January 26, 2017

[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RE: Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; Draft Guidance for Industry (FDA-2017-D-6526-0001)

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to provide a response to the Food & Drug Administration's ("FDA") Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; Draft Guidance for Industry ("Draft Guidance").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 is pleased FDA provided clarity regarding grandfathered products and dispensers handling of such products. However, APhA has concerns the draft guidance may place a greater burden on dispensers' handling of grandfathered products and offers the below recommendations.

I. Accepting Grandfathered Products

The Draft Guidance indicates packages or homogenous cases of product that are not labeled with a product identifier are exempted from certain requirements in Section 252 where there is documentation that is was packaged by a manufacturer before November 27, 2018. In addition, the Draft Guidance states, "If the transaction information or transaction history does not include a sale before November 27, 2018, and absent other indicia that a product may be suspect or illegitimate, the transaction statement is one indication that the product was in the pharmaceutical distribution supply chain before the date." APhA is concerned that the Draft Guidance is unclear as it may set the expectation that dispensers must review the transaction information and transaction history for grandfathered product, as opposed to accepting grandfathered product on the basis of the transaction statement. The transaction statement

provides confirmation that an authorized trading partner has processes and systems in place to comply with DSCSA's Section 582 verification requirements and has not knowingly sent suspect to illegitimate product. APhA is concerned that a requirement to review each unserialized product's transaction history and transaction information would unnecessarily interrupt dispensers' work flow and increase their administrative burden as well as negatively impact patient access to medications. APhA strongly advocates that FDA clarify that receipt of the transaction statement alone can be relied upon by a dispenser determining whether unserialized product meets DSCSA's grandfathered product requirements.

Also regarding the date a product was introduced in the pharmaceutical distribution supply chain, FDA notes, "manufacturers retain packaging date information in the ordinary course of business…. And they should provide the packaging date to subsequent trading partners if they request it." APhA recommends FDA clarify wholesale distributors may also be a source for additional information for trading partners, including dispensers, deciding whether to accept non-serialized product.

II. Dispenser-to-Dispenser Specific Patient Need Transactions with Grandfathered Products

The Draft Guidance does not contemplate the permissibility of specific-patient need transactions with grandfathered products. Dispensers engaging in a transaction for a specific-patient need are not required to provide the product tracing information, history or statement to the receiving pharmacy. To prevent confusion, burden on dispensers, and possible patient access issues, APhA encourages FDA to clarify receiving pharmacies in specific patient need transactions may accept unserialized products without having to obtain or review the transaction history, transaction statement or transaction information from the previous transaction.

III. Education Regarding Grandfathered Product and Exemptions

APhA recognizes the difficulty in determining the quantity of product expected to be grandfathered and how the quantity of grandfathered product is expected to decrease with time. However, APhA believes it is important FDA provide resources to help educate dispensers regarding grandfathered products and exempted products and scenarios. As noted in past comments, dispensers rely heavily on wholesale distributors for DSCSA compliance and may not have resources or capability to interpret DSCSA's requirements and intricacies. While dispensers may have an understanding of key requirements of the law, such as only accepting serialized product, they are less likely aware of exemptions and exceptions (i.e. grandfathered products) and how to practically address such circumstances. To prevent misapplication of the law or unnecessary suspect product investigations that could slow the movement of products from manufacturer to patient, APhA recommends FDA provide education and resources to pharmacists regarding grandfathered and exempted products.

APhA appreciates FDA's efforts to secure the drug supply chain by clarifying dispenser responsibilities regarding grandfathered products. 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, 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