April 2, 2018

[Submitted electronically to http://www.regulations.gov]

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

RE: Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to provide a response to the Food & Drug Administration's ("FDA") Draft Guidance, Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act (hereinafter "Draft Guidance"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with FDA and other health professionals and stakeholders 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 Drug Supply Chain Security Act). In the Draft Guidance, FDA provides additional clarification to the terms *counterfeit, diverted, fraudulent* and *unfit for distribution.* Generally, APhA is concerned FDA's interpretation of what could constitute as a suspect or illegitimate product is too broad. Over-identification of suspect or illegitimate products could impede patient access to needed medications as product would be quarantined, instead of dispensed.

I. Diverted

FDA indicates *diverted* refers to a (1) product left in the drug distribution system in the United States and is reintroduced in a transaction with an authorized trading partner; or (2) product that is labeled for sale in a non-U.S. market and that is introduced into the U.S. prescription drug system to an authorized trading partner.

In regards to drugs leaving the U.S. drug distribution system, APhA is concerned that dispensers may have difficulty determining whether a product has left the U.S. drug distribution system and subsequently 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. 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 patient that is 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 FDA provide additional examples of diverted product.

APhA is also concerned the interpretation of diverted may pose issues for different state prescription drug return, reuse and recycling laws. These programs vary substantially by state and such transactions may not meet an exemption to the definition of transaction. APhA requests FDA work with states to identify mutually agreeable approaches that can maintain patient safety and subsequently, clarify permissible activities.

In regards to legally imported foreign drug products, APhA requests FDA provide flexibility so dispensers and other trading partners can provide patients with needed medications during shortages. For example, as FDA permits products in shortage to be purchased from approved foreign sources and introduced into the U.S. prescription drug distribution system. However, such products would also meet FDA's interpretation of diverted since they are labeled for sale in a non-U.S. market. While such an exchange may be exempt from DSCSA's definition of transaction, APhA encourages FDA to clarify that diverted products legally obtained foreign products due to shortage.

II. Fraudulent Transaction

As DSCSA implementation continues, trading partners may have different recording systems or make errors in their transaction information, transaction history or transaction statement. FDA's Draft Guidance indicates a *fraudulent transaction* is one in which the transaction information, transaction history or transaction statement contains falsified information, however, FDA does not clarify what may constitute falsified information. APhA is concerned errors could be included as falsified information, potentially causing products to unnecessarily be identified as suspect which creates delays in patient access. Therefore, APhA recommends FDA provide additional clarity regarding falsified information which is generally created with an intent to deceive.

III. Unfit for Distribution

FDA indicates *unfit for distribution* refers to a prescription drug whose sale would violate the Federal Food Drug & Cosmetic Act, 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. APhA is concerned FDA's interpretation of *unfit for distribution* is unnecessarily broad and ignores the language in DSCSA, "such that the product would result in serious adverse health consequences or death to humans" as it is not contemplated in the Draft

Guidance. APhA recommends FDA incorporate this language in the Draft Guidance to reflect Congressional intent.

IV. Education

As FDA moves forward on implementing the DSCSA, APhA urges the Agency to increase educational outreach efforts to pharmacists and pharmacies. Despite efforts by APhA and other pharmacy organizations to inform pharmacists about DSCSA requirements and compliance, APhA remains concerned that dispensers are not fully aware of DSCSA policies and requirements, and thus, are not prepared to effectively implement future requirements.

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 future requirements. While APhA will continue to educate its members on DSCSA implementation, we believe that FDA involvement would increase awareness and improve message consistency, ultimately advancing compliance and the safety and security of the supply chain. APhA is willing to help FDA's outreach efforts to dispensers by reviewing and disseminating dispenser-specific materials FDA develops.

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 please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs