CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

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Robert Femia, Ph.D., Senior VP
Clydewyn M. Anthony, Ph.D., Senior Scientific Liaison
Michael Chang, Ph.D., Scientific Liaison
US Pharmacopeia ("USP")
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Correspondence Numbers C137586 and C127215

Dear Drs. Femia, Anthony, and Chang:

On behalf of the Consumer Healthcare Products Association (CHPA), a 136 year-old trade association representing the nation's leading over-the-counter (OTC) medicine and dietary supplement manufacturers, I'd like to thank you for this opportunity to comment on modernization of the USP compendia for OTC pharmaceuticals. CHPA supports improving the compendial test methods and establishing product standards which can provide a measure of safety for OTC products.

CHPA generally supports the improvements included in recent monograph revisions but is concerned that the USP has not gained alignment with industry and regulators on an over-arching, economically practical and feasible approach to monograph modernization. Rather, USP continues to add Ultra High Performance Chromatographic (UHPLC) instrumentation and chromatographic columns to product monographs when adequate separation can be obtained with conventional HPLC instrumentation and equipment, and incorporation of inductively coupled plasma-optical emission spectroscopy (ICP-OES) where a titration is suitable.

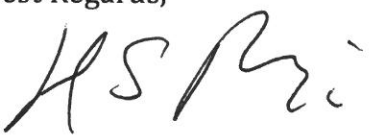
Assigning a method for a public standard should take in to account the economic impact to the industry. Methods that have been used for decades for salicylic acid plasters and selenium sulfide topical suspensions would now have to be shown to be equivalent to the compendial methods by purchasing and validating equipment and procedures or using a contract laboratory to perform the testing. Furthermore, while USP frequently cites its international recognition in laws and regulations, we question the availability of UHPLC

and ICP-OES in many of the countries that would rely on these methods for enforcement or surveillance activities.

Our member companies support modernizing USP NF and drug substance monographs but not only does the majority of the industry not use those published methods, choosing to employ alternative methods, we understand that even when analytical methods are detailed in a current product monograph, FDA during their surveillance activities have relied on either in-house "screening methods" or methods routinely used within the company that manufactured the product which was obtained by a request from the agency lab.

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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