USP Invites Public Comments on its Dietary Supplement Safety Review Process

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Background

In order to select and prioritize dietary ingredients for monograph development, the United States Pharmacopeial Convention (USP) developed in 2002 the Admission Criteria for Dietary Ingredients [1, 2] (Safety Review Process), which includes, among other things, the evaluation of the safety profile of the ingredient by the USP Dietary Supplements Information Expert Committee (DSI–EC). DSI–EC has decided to revisit the Safety Review Process at its upcoming meeting on February 5, 2009, based on experience and internal discussions, comments received from interested parties on recent evaluations, [3, 4] and taking into account other factors like the recent implementation of mandatory requirements for reporting serious adverse events. [5,6] USP values public input and therefore invites public comments and suggestions to improve the USP Dietary Supplement Ingredient Safety Review Process.

Current Dietary Supplement Ingredient Safety Review Process

Under the current Dietary Supplement Ingredient Safety Review Process, DSI–EC reviews safety information for selected dietary supplement (DS) ingredients from diverse sources, including but not limited to human data from clinical studies and adverse event reports, animal pharmacological and toxicological data, historical use, regulatory status, and current uses worldwide.

After reviewing the safety information cited above, the DSI–EC recommends the inclusion of a candidate dietary ingredient into one of the following classes:

Class 1. Articles for which the Committee is unaware of significant safety issues present when the article is used and formulated appropriately that would prohibit a monograph being developed.

Class 1a. Articles for which the Committee is aware of limited human scientific data concerning safety of the article, but is unaware of significant safety issues present when the article is used and formulated appropriately that would prohibit a monograph being developed.

Class 2. Articles for which the Committee is unaware of significant safety issues present when the article is used and formulated appropriately that would prohibit a monograph being developed, provided there is a warning statement in the labeling section.

Class 3. Articles for which the Committee is aware of significant safety issues present that would prohibit a monograph being developed.

In keeping with USP's "continuous revision" approach,[7] safety class assignments may be revised at any time in light of new data and/or adverse events. USP monitors the safety information for all dietary ingredients for which monographs are developed, so that a safety signal can prompt a safety re-evaluation and possible re-classification.

According to the existing Safety Review Process, if an article falls within Class 2, a safety concern is communicated to the public only through a warning labeling statement. Currently, black cohosh, echinacea, licorice and St John's wort require such cautionary statements in the labeling sections of their *USP–NF* monographs. However, in revisiting the Safety Review Process, USP may consider providing for alternative modes of communication commensurate with the level of safety signal.

Questions for Stakeholders

1. What are your comments on the current Dietary Supplement Ingredient Safety Review Process? Does USP need a change in the current system of evaluations?
2. What information do you think needs to be reviewed for the analysis and monitoring of DS safety?
3. Should DS safety information continue to be part of the USP quality monograph labeling section or should other options for communicating safety information be considered?
4. What would you propose as alternative means for USP to disseminate the DS safety information?
5. Do you have any additional comments or suggestions?

Please send detailed comments or questions to: Dandapantula N. Sarma, PhD, Senior Scientist, Documentary Standards Division, US Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852-1790; tel. 301.816.8354; e–mail dns@usp.org. Comments should be received by January 12, 2009 to ensure consideration. **Note: The deadline for comments has been extended to January 30, 2009.**

References

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5. Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462, 120 Stat. 3469), December 22, 2006.
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