Consumer Healthcare
Products Association

January 25, 2005

Roger Williams M.D.
President and Chief Executive Officer
U.S. Pharmacopeia
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Rockville, MD 20852

RE: Stimuli Article in PF Vol. 30(5) entitled "Development of a New Official Compendium, Separate from USP-NF, for Articles Not Legally Marketed in the U.S."

Dear Dr. Williams:

The Consumer Health Products Association (CHPA) would like to thank you for the invitation to participate and provide input on the stimuli article proposing a new Official Compendium separate from the USP-NF for Articles Not Legally Marketed in the US which appeared in the Pharmacopeial Forum Volume 30, Number 5. As a trade association representing manufacturers of over-the-counter drug products and dietary supplements, CHPA has a strong interest in compendial matters. The proposal to develop standards for use outside the US has direct impact for many of our members who market their products globally.
In addition to the benefits and costs already delineated, CHPA will add the following for your consideration:

Benefits:

1. Aiding the World Health Organization keeping in mind the current international compendia issued by WHO.
2. Aid FDA and international relief groups in dealing with drug products standards.
3. Facilitate efforts to keep sub-standard articles out of US commerce and benefit the public by assuring the quality of imported products.
4. Use by countries currently not using other compendia.

Considerations:

1. Please consider delineation of specific distinctions between USP-NF and USPI. It may include NF scope, content and compatibility. It's value to our members will be clearer if there was consensus regarding the positioning of this compendia among current compendia. This includes harmonization issues. *(Would the proposed international compendia only cover monographs not already included in other compendia, such as the European Pharmacopoeia, the British Pharmacopeia, and the Japanese Pharmacopeia?)*

2. Administration of the proposed compendia is of interest to us including among other issues the processes required to manage revisions. We note that the stimuli article

proposes that "General Chapters and other useful information" could be transferred from the current compendia to the new compendia. We also note that the stimuli article proposes to use the existing PF "as a means of eliciting public comment on draft monographs for the separate compendium". We would anticipate that the transfer of standards and the use of a shared PF would be problematic (e.g. in terms of justifying any differences in requirements, in terms of expanding the scope of shared standards to encompass stakeholders on a global basis, etc.).

3. The concern regarding intellectual property as it might relate to an open standard is merely the state of enforcement and administration of effective and adequate regulations in the countries currently without similar standards.

4. The impact of USPI on the status of FDA approved products. We would be interested to explore the issue further in order to develop a better understanding both from FDA and USP.

5. The capacity of the organization and its volunteers to maintain, support and improve the USP-NF (e.g. revision and updating of monographs). The stimuli article acknowledges that USP is currently challenged with respect to missing and outdated monographs in the existing compendia. Creation of a new and separate compendia may further strain limited resources and significantly compromise the ability of the organization and its volunteers to maintain and improve the current USP-NF.

6. The effect of the proposed USPI on the USP-NF in how standards are developed and subsequent migration of content and creation of competing tiers of quality. We note that the stimuli article suggests that the separate compendia might include "classical procedures (less demanding tests), as well as basic and screening tests, to help reduce the circulation of counterfeit and substandard drugs". This objective implies that different standards might be tolerated in the new compendia.

In conclusion, CHPA applauds USP's willingness and desire to serve the international community.
We hope our comments are helpful and we would welcome an opportunity to discuss this topic further.

Sincerely,

F. Razzaghi

Frederick Razzaghi
Director – Technical Affairs

FR/mm