Contents

USP Dietary Supplements Compendium

Volume 1

Volume 2

Dietary Supplements Admission Evaluations

This section includes summaries for some of the admission evaluations completed by the USP Dietary Supplements Information Expert Committee [2005–2010] and by the USP Monographs—Dietary Supplements and Herbal Medicines Expert Committee [2010–2015] for commonly used dietary ingredients. USP's admission evaluation of a dietary ingredient under the Admission Criteria and Safety Classification for Dietary Supplements Guideline[1] is performed for the sole purpose of helping to inform the Dietary Supplement and Herbal Medicine Expert Committee's determination whether to proceed with consideration for admission into the compendia and should not be relied upon as any finding about the intrinsic safety or effectiveness of the dietary supplement ingredient under review. Summaries of Admission Evaluations are available for articles that were cleared for monograph development. The following articles did not clear the admission review stage and are not undergoing monograph development: Natto Extract, Phyllanthus amarus Extract, and Calcium Magnesium Phytate. Additional information on these articles may be available upon request under USP's document disclosure process.[2]

[1] Available at http://www.usp.org/sites/default/files/usp_pdf/EN/dietarySupp/admissiondsguideline_vers_1.1.pdf

[2] Available at http://www.usp.org/sites/default/files/usp_pdf/EN/aboutUSP/document_disclosure.pdf

USP Dietary Supplement Verification Program

USP conducts voluntary verification programs for manufacturers of dietary ingredients and dietary supplements. Through these programs, USP verifies the identity, strength, purity, and quality of ingredients and finished products. In this section, we include overviews, process flow charts, and checklists for these USP Dietary Supplement and Ingredient Verification Programs. This information is excerpted from the participant manuals for the verification programs. The complete and current version of the participant manual is available free of charge on the USP website at www.usp.org.

Dietary Supplements Regulatory Framework

This section of the compendium contains excerpted information on U.S. federal legal and regulatory requirements that are pertinent to dietary ingredients and dietary supplements.

The publication of FDA guidances and other regulatory information in the *USP Dietary Supplements Compendium* is for informational purposes only and is not intended as legal advice or to impart any legal effect. Note that the information in this section may be revised from time to time, and it is the responsibility of the user to ascertain the most current version of these documents.

Tables of Dietary Intake Levels

This section contains an international comparison of Dietary Reference Intakes (DRIs), Recommended Daily Intakes (RDIs), and Tolerable Upper Intake Levels (UL) of vitamins, minerals, and electrolytes for adults compiled by regulatory authorities and organizations.

Guidance Documents

These ancillary documents have been provided by stakeholder organizations. USP acknowledges the American Herbal Products Association, Natural Products Association, Consumer Health Products Association, and the Council for Responsible Nutrition for their contributions to this section.

Illustrations

This section contains additional information for selected articles generally organized in two sections: botanical characteristics and chemical characteristics. The information provided in this section is not intended to impose any monograph requirements and is not official text.

Botanical characteristics include macro/microscopic photographs and diagrams that are provided to aid in the interpretations of pharmacopeial descriptions of plant materials. These photographs and diagrams are intended to help users in the identification of plant specimens and determination of contamination with closely related plant species.

Chemical characteristics include chemical structures of relevant constituents and marker compounds and chromatograms. The chromatograms are TLC color pictures and HPLC or GC of representative articles, provided to assist in the performance of compendial tests.