American Pharmacists Association

Via Electronic Submission to: www.regulations.gov

June 22, 2021

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

Re: FDA-2020-N-1862: The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Reopening of Comment Period

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 reopening of the comment period on the agency's December 8 - 9, 2020 public meeting titled "The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security" (86 Fed. Reg. 15685). APhA appreciates FDA's convening of this public meeting and discussion of the issues surrounding DSCSA compliance by the November 27, 2023 implementation deadline. 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) and offers the following comments on the DSCSA Pilot Project Program Public Meeting and enhanced drug distribution security. Specifically, FDA should:

- **Focus on the Core DSCSA Requirements that Go into Effect on November 27, 2023**

  While there was much discussion at the public meeting about value-added enhancements to drug supply chain security (such as the use of RFID tags and blockchain), **the fast-approaching 2023 implementation deadline and the significant**

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work that must go into building compliant systems and processes, testing and troubleshooting, and education and training necessitates that FDA and trading partners focus solely on the core requirements of the DSCSA. Potential enhancements to drug supply chain security that go beyond the 2023 statutory requirements should be addressed at a later date. Dispensers across the country have been on the front line focusing on providing COVID-19 testing, immunizations, and patient care throughout the pandemic. With the DSCSA 2023 implementation deadline approaching, new systems, processes, hardware, and software must be laser focused to efficiently, effectively, and economically meet the DSCSA requirements in order to ensure successful uptake and implementation.

- **Produce Additional DSCSA Education, Guidance, and Listening Sessions**

As dispensers move towards full implementation of 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 colleagues to educate our members on DSCSA compliance issues, there is no substitute for FDA-sponsored or supported education and resources. For example, APhA recently found Dr. Jung's June 1, 2021 "FDA Drug Topics: Enhanced Drug Distribution Security: 2023 and Beyond" webinar presentation to be a helpful resource.

APhA also appreciated FDA's issuance of four DSCSA guidances on June 4, 2021, and 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 -- 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.

- **Identify and Encourage Systems and Processes to Facilitate Prompt Product Verification Responses**

  Enhanced product verification was the subject of discussion at the December 8-9, 2020 public meeting. As the last point in the supply chain before the product is dispensed to patients, dispensers will need efficient and prompt means to verify product identifiers if there is a need. This must occur in a way that does not impact pharmacy workflow or hold up dispensing of a drug product to a patient. Dispensers cannot take a lot of time to track down who to contact or wait long for a response. APhA recommends that FDA identify and encourage systems and processes to facilitate prompt verification responses.

- **Address Hospital and Health-System Pharmacy Concerns**

  The DSCSA raises specific issues for APhA's hospital and health-system pharmacy members, such as accommodating drop shipments, 340B transactions, investigational new drugs, and drug transfers to address shortages. In addition, APhA requests clarity from FDA on whether "white-bagging" (where insurers purchase drugs outside of a providers' supply chain and send them directly to a hospital or clinic) complies with the DSCSA. This practice has been increasingly forced upon hospitals and health systems from plans and pharmacy benefit managers, raising supply chain integrity and security concerns.

Dispensers across the supply chain are working diligently to implement systems to comply with the DSCSA requirements by the November 27, 2023 deadline. APhA supports efforts to protect the integrity of our nation's drug supply and appreciates the opportunity to submit these comments and maintain a dialogue with FDA on important DSCSA issues. If you have any questions or need additional information, please feel free to contact me at ibernstein@aphanet.org or (202) 429-7533.

Sincerely,

Ilisa BG Bernstein

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