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March 29, 2013

Shawn Dressman, Ph.D.
Vice President
New Monographs
US Pharmacopeia ("USP")
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Stimuli to the Revision Process, USP's Monographs in Support of FDA's OTC Monograph System: Modernization Opportunities, Pharmacopeial Forum, Vol. 39(1) [Jan.-Feb. 2013]

Dear Dr. Dressman:

On behalf of the Consumer Healthcare Products Association (CHPA), a 131 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 U.S. Pharmacopeia's Stimuli article: **USP's Monographs in Support of FDA's OTC Monograph System: Modernization Opportunities, Pharmacopeial Forum, Vol. 39(1) [Jan.-Feb. 2013].**

CHPA supports advancing modernization of USP's quality monographs, updating and improving the compendial test methods and establishing product standards which can provide an additional measure of safety for OTC products while eliminating non-value added testing. CHPA is open to discussing and evaluating alternative means of standards development and exploring the feasibility of the product-class monograph approach proposed in this Stimuli article. CHPA supports the USP proposal to develop and validate methods (in-house) for drug substances and believes that effort will require CHPA, USP and FDA working together to ensure API

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manufacturer participation in providing drug substances for method development and standards acquisitions.

CHPA agrees that eliminating non-value added testing is an improvement to be included in any modernization effort for example: removing dissolution testing for immediate release solid dosage forms of highly soluble actives and replacing it with disintegration testing. This would allow resources to be reallocated to other testing.

CHPA agrees with the proposal to increase the USP in-house effort to develop and validate methods for drug substances. We recognize the ideal scenario would have the producers of APIs develop test procedures since the manufacturers usually have a good understanding of their processes and may know the best approach especially concerning impurities. Absent engagement of API suppliers to assist in this effort, CHPA supports USP moving forward as proposed. We agree that adaptation and harmonization with alternative sources such as European Pharmacopeia drug substance monographs is an excellent starting point.

CHPA generally supports exploring the feasibility of implementing performance-based monographs (PBM). PBMs may be one option useful for drug products where many forms exist and products may be complex and/or multi-active. The PBM approach could accelerate USP monograph modernization. Our members have many questions about PBM, and we look forward to dialogue with USP on this proposal.

In summary, CHPA supports advancing modernization of USP's quality monographs, updating and improving the compendial test methods and establishing product standards which can provide an additional measure of safety for OTC products while eliminating non-value added testing. CHPA generally supports exploring the feasibility of the product-class monograph approach and the USP proposal to develop and validate methods (in-house) for drug substances but believes that effort will require CHPA, USP and FDA working together.

CHPA appreciates the opportunity to comment on the Stimuli article. I am happy to speak to you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,

John S. Punzi, Ph.D.
Director Quality Assurance and Technical Affairs

Cc Todd Cecil, Ph.D.