September 1, 2017

Food and Drug Administration
Division of Drug Information
Center for Drug Evaluation and Research
10001 New Hampshire Ave.,
Hillandale Building, 4th Floor
Rockville, MD 20852

RE: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy; Draft Guidance for Industry (FDA-2017-D-2232)

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to provide feedback in response to Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy; Draft Guidance for Industry (available in Docket: FDA-2017-D-2232) (hereinafter, "Draft Guidance").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 members of the supply chain to enhance the safety and security of pharmaceuticals. APhA appreciates the Agency's efforts to seek stakeholder input as it continues to implement policies resulting from the Drug Supply Chain Security Act ("DSCSA"). APhA applauds FDA for listening to manufacturers' concerns regarding their readiness to meet November 2017 deadlines related to product identifiers, and appreciates the agency's decision to grant enforcement discretion until November 26, 2018.[1] After reviewing the Draft Guidance, APhA is concerned it may set unreasonable expectations for dispensers. As such, we offer recommendations.

I. Future Compliance Dates

APhA appreciates FDA's responsiveness to manufacturers' concerns regarding the November 2017 deadline to imprint or affix the product identifier to their packages and homogeneous cases. However, we are concerned enforcement discretion was not granted for subsequent deadlines relying on the product identifier, such as a requirement that dispensers only

[1] As described in the Notice, "FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to their packages and homogeneous cases of product that are intended to be introduced in a transaction into comments between November 27, 2018 and November 26, 2018.

purchase products with the product identifier by November 27, 2020. Based on the deadlines specified in DSCSA, APhA believes compliance deadlines were intended to provide the different types of supply chain stakeholders sufficient time to prepare for requirements. FDA's decision not to grant other members of the supply chain enforcement discretion creates uncertainty regarding future compliance dates. APhA recommends FDA revise the guidance as soon as possible to provide a cascading effect for the compliance date for subsequent deadlines to allow stakeholders adequate time to plan and implement DSCSA requirements.

II. Potential New Requirement for Dispensers and Wholesale Distributors

According to the Draft Guidance, "beginning November 27, 2018, wholesale distributors and dispensers who purchase products from a repackager should ensure that they bear product identifiers." APhA believes the Draft Guidance is in conflict with DSCSA which requires dispensers to transact only in serialized product beginning November 27, 2020. The law does not include a requirement for dispensers to check whether products bear a product identifier in advance of 2020. In addition, it may be difficult for dispensers to easily distinguish between products that have and have not been repackaged, making the new requirements unreasonable in practice and unnecessarily burdensome. APhA urges FDA to remove this language from the Draft Guidance.

III. Need for Education and Training

As FDA moves forward on DSCSA implemention, APhA continues to urge 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 dispensers are not fully aware of DSCSA policies and requirements, and thus, are not prepared to effectively implement future requirements or adapt to changes. APhA is willing to help FDA's outreach efforts to pharmacies by reviewing and disseminating dispenser-specific materials FDA develops.

Thank you for your leadership and work on this issue. 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, Associate Director for 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