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July 24, 2014

Ren-Hwe Yeh
Scientific Liaison
US Pharmacopeia ("USP")
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Sodium Salicylate Proposed Monograph *Pharmacopeial Forum*, Vol. 40(3) [May-June 2014]

USP Correspondence Number— C132966

Dear Dr.Yeh:

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 U.S. Pharmacopeia's proposal **for Sodium Salicylate Proposed Monographpublished for comments in *Pharmacopeial Forum*, Vol. 40(3) [May-June 2014]**.

CHPA's comments are primarily focused on the use of Ultra-High Performance Liquid Chromatography (UHPLC) as the method of choice for assay and organic impurities. We believe this monograph would set a precedent for the routine use of UHPLC for the development of assay and/or organic impurities methods and will result in a significant economic burden for our industry and consequently an increased cost to consumers. CHPA believes that the use of UHPLC and should only be employed where it can be clearly demonstrated that conventional HPLC is not an option for the analysis.

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UHPLC is not an acceptable tool for QC labs:

- Standard High Performance Liquid Chromatography *(HPLC) is a well-established technique* for the development of assay and impurities methods for drug products, is routinely used in the research and development laboratory and a mainstay in quality control laboratories. In contrast UHPLC has only recently been embraced for seamless transition from R&D to quality control laboratories and only by a few companies.

- The *cost of a UHPLC systems* is nearly double (~$90,000) that of a standard HPLC system (~$50,000). The increased cost represents a significant economic burden for industry but especially on our smaller companies, to place UHPLC systems into quality control laboratories for routine release testing to comply with USP monograph requirements. In other cases if the manufacturers choose to outsource the testing of articles that required UHPLC, this would result not only in longer release times and supply chain challenges but an additional burden for the contract laboratories who would need to purchase a significant number of UHPLC systems to support their customers.

- Even if a manufacturer chose to develop an alternate method using the more common conventional HPLC in place of the UHPLC method for routine testing, the manufacture *would still need UHPLC capability* to demonstrate that the alternate method gives equivalent or better results as outlined in USP General Notice 6.30. Alternative and Harmonized Methods and Procedures. In addition to the cost of the UHPLC system is the added cost for method development and validation of the proposed alternate procedure.

CHPA's position is that UHPLC is not an appropriate tool to be used for the development of public standards unless it is clearly demonstrated that the current HPLC methods are inadequate and that UHPLC is necessary to meet the requirement of demonstrating the quality of the raw material and/or finished product. UHPLC should not be used in the routine development of

public standard methods for raw materials or finished products but only used rarely in specific cases where there is a clear public interest in safety and quality.

In summary, CHPA strongly supports improving USP test methods to establish specifications for drug substances and drug products. Modern assay and impurities methods can provide an additional measure of safety for OTC products. CHPA supports the improvement of the monographs but is concerned with the economic burden imposed by a UHPLC equipment requirement. CHPA believes that smaller companies and contract laboratories will bear disproportionate economic burden.

CHPA appreciates the opportunity to comment on the proposed monograph revision. 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