

## **Summary of Meeting with US Pharmacopeia Rockville, MD May 18, 2005**

In attendance at the meeting:

- Mary Ellen Sanders, Ph.D.
- James Heimbach, Ph.D.

From the USP Department of Standards Development:

- Gabriel Giancaspro, Ph.D., Associate Director, Latin American Specialist
- Ian DeVeau, Ph.D., Associate Director
- Lawrence Evans, Ph.D., Scientist
- Radhakrishna Tirumalai, Ph.D., Information and Standards Development

From USP Department of Dietary Supplements:

- David Roll, Ph.D., Director, Dietary Supplements

Participating by phone:

- Tina M. Engel, PhD, Principal Scientist, Procter and Gamble Health Care

During the 2004 ISAPP Industry Advisory Committee meeting in Copper Mountain, Colorado, the need for improved quality of probiotic products was discussed. See “Establishing Standards for Probiotic Products: ISAPP’s Role” at [www.isapp.net/IS\\_inthenews.htm](http://www.isapp.net/IS_inthenews.htm).

On May 18, 2005, on behalf of ISAPP, Drs. James Heimbach and Mary Ellen Sanders met with representatives of U. S. Pharmacopeia (USP) to discuss development of standards of quality for probiotics. USP ([www.usp.org](http://www.usp.org)) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. For 185 years, USP has been setting standards for the quality of these products. USP's standards are also recognized and used in many other countries outside the United States, and both Japan ([jpdb.nihs.go.jp/jp14e/](http://jpdb.nihs.go.jp/jp14e/)) and Europe ([www.pheur.org](http://www.pheur.org)) have related organizations. USP has programs for both standards development marked by the publication of a monograph delineating reference materials and methods and verification, which provides 3<sup>rd</sup> party validation of compliance with standards and allows companies to display the USP verification seal ([www.usp.org/USPVerified/](http://www.usp.org/USPVerified/)).

A letter from the American Medical Association to the FDA regarding proposed regulations for GMPs highlights the value placed on USP:

“...the AMA recommends that the FDA designate the United States Pharmacopeia (USP) to develop appropriate standards for the identity, purity, strength, and composition of dietary ingredients and dietary supplements. The USP has an extensive track record, dating back to 1820, for developing such quality standards for drugs and is officially recognized by the United States government. Thus, the USP would be the ideal body to develop quality standards for dietary supplements.”

In many countries, there are inadequate mechanisms in place to assure consumers that a probiotic-containing product they select will provide them adequate levels of a validated probiotic. In the absence of government assurances, manufacturers have not embraced the approach of providing consumers with third party verification of their

products. An opportunity exists for probiotic manufacturers to partner with organizations such as USP to establish voluntary standards for their products. Companies participating in this program would benefit by being able to provide consumers assurance that their products conform to standards established by a science-based, independent organization.

USP scientists and directors indicated interest in participating in this undertaking. To proceed, USP must be approached by a company interested in developing a standard. Reference strains and methodologies must be provided by a submitting manufacturer. USP would proceed with review of submitted methods and validation data, publication and invitation for comment from industry and then final publication of a monograph. Companies in compliance with the standard would be able to display the USP symbol. In addition, companies could elect to participate in the USP Verification Program which involves product testing.