November 01, 2022

Ms. Jessica Simpson
Senior Manager, Executive Secretariat
The United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852

REF: 11-22-002-AB

Dear Ms. Simpson:

This letter reiterates FDA's recommendations on pharmaceutical glass type classification. In 2017, FDA provided USP a recommendation to revise the definition of Type I glass from composition-based characteristics to performance-based characteristics to allow for innovation in the manufacturing of glass intended for parenteral packaging. We shared published information to support this recommendation and noted that a performance-based classification instead of a chemical composition-based classification would be beneficial for public health.[1] Over the last two years, there have been reported global shortages of glass vials, potentially creating a bottleneck for the delivery of the COVID-19 vaccine and threatening the availability of some existing parenteral products.

FDA is supportive of the use of new glass compositions if they demonstrate equivalent or superior performance characteristics such as improved thermal and hydrolytic resistance compared to the current compendial glass compositions and demonstrate suitability for the drug product; however, restrictive compendial definitions have impeded adoption of new glass compositions with such characteristics. Several official monographs specify the use of specific glass chemical composition; drug product manufacturers submitting a drug application to FDA in which they have proposed use of glass that performs equivalently (based on testing) but differs in chemical composition will face additional time-consuming administrative steps during consideration for FDA approval (See Federal Food, Drug, and Cosmetic Act, Section 502(g)).

FDA appreciates the engagement and dialogue with USP staff and expert volunteers to determine the best path forward with no adverse impact on current marketed products. To retain the strict scientific standards for glass packaging while maintaining inclusivity for new glass compositions, FDA strongly recommends that glass be defined by its performance characteristics and not solely on its composition. We are supportive of an approach to rapidly revise the definition of Type I glass (as found in the latest proposal of General Chapter <660> *Containers – Glass*) while concurrently updating monograph requirements with language reflecting the new performance-based Type I glass definition.

[1] Schaut, R. A., Peanasky, J. S., DeMartino, S. E., & Schiefelbein, S. L. (2014). A new glass option for parenteral packaging. PDA journal of pharmaceutical science and technology, 68(5), 527–534. https://doi.org/10.5731/pdajpst.2014.00998

Given the current global issues regarding glass production and our concerns about the resulting drug shortages, we request that USP make timely compendial revisions to ensure that drug product manufacturers can adopt equivalent or superior glass compositions that are deemed acceptable by FDA through the application assessment process without facing regulatory hurdles due to restrictive compendial definitions. We again thank USP for engaging with us on this important issue. Please do not hesitate to contact me with any questions. Please use the reference number provided above on any ensuing correspondence.

Sincerely yours,

Ashley B. Boam -S

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Date: 2022.11.01 16:17:52 -04'00'

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