American Pharmacists Association

Via Electronic Submission to: www.regulations.gov

August 3, 2021

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

Re: Docket No. FDA-2018-D-0338: Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act; Draft Guidance for Industry

Dear Food and Drug Administration Staff:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Food and Drug Administration (FDA) on the draft guidance for industry titled ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act" (hereinafter "Draft Guidance"). Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA strongly supports the purpose and goals of the Drug Supply Chain Security Act (DSCSA) to enhance the safety and security of the pharmaceutical distribution supply chain. APhA appreciates FDA's efforts to clarify definitions of *Suspect Product* and *Illegitimate Product*, which are set forth in section 581 of the Federal Food, Drug & Cosmetic Act (Section 202 of the DSCSA). In the Draft Guidance, FDA provides additional clarification of the terms *counterfeit*, *diverted*, *stolen*, *fraudulent transaction*, and *unfit for distribution*. APhA is a member of the Pharmaceutical Distribution Security Alliance (PDSA) and incorporates PDSA's submitted comments by reference. We will not repeat the points made by PDSA, unless noted below.

APhA offers the following additional comments on the Draft Guidance:

Diverted

FDA indicates *diverted* refers to a:

- "Product that left the U.S. pharmaceutical distribution supply chain and is reintroduced in the United States in a transaction with a trading partner. For example, this would include product that is dispensed to a consumer or patient and then reintroduced into the U.S. pharmaceutical distribution supply chain to a trading partner; or

- Product that is labeled for sale in a non-U.S. market and that is introduced into the U.S. pharmaceutical distribution supply chain through a transaction with a trading partner."

FDA explains "a product would not be considered diverted as described above and, therefore, would generally not be considered a suspect or illegitimate product under DSCSA, solely if a trading partner obtains that drug product:

- Through surveillance activities outside the U.S. pharmaceutical distribution supply chain;

- From a consumer or patient who obtained the product from outside the U.S. pharmaceutical distribution supply chain;

- Obtained as a result of FDA's regulatory action to address a drug shortage; or

- Where an Emergency Use Authorization has been issued."

<u>APhA Comments</u>

With regard to products that left the U.S. pharmaceutical distribution supply chain, APhA is concerned that dispensers may have difficulty determining whether a product has left the U.S. supply chain and subsequently been reintroduced. While tracing information can be informative, dispensers are unlikely to verify the licensure of each entity who held the product as it moved throughout the supply chain, relying on the authorized trading partner from whom the product was purchased and the transaction statement. In addition, dispensers would likely have difficulty identifying diverted product based solely on appearance.

APhA is concerned the example provided is too narrow as it focuses only on product dispensed to a consumer or patient that is then reintroduced into the supply chain. APhA believes it is

important to educate dispensers and other members of the supply chain regarding diversion vulnerabilities associated at different points in the drug supply chain, not just after the point of dispensing. Accordingly, we recommend that FDA provide additional examples of diverted product.

With regard to legally imported foreign drug products, APhA appreciates FDA's clarification that products "obtained as a result of FDA's regulatory action to address a drug shortage" would not be considered diverted and therefore would generally not be considered a suspect or illegitimate product under DSCSA. This clarification provides flexibility so dispensers and other trading partners can provide patients with needed medications during shortages.

Stolen

FDA indicates *stolen* refers to:

- "Any product in its entirety (i.e., the prescription drug and its packaging) that has been taken or removed without permission of the owner of the product (e.g., a bottle and all of its content of drug are taken or removed from the trading partner, or product taken as the result of cargo theft, warehouse theft, or courier theft);

- Any packaging of a product that has been taken or removed without the permission of the owner (e.g., only the empty bottle or outer carton is taken or removed from the trading partner);

- Any prescription drug that has been taken or removed without permission of the owner of the product (e.g., all or some of the tablets are removed from a bottle and then taken or removed from the trading partner); or

- Any prescription drug and/or its packaging, in physical custody of a trading partner, that is missing all or any portion of the drug as a result of the drug being taken or removed without permission of the owner (e.g., half of the tablets are removed from a bottle and the bottle with the remaining tablets is left with the trading partner subject to the theft, or all the tablets are removed from the bottle and the bottle is left with the trading partner subject to the theft)."

APhA Comments

APhA appreciates FDA's clarification of the term *stolen* in the Draft Guidance. However, APhA believes it is critical for FDA to recognize that there are several reasons why a product may be unaccounted for without being stolen. An unaccounted-for product should not constitute stolen product unless there is reason to believe that the product is in fact stolen. For example, a product might be misplaced on the pharmacy shelf and then later located. In this case, where no one had unauthorized access to the pharmacy and the pharmacist did not have reason to believe the product was stolen, suspect product reporting should not be triggered until an investigation has been completed determining that the product is in fact stolen (or otherwise suspect).

Fraudulent Transaction

FDA indicates *fraudulent transaction* refers to "a transaction in which the transaction information, transaction history, or transaction statement contains information knowingly falsified by a trading partner who has provided or received the information."

APhA Comments

APhA appreciates FDA's clarification in the Draft Guidance that fraudulent transaction refers to "information *knowingly* falsified by a trading partner" (emphasis added). APhA believes the addition of "*knowingly*" is important so that errors in transaction information, transaction history, or transaction statements are not considered falsified information, which might cause products to unnecessarily be identified as suspect and thus create delays in patient access.

APhA believes it would be helpful for FDA to provide examples in the guidance to assist trading partners in determining whether a product has been subject to a fraudulent transaction. Specifically, APhA would like to call the Agency's attention to PDSA's comments, which note: "there may be product in the possession of a dispenser for which the TI, TH, or TS information is incorrect (though not knowingly falsified). Absent other conditions, we believe there should not be restrictions placed on dispensing product if the TI, TH, or TS has an obvious clerical error that is being addressed. Further guidance from the Agency around how to distinguish clerical errors and knowingly falsified information would be of practical benefit to trading partners."

Unfit for Distribution

FDA indicates *unfit for distribution* refers to "a prescription drug whose sale would violate the FD&C Act and there is a reason to believe or credible evidence shows that the product would be reasonably likely to result in serious adverse health consequences or death to humans. This includes prescription drugs identified as suspect or illegitimate (see section 582(c)(4) of the FD&C Act); adulterated (see section 501 of the FD&C Act) (21 U.S.C. 351)), including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (see section 501(a)(2)(B) of the FD&C Act); or misbranded (see section 502 of the FD&C Act (21 U.S.C. 352)) where there is a reason to believe or credible evidence shows that such product would be reasonably likely to result in serious adverse health consequences or death to humans."

"This definition of unfit for distribution, used to determine whether a product could be considered suspect or illegitimate, does not include product that is awaiting reverse distribution and processing and will not be distributed to patients. These products awaiting reverse distribution are not considered unfit for distribution within the context of initiating an investigation of suspect product. Similarly, product granted a waiver, exception, or exemption under section 582(a)(3) of the FD&C Act and product grandfathered under section 582(a)(5) would not be considered unfit for distribution. Although such product is not considered unfit for distribution solely because it fits in one of these categories, such product could be unfit for distribution because it otherwise falls under the definition laid out in this section."

<u>APhA Comments</u>

As APhA had recommended in our April 2018 comments, we appreciate FDA's inclusion in the definition of *unfit for distribution* the language in DSCSA, "such that the product would result in serious adverse health consequences or death to humans"[1] as this reflects Congressional intent.

However, we agree with the PDSA comment letter expressing concern that the Draft Guidance's reference to "misbranded" in the definition of *unfit for distribution* would "expand the scope of suspect product far beyond the intent of the DSCSA." There are numerous reasons a product could be misbranded. As PDSA notes: "As currently drafted, a dispenser could need to quarantine product simply due to an operational error that could be easily rectified and allow quality product to be dispensed." Accordingly, APhA reiterates PDSA's request that FDA

[1] 21 U.S.C. § 360eee(8)(B).

appropriately narrow the definition of *unfit for distribution* to account for conditions that should not render a product as suspect.

With regard to product that is returned, recalled, damaged, or expired, we ask FDA to please clarify that these situations do not, in and of themselves, trigger suspect product reporting requirements.

DSCSA Education

As FDA moves forward on implementing the DSCSA, APhA recommends that FDA sponsor or support a public education campaign on meeting the core DSCSA requirements that go into effect in November 2023. While APhA will be working with its colleagues to educate our members on DSCSA compliance issues, there is no substitute for FDA-sponsored or supported education and resources. Educational efforts could focus on a variety of topics, such as the identification of suspect and/or illegitimate products, methods to store and share transaction information, verification, grandfathering provisions related to the product identifier, and other important DSCSA requirements.

In addition to this Draft Guidance and the three other DSCSA guidances released on June 4, 2021, APhA urges FDA to issue additional guidances on the following topics as soon as possible:

- standards for interoperable data exchange;
- how trading partners should handle grandfathered products following the November 27, 2023 implementation date; and
- FDA's expectations regarding product tracing requests and responses, including for products that were introduced into the supply chain prior to November 27, 2023.

In order to answer specific DSCSA implementation questions, APhA recommends that FDA continue to sponsor stakeholder listening sessions more regularly -- including dispenser sessions -- and update its FAQ documents. In addition, we recommend FDA establish a system, process, or mechanism to respond to stakeholder questions more quickly and flexibly.

Conclusion

APhA appreciates FDA's efforts to secure the drug supply chain by providing guidance regarding suspect product and illegitimate product for verification obligations under DSCSA. We look forward to supporting FDA's efforts and working to improve the safety and security of the drug supply chain using practical and feasible implementation approaches. If you have any

questions or need additional information, please feel free to contact me at ibernstein@aphanet.org or (202) 429-7533.

Sincerely,

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Senior Vice President, Pharmacy Practice and Government Affairs