



November 19, 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: Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers (FDA-2018-D-3175-0001)

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide a response to the Food & Drug Administration’s (“FDA”) Draft Guidance, Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers (hereinafter “Draft Guidance”).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 its interpretation of requirements related to product identifiers for packages and homogenous cases of certain drug products and their impact on linear barcode requirements under 21 CFR 201.25. However, APhA continues to have concerns that product identifier deadlines for manufacturers and repackagers will affect pharmacists’ workflow prior to dispenser deadlines. APhA also provides the following responses to the Draft Guidance.

I. Linear Barcode Requirements Under 21 CFR 201.25

APhA appreciates FDA recognizing linear barcode requirements were established for different purposes than the DSCSA requirements and apply to additional FDA-regulated products and packaging. APhA’s members emphasized the importance of the NDC for practice purposes, such as to reduce errors and verify the accuracy of patients’ medications at the point of dispensing, among other benefits. While the Draft Guidance adds clarity in table format regarding examples of individual saleable units and different barcode requirements based on the unit type, APhA is concerned FDA may consider changing 21 CFR 201.25 requirements to better align barcode types and reduce the need for multiple barcodes. Should such future changes allow

the NDC, for instance, to be embedded in the Global Trade Item Number (GTIN), APhA believes patient safety will be at risk since pharmacists and pharmacy technicians, among other health care stakeholders and systems, rely heavily on the NDC. Barcode format modifications may have implications beyond product packaging, such as for billing systems and verification at the point of dispensing and/or administration. Accordingly, APhA requests FDA include broad stakeholders as early as possible in any consideration or development of barcode harmonization and associated requirements.

II. Efforts Beyond DSCSA

Based on stakeholder discussions during FDA's public meetings, APhA is aware of interests in patient-level tracking and other enhancement to tracking beyond those required by DSCSA. While we discourage mandates beyond the law's scope, before FDA finalizes this guidance, we encourage the agency to gain feedback regarding how different technology providers are planning on using data related to DSCSA, including NDCs, to improve patient care and workflow.

III. Education

APhA requests FDA provide additional education to dispensers regarding DSCSA compliance and the agency's expectations, including information related to standization, for manufacturers and repackagers regarding product identifiers as portions of those expectations are relevant to pharmacists evaluating the safety and security of products. APhA believes visual aids contrasting compliant and noncompliant product identifiers will be particularly helpful. APhA appreciates FDA's website dedicated to pharmacists and DSCSA compliance. We encourage the agency to also use this website to provide more webinars and resources to pharmacists. Such resources should be communicated in simple, clear terms regarding contents of guidance documents and regulatory activity relevant to DSCSA, such as efforts to modify the National Drug Code (NDC), status of pilot projects, and guidance documents targeting other members of the supply chain but have downstream implications for pharmacists. APhA believes such website enhancement will improve DSCSA implementation and pharmacists' ability to help secure the drug supply chain.

APhA appreciates FDA's continued efforts to inform stakeholders on DSCSA implementation. 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