its physical possession. Thus, we request that FDA delete the phrase "when a trading partner lacks physical possession of the product" in lines 281-282.

[4] We recognize that FDA has presented in guidance its expectations that a trading partner will make a Form 3911 report to the agency where the trading partner has credible evidence that product was stolen from it, even though the product is no longer in the trading partner's possession or control. *See, e.g.*, Draft Guidance for Industry, Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act, 86 Fed. Reg. 30056 (June 4, 2021). While HDA has disagreed with this interpretation of the DSCSA in comments (*see*, for example, here), we believe that 3911 reporting of product not within a trading partner's possession or control, differs from attempting to quarantine what the trading partner does not physically have and which is, from an operational systems perspective, not possible.

c. "Alerts" as described in the 2022 Draft Guidance do not appear relevant to robust quarantine systems and processes

We are also concerned with Lines 476-480 that "a system be able to alert the trading partner if it receives product that has the same product information (*e.g.*, having the same transaction information or the same data elements in its product identifier, particularly the serial number) that the trading partner has already identified as illegitimate in the system so the received product may be properly quarantined and dispositioned." These Lines are not in the Section III.B. regarding quarantine of suspect product. Nor does an "alert" regarding inbound product receipt seem relevant to the purposes of this Section – which describes what constitutes adequate quarantine for illegitimate product.

Regardless, we believe that in most instances, the core systems a wholesale distributor uses will not even permit the receipt of a product bearing the same identifier as one already identified in the wholesale distributor's systems as not saleable. The platform would likely reject an inbound product bearing the same identifier as one already received.

We, of course, concur with the assumption of Lines 476-480 that trading partners have systems and processes in place to prevent the re-entry into the supply chain of products bearing identifiers the trading partner has identified as illegitimate. The DSCSA has built layers of protections that, if trading partners follow and implement them, substantially reduce the risk of illegitimate products entering, or re-entering, the supply chain, such as doing business only with authorized trading partners and working with trading partners to investigate suspect products.[5] Trading partners should also have systems and processes in place to confirm that any product it sells is within expiry, properly whole and intact and that it is checked against internal records to ensure it is not subject to a suspect product investigation or an illegitimate product notification, and not subject to a recall.

Trading partners also recognize that the status of products and the identifiers associated with them need to be kept current and be communicated to prevent the entry or re-entry of illegitimate or recalled product into the supply chain.[6] There are separate business processes for sending recall notifications to downstream trading partners and for downstream trading partners to rigorously check inventory to identify, quarantine, and disposition any products subject to the recall.

We believe the "alert" contemplated in Lines 476-480 is subsumed within these layers of protection in the "robust" verification systems and processes a trading partner should have to identify illegitimate product; the "alert" does not seem pertinent to the adequacy of quarantine of already identified illegitimate product. We recommend deleting Lines 476-480 entirely or, altering them to align with the systems and processes for quarantining illegitimate product.

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[5] The recent examples of illegitimate and counterfeit product entering the supply chain through purchases from trading partners that were not authorized underscores where we believe the greatest risks arise for the U.S. pharmaceutical supply chain. The Licensure Proposed Rule takes important steps to address these vulnerabilities.

[6] The Foundational Blueprint for 2023 published by the Partnership for DSCSA Governance (PDG) (available here), Requirement-Ver-001 recognizes that the trading partner performing a product identifier verification and the manufacturer/repackager should utilize processes to exchange the known statuses of products – such as whether the product has been identified as illegitimate or is subject to a recall. "Additional stakeholder discussion is needed in regard to how this [status update] could be accomplished, recognizing there are existing systems and processes in place today (e.g., the 3911 process and the inclusion of expiration date in the product identifier and TI) to communicate these changes." PDG Blueprint Footnote 46.

d. Suggested changes to Sections III.B. and III.D.

In light of the above, we recommend the following modest changes to Lines 281-293 (footnotes omitted) (emphasis in original):

> Quarantine of a suspect product may be accomplished using physical separation and/or other procedures. FDA interprets "other procedures" to include electronic means~~, when a trading partner lacks physical possession of the product.~~ FDA encourages trading partners to use both physical and electronic quarantine when possible to ensure accurate record keeping. FDA understands *quarantine by electronic means* (or *electronic quarantine*) to be ~~an~~ electronic systems or processes that designate~~s~~ specific products as being quarantined to prevent the sale and further distribution of the product. For example, if a trading partner places a product in quarantine using electronic means, the trading partner's systems should designate the product as quarantined so that information retrieved from the systems about that product would indicate that the product is currently quarantined and should not be sold or further distributed.
>
> The systems for quarantine should be robust enough to ensure that the suspect product is not inadvertently distributed.

We recommend the following changes to Section III.D.1., lines 470-486, (footnotes omitted):

> Quarantine of an illegitimate product may be accomplished using physical separation and/or other procedures. As explained above in section III.B.I, "other procedures" may include electronic means~~, when a trading partner lacks physical possession of the product~~. FDA encourages trading partners to use both physical and electronic quarantine when possible to ensure accurate record keeping.
>
> ~~FDA also suggests that a system be able to alert the trading partner if it receives product that has the same product information (e.g., having the same transaction information or the same data elements in its product identifier, particularly the serial number) that the trading partner has already identified as illegitimate in the system so the received product may be properly quarantined and dispositioned.~~ The systems for quarantine should be robust enough to ensure that an illegitimate product is not inadvertently distributed. Authority to release the illegitimate product from quarantine should only be exercised by appropriate people in the organization who are expressly authorized to terminate quarantine for the illegitimate product. For example, a member of the Quality Control Unit for a manufacturer or repackager, a facility manager or responsible person for a wholesale distributor, or a pharmacist-in-charge for a dispenser may be an appropriate person to exercise such authority.

Deleting Lines 476-480 results in a structure more parallel to Section III.B. regarding quarantine of suspect product and keeps the focus of this Section on quarantine rather than more general systems and processes for identification of illegitimate product. For these reasons, we strongly recommend outright deletion of these lines as shown above. However, should the agency believe that

additional instruction on illegitimate product identification and subsequent quarantine is necessary, language such as the following could replace proposed Lines 476-480:

> FDA also suggests that a trading partner have systems and processes ~~be able to alert the trading partner if it receives product that has the same product information (e.g., having the same transaction information or the same data elements in its product identifier, particularly the serial number) that the trading partner has already identified as illegitimate in the system~~ so ~~the~~ that received product may be properly quarantined and dispositioned if there is credible evidence that it is illegitimate.

e. Additional suggested change

Lines 243-246, describing the systems to determine if a product is suspect, state: "Trading partners should focus on drugs that potentially fall into one of the categories of drugs listed in the definition of suspect product in section 581(21) of the FD&C Act: product that ***may be*** counterfeit, diverted, stolen, intentionally adulterated, the subject of a fraudulent transaction, or unfit for distribution" (emphasis supplied).

The phrase "may be" is not consistent with the DSCSA, particularly § 581(21), which states that a trading partner must have "reason to believe" a product is suspect. We recommend deletion of "may be" in Line 245 and replacing it with "the trading partner has reason to believe is" in order to align with the DSCSA.

2. Section III.F. and III.G., Verification of Product Identifier

The 2022 Draft Guidance considerably expanded the discussion of verification of product identifiers in Section III.F. and III.G. We appreciate the challenges verification of the product identifier poses and FDA's efforts in these Sections to address them.

At the outset, we raise an issue identified in our comment to the 2018 Draft Guidance regarding confusion arising from the multiple meanings of "verification" – as both the specific act of verification of the product identifier as defined in § 581(28) that manufacturers and repackagers must perform, and the general verification systems around suspect and illegitimate products each trading partner must have (§ 582(b)(4), (c)(4), (d)(4) and (e)(4)). We appreciate that the 2022 Draft Guidance, *e.g.*, Lines 171-185, acknowledges this distinction. However, even with the changes made, it can become very confusing to determine which "verification" the 2022 Draft Guidance is addressing. As Sections III. F. and G. are specifically focused upon Verification of the Product Identifier, we suggest that FDA make the distinction even clearer, perhaps by placing these two subparts in their own section, with additional explanation and context. Use of the term "verification of the product identifier" when addressing verification as described in § 581(28) might also be helpful.

a. Parts of Section III.F. could be better aligned with the DSCSA

Lines 562-564 and 576-582 of the 2022 Draft Guidance (footnotes omitted) state:

> FDA also suggests that systems for verification allow for the manufacturer or repackager to include other pertinent information, such as whether the product has been the subject of a recall or is known to be illegitimate.
> …

> These 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. In addition, these systems should be integrated with SOPs and business practices used to identify suspect product and illegitimate product. If the manufacturer or repackager has reason to believe that the product is illegitimate, it must indicate as much in its response to a request for verification from a trading partner and should inform the trading partner why it believes that the product is illegitimate.

We support the statement at Lines 578-579 that product identifier verification should be integrated with SOPs and business practices. This is a welcome change from the 2018 Draft Guidance where we found the discussion of system "integration" confusing.

Other parts of Lines 562-564 and 576-582, however, raise concerns. In the context of a guidance document, and without a clear statutory mandate, we do not believe it is appropriate for Lines 579-582 to state that a manufacturer or repackager "must" include a notification in its verification response if it "has reason to believe the product is illegitimate." Additionally, "reason to believe" is the standard for suspect product – there must be "credible evidence" that a product is illegitimate. *Compare* § 581(21) (definition of "suspect product") and § 581(8) (definition of "illegitimate product").

We are also concerned that Section III.F. of the 2022 Draft Guidance suggests that a verification response could supplant other mandated notification requirements. Lines 579-582 state that a manufacturer or repackager must include a notification in its verification response if it has reason to believe the product is illegitimate and Lines 562-564 recommend that the verification response include pertinent information such as whether the product is subject to a recall. However, illegitimate product and recall notification requirements do not arise from, and are distinct from, the verification response obligations manufacturers and repackagers have. The Draft Guidance seems to mix or collapse verification responses with illegitimate product and recall notifications when each is an independent, legal requirement.

a. Verification of the product identifier does not tell "the whole story"

Under the DSCSA, the verification response is, technically, and as defined in the law, very, very narrow. It is limited ***solely*** to "determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager." § 581(28) (definition of "verify" and "verification"). Successfully confirming that a product identifier is one the manufacturer or repackager assigned is one part of a comprehensive process and does not, by itself, definitively answer the very important question of whether the product bearing that identifier should be distributed. For example, even if recalled or expired products were to be successfully "verified" because they bear identifiers assigned by the manufacturer or repackager, these products should not be distributed.

As we cautioned in our comment on the 2018 Draft Guidance, a verification response does not "tell the whole story:"

> A product can be verified and yet still be suspect (for instance, if the identifier that is the subject of the request is one the manufacturer assigned and has since decommissioned). A verification on a "good" product could fail (due to a scanning, formatting or user error). A product identifier could be verified as a

> "good match" and the product associated with the verified identifier could be legitimate, but nevertheless the product should not be dispensed or sold for other reasons.

Because verification of the product identifier is just one part of a bigger process, we similarly do not believe that every verification problem should automatically trigger a suspect product investigation.

b. An unsuccessful verification or no response to a verification request should not automatically trigger a suspect product investigation

Section III.F., Lines 566-568 states:

> To avoid a public health risk, if a trading partner does not receive a response from a manufacturer or repackager within 24 hours of making a request for verification, the product should be considered to be suspect product and should not be further distributed or dispensed.

In the discussion of Saleable Returns, Section III.G., Lines 596-599 state (footnotes omitted):

> A saleable returned product may not be further distributed until the product identifier has been verified. If the product identifier is not successfully verified, the product should be handled as a suspect product (i.e., it must be quarantined and investigated).

HDA has previously explained why we believe that that an unsuccessful verification should not automatically trigger a suspect product investigation.[7] A suspect product investigation is a very serious and rigorous undertaking that requires ***significant*** resources and documentation. HDA explained in its comments to the 2018 Draft Guidance:

> In pilots, the HDA-facilitated VRS Task Force has found there are many reasons why automated verification requests fail, particularly with a system that is so immature. Certainly, a wholesale distributor may not resell a returned product unless it verifies the product identifier. We ask for greater flexibility so that wholesale distributors can follow SOPs and business processes to investigate verification failures without the matter becoming a full suspect product investigation under the DSCSA. We believe wholesale distributors should be able to resubmit verification requests, contact manufacturers, check the human readable interpretation of the product identifier, and review their own documentation and transaction data before launching a formal suspect product investigation under the DSCSA.

These points remain valid and accurate. As an example, a product that is being recalled should not be distributed but its unsuccessful verification should not trigger a suspect product investigation.

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[7] *See, e.g.,* Cover Letter and Comment of the Healthcare Distribution Alliance (Dec. 20, 2018), Dkt. No. FDA-2018-D-3452, https://www.regulations.gov/comment/FDA-2018-D-3462-0004. *See also Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Draft Guidance* (June 2021) where the agency acknowledges that use of aggregation and inference, particularly when these systems are relatively immature, may result in discrepancies "that may not be indicative of a suspect product" (Lines 353-355).

Every trading partner should have systems and processes to evaluate any product that cannot be successfully verified. This evaluation may reveal a minor and easily resolved issue with no impact on product integrity. Or, the evaluation may result in a determination that the product is suspect, at which point, under the DSCSA, the trading partners must undertake further investigation under their verification systems processes to determine if the product is illegitimate. We urge flexibility so that trading partners can work together to resolve issues without elevating every initial verification challenge to a suspect product investigation.

c. Suggested changes to Sections III.F. and III.G.

In light of the above, we suggest the following modest changes to Sections III.F. and G. to better reflect business realities while still protecting the supply chain from illegitimate products (footnotes omitted):

> …The systems must allow the manufacturer or repackager to respond to the trading partner inquiring whether the product identifier, including the SNI, that is the subject of the request corresponds to the product identifier affixed or imprinted by that manufacturer or repackager. FDA also suggests that systems for verification allow for the manufacturer or repackager to include other pertinent information, such as whether the product has been the subject of a recall or is known to be illegitimate.
>
> To avoid a public health risk, if a trading partner does not receive a response from a manufacturer or repackager within 24 hours of making a request for verification, the product ~~be considered to be suspect product and~~ should not be further distributed or dispensed until the issue is evaluated and resolved. It may be necessary for the trading partner to classify the product as suspect and initiate an investigation to determine if it is illegitimate. In addition, on a case-by-case basis, FDA may consider "other such reasonable time" for responding to requests for verification under limited circumstances, such as in the event of a large infrastructure failure because of a natural disaster. In those situations, the trading partner making the request for verification should also wait until the manufacturer or repackager is able to verify the product identifier before the product is further distributed or dispensed, if appropriate.
>
> These 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. In addition, these systems should be integrated with SOPs and business practices used to identify suspect product and illegitimate product. If the manufacturer or repackager has ~~reason to believe~~ credible evidence that the product is illegitimate, it must indicate as much in its response to a request for verification from a trading partner and ~~should~~ must make the required illegitimate product notification under § 582. ~~inform the trading partner why it believes that the product is illegitimate.~~

We suggest the following changes to Lines 596-597 (footnotes omitted):

> A saleable returned product may not be further distributed until the product identifier has been verified. If the product identifier is not successfully verified,

> the product should be evaluated and may need to be handled as a suspect product (i.e., it must be quarantined and investigated).

3. Section III.G., Additional Considerations for Verification of Saleable Returns

Lines 608-612 (footnotes omitted) discuss certain obligations of wholesale distributors as follows:

> Before a wholesale distributor may further distribute returned product, it must first verify that the product identifier imprinted upon or affixed to the package or homogenous case corresponds to the information assigned to the product the wholesale distributor received from the manufacturer or repackager of such product, as explained above in section III.B.2.

We believe this language is recognizing that wholesale distributors may opt to verify products against the transaction data received from the manufacturer – what is often referred to as verification against "replicate data."[8] If this is what was intended in the 2022 Draft Guidance, we support its inclusion and thank FDA.

Second, the last sentence of the 2022 Draft Guidance (Lines 612-614) states: "Until November 27, 2023, a dispenser may return product to the trading partner it purchased the product from without providing the related transaction history, transaction information, and transaction statement." This sentence is supported by Footnote 72 which cites § 582(d)(1)(C)(i) – "A dispenser may return product to the trading partner from which the dispenser obtained the product without providing [transaction information, transaction statement, or transaction history] required under subparagraph (A)." Footnote 72 also cites § 582(k)(2) which provides that § 582(d)(1)(C)(i) sunsets on November 27, 2023.

This sentence has led to some concern among stakeholders that, after November 27, 2023, FDA assumes that dispensers must begin providing to their wholesale distributor the transaction data for each saleable return (returns being limited to those products the dispenser purchased from that wholesale distributor, § 581(17)). Though not cited in the 2022 Draft Guidance, § 582(c)(1)(A)(ii) makes clear that the dispenser does not have to provide transaction data for this saleable return:

> A dispenser … prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (***but not including dispensing to a patient or returns***) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; … (emphasis supplied)

[8] In the PDG Blueprint, 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. To be able to verify a saleable return against replicate data, the wholesale distributor must have purchased the package directly from the manufacturer/repackager or its exclusive distributor and received transaction data for that product from the manufacturer or repackager, it must have the product in its possession and ownership, and the trading partners must provide and exchange updates on the status of products (such as whether products are expired, recalled, or subject to a Form 3911 report).

Section 582(c)(1)(A)(ii) does not sunset. It would be helpful if FDA clarified that, where the dispenser is returning product to the wholesale distributor it purchased the product from, the dispenser does not need to provide transaction data to the wholesale distributor, even though a change of ownership is occurring.

* * *

We wish to draw attention to one consequence of the agency's continuing use of the National Drug Code (NDC), including repeated reference to the NDC in the 2022 Draft Guidance. As we have cautioned, an NDC, even if serialized, may not be unique. Consequently, a serialized NDC cannot be verified. Depending upon how a manufacturer has serialized its packages, homogenous cases, and other packaging configurations, the only difference in the product identifier between a homogenous pallet, a homogenous case on that pallet, a carton within that case, and a package within that carton, is the GTIN[9] – a pallet, a case, a carton and a package could all have the same NDC and serial number. If a verification request is initiated with only the serial number and NDC, and not the GTIN, it may fail or return inaccurate information.[10]

* * *

HDA thanks FDA for this opportunity to submit comments and suggestions on FDA's reissued Draft Guidance for Industry, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs. Our chart with additional comments is attached. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachment

[9] As stated in the GS1 website's description of the GTIN: "Global Trade Item Number (GTIN) can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain."

[10] As we have addressed previously, we believe that the NDC alone in the product identifier, without the GTIN around it, in fact, does not comply with the DSCSA given that Congress was explicit that the product identifier must conform to the standards of an international standards development organization – which is fundamental to achieving interoperability. The GTIN complies with international standards; the NDC does not. *See, e.g., HDA January 18, 2022 Comment, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Public Meeting; Request for Comments, 86 Fed. Reg. 57435 (Oct. 15, 2021), Docket No. FDA–2021–N–1004, footnote 9, available here.*