CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

July 30, 2015

Desmond Hunt, Ph.D.
US Pharmacopeia ("USP")
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Packaging and Storage Requirements <659>, Correspondence C141017

Dear Dr. Hunt:

On behalf of the Consumer Healthcare Products Association (CHPA), a 133 year-old trade association representing the nation's leading over-the-counter (OTC) medicine and nutritional supplement manufacturers, I'd like to thank you for the opportunity to comment on the proposed revisions to USP General Chapter-Packaging and Storage Requirements <659> published in PF 41(3) .

CHPA is generally supportive of the revision proposal to update and clarify the Chapter. We would however request that the implementation of the requirements in this Chapter be delayed for 24 months in order for all of the products from our member companies to comply with metric units on dosing devices for orally ingested liquid drug products, associated label changes and subsequent FDA approvals, where appropriate. Alternatively the industry would consider a phased-in implementation based on perceived risk to the patient (i.e. infant/children dosing and devices).

CHPA encourages USP to republish the Packaging and Storage Requirements <659> Chapter proposal in PF after reviewing all of the comments received and understanding the extent of the impact to our members' products through continued dialogue with our industry.

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Many CHPA members follow industry voluntary guidance for metric labeling on orally ingested pediatric liquid drug products including metric units on dosing devices and have already implemented this recommendation for infants' oral products and to a large extent for liquid products in general. Implementing metric units on product labeling and dosing devices simultaneously would be challenging in order to meet the proposed USP effective date of August 2016 for some of our members. For example the impact of the change to metric units on product labeling and dosing devices for CHPA members will range from over forty stock-keeping units (SKUs) from one company to more than 1600 SKU's for another. These include NDA products and global manufacturing sites.

Prior approval labeling supplements for some products must be submitted to the FDA and sufficient time must be allowed for Agency approvals, internal approvals, and implementation.

Additionally we would like to propose text to clarify the applicability of metric units to both prescription and OTC drugs. In the proposed revision the following sentence should be modified:

> The associated volume markings shall be in metric units and limited to a single measurement scale that corresponds with the dose instructions on the prescription container label (see Prescription Container Labeling ⟨ 17 ⟩).

The OTC industry may interpret the above sentence to limit applicability of metric units to only prescription products and associated components. CHPA recognizes the importance of updating volume measurements to metric units for both oral nonprescription and oral prescription products. USP should clarify the applicability of metric units to all prescription and nonprescription oral liquid drug product labels and associated components in the Chapter.

For example, the revised text would be inclusive of OTC products:

The associated volume markings for oral liquid drug products shall be in metric units and limited to a single measurement scale that corresponds with the dose instruction on the OTC or prescription container label *(see applicable FDA guidance(s), or Prescription Container Labeling <17>)*

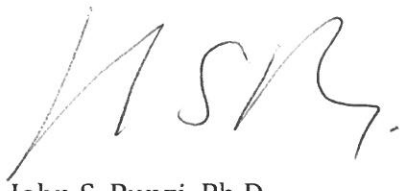
General Definitions that would provide clarity are provided in the following Table:

Proposed <659>	Suggested Change	Rationale
Primary packaging component: A *Packaging component* that is in direct contact with or may come into direct contact with the article.	Primary packaging component: A *Packaging component* that is in direct contact with or may come into direct contact with the article during storage.	There are components that come in contact with product briefly during use (actuators etc.) that should not be considered primary pkg. Only what potentially contacts the product during stability storage (any orientation) is primary packaging.
Medicine dropper: A measuring device consisting of a transparent or translucent barrel or tube that is generally fitted with a collapsible bulb. It may be packaged with ~~oral~~ liquid articles.	Medicine dropper: A measuring device consisting of a transparent or translucent barrel or tube that is generally fitted with a collapsible bulb. It may be packaged with ~~oral~~ liquid articles.	A dropper may be used with non oral products, such as topical solutions
Graduated associated components described in this section are for general use	Delete/reconsider or reword	Dosing components packaged with a product by manufacturer are generally calibrated "with product/to deliver" (as opposed to selling a device on its own, for general use). Especially for viscous products, the residual left in cups can be significant which may lead to overdose if used to measure another less viscous product or conversely, under dose if calibrated for less viscous product and then used to measure more viscous product
Graduated markings should be legible, indelible, and on an extraoral surface that does not contact the product.	Graduated markings should be legible, indelible, and on an extraoral surface ~~that does not contact the product~~	It is unavoidable for markings to contact product in some cases, for example, dropper barrels are dipped into liquid product so there is contact inside and outside the barrel. Also, there are configurations with "leave in" the product droppers. Contact should be allowed, provided data is available to support (compatibility, safety etc.).

In summary, CHPA strongly supports improving USP General Chapters and Monographs to establish standards and specifications for drug substances and drug products. Consistent metric labeling and markings on dosing devices can provide an additional measure of safety for OTC products. CHPA generally supports the revision proposal to update and clarify the Chapter. We would however request that the implementation of the requirements in this Chapter be delayed for 24 months (August 01, 2018) in order for all of the products from our member companies to comply. Alternatively the industry would consider a phased-in implementation based on perceived risk to the patient. CHPA encourages USP to republish the proposal and to understand the extent of the impact to our products through continued dialogue with our industry prior to setting an implementation date.

CHPA appreciates the opportunity to comment on the proposed General Chapter proposal for Packaging and Storage <659>. I am happy to speak with you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,



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