



December 24, 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: Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs (Docket No. FDA-2018-D-3462)**

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to respond to the Food & Drug Administration’s (“FDA”) Draft Guidance, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs (hereinafter “Draft Guidance”).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 components of the different systems required under the Drug Supply Chain Security Act (DSCSA). While APhA agrees additional clarity is needed regarding DSCSA system requirements, we believe aspects of the Draft Guidance may create confusion and thus, offer recommendations.

**I. Unique Trading Partner Requirements**

DSCSA specifies types of trading partners and outlines separately each trading partners’ requirements. In the Draft Guidance, all trading partner types are grouped together in sections identifying and describing the different verification systems required in the law. APhA is concerned grouping all trading partners together throughout the Draft Guidance may be interpreted to mean there will be consistency among trading partners’ systems, and subsequent enforcement decisions for a certain type of trading partner will be applicable to all types of trading partners. For example, the Draft Guidance identifies the use of appropriate laboratory standards, controls and techniques as components of a robust investigation for trading partners. However, the capability of a pharmacy to carry out such an investigation is significantly different than a manufacturer given the staffing and resources available. Yet, it is not clear in the draft

guidance whether FDA's interpretation of "appropriate laboratory standards, controls and techniques" will vary depending on the type of trading partner. APhA requests FDA clarify that the agency's decision to group trading partners together within the guidance was not intended to impose similar requirements or expectations for all trading partners. Alternatively, APhA suggests FDA emphasize that components of the systems not specifically contemplated in DSCSA should be interpreted as suggestions to enhance systems and should not be considered in inspections or enforcement activity.

## **II. Systems for Suspect Product Quarantine and Investigation**

### **1. *Electronic Quarantine***

The Draft Guidance indicates systems for suspect product quarantine and investigation may satisfy quarantine requirements through "electronic means," but does not provide additional context. To add clarity, APhA encourages FDA to provide examples of permissible "electronic means" for quarantine procedures.

### **2. *Investigation***

The Draft Guidance indicates the dispenser, in coordination with other trading partners, is required to promptly conduct an investigation as to whether the suspect product is legitimate. During the investigation, the Draft Guidance states, trading partners may rely on the manufacturer's lab results if testing is done in a timely manner and the dispenser receives adequate assurance from the manufacturer that the results are reliable. APhA is concerned placing the burden on the dispenser to obtain such an assurance from a manufacturer may be difficult as there is no incentive or requirement for the manufacturer to share such information. In addition, there is ambiguity regarding what dispensers should do if the manufacturer does not share such information as it is not reasonable or practical to expect dispensers to perform testing. APhA suggests FDA provide dispensers with flexibility regarding components of their investigation and exempt dispensers from requirements related to testing.

## **III. System for Cleared Product Notifications Regarding Suspect Products**

### **1. *Resource Development***

The Draft Guidance outlines the written components of a cleared product notification. To better facilitate standardization and compliance, APhA recommends FDA create a form with instructions that trading partners have the option to use for cleared product notification.

### **2. *Distribution or Disposition of the Product***

In the Draft Guidance, FDA indicates cleared product notification forms are to include information about the distribution or disposition of the product, including the date the product was distributed or appropriately dispositioned. APhA believes obtaining distribution/disposition information would require dispensers to track products beyond the law's requirements and may

be excessively burdensome for dispensers to capture. Should FDA continue to request this information, APhA urges FDA to make clear this information is optional.

#### **IV. System for Responding to Requests for Verification**

While only manufacturers and repackagers are required to have systems for responding to requests for verification, the Draft Guidance notes these requests may be initiated by other trading partners. APhA recommends FDA work with trading partners to create standardized processes for manufacturers and repackagers to better facilitate trading partner initiated requests. Once such standardized processes are developed they should be communicated for better awareness and use.

#### **V. Education**

Consistent with past comment letters, APhA reiterates the need for FDA to provide dispensers additional education regarding DSCSA compliance, especially components of the law that are not related to data collection or storage. APhA consistently hears from members that they rely heavily on wholesale distributors for their compliance plans for DSCSA. However, because several provisions of the law are applicable only to dispensers, wholesale distributors are unlikely assisting dispensers with these requirements. APhA appreciates FDA's recent webinar regarding DSCSA compliance for pharmacists and encourages the agency to continue to provide DSCSA educational resources targeted for pharmacists. Such education could address dispensers' review of the completeness of transaction information or components of verification system requirements.

APhA appreciates FDA's efforts to secure the drug supply chain by providing guidance regarding verification systems 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](mailto: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