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New Compendium Offers Freely Available Testing Standards to Help Ensure the Quality of Herbal Ingredients Used in Traditional Medicines

First Set of Standards in USP's Herbal Medicines Compendium Proposed for Public Review and Comment from Parties Around the Globe

Rockville, Md., May 20, 2013 — With herbal medicines relied upon by consumers worldwide, a new online resource available from the U.S. Pharmacopeial Convention (USP) will provide freely available public standards to help ensure the quality of the herbal ingredients used in these products. Today, USP proposes the first 23 ingredients to be included in the new *Herbal Medicines Compendium (HMC)* for comment by all interested stakeholders worldwide at hmc.usp.org. *HMC* will provide standards for herbal articles, but will not include standards for ingredients of animal origin, synthetic chemicals or biotechnology-derived medicines.

USP is an independent, nonprofit organization that establishes standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. USP's standards for pharmaceuticals are contained in the *United States Pharmacopeia* and the *National Formulary (USP–NF)*, which are recognized in U.S. law and used throughout the world. Through the new *HMC*, USP now has a forum for advancing standards for herbal ingredients used in herbal medicines worldwide. These ingredients might appear in *USP–NF* or in an associated compendium, the *USP Dietary Supplements Compendium (DSC)*, but would do so as dietary supplements legally marketed in the United States.

“USP believes that [public standards are critically important](#) to help ensure the quality of all medicines, including herbal medicines,” said Roger L. Williams, M.D., chief executive officer of USP. “Given medicines’ key role in maintaining health and treating disease for a majority of the world’s population, the importance of public standards for all medicines, including herbal preparations, cannot be overstated. Through the *Herbal Medicines Compendium*, we will now have the ability to better meet the needs of our worldwide stakeholders who seek public standards for herbal medicinal ingredients.”

“With herbal medicines increasingly crossing borders in international commerce, it is important to consider the need for global public standards,” said Dennis Gorecki, Ph.D., chair of USP’s Dietary Supplements and Herbal Medicines Expert Committee, which is part of the USP Council of Experts—the body that makes USP’s scientific and standards-setting decisions. “Standards such as those in the *Herbal Medicines Compendium* may be used by regulators and other stakeholders in many countries as a tool against adulterated or poor-quality herbal medicines—which are a growing problem. These standards will advance modern analytical techniques—necessary to deal with the scientific complexities associated with plant-based ingredients.”

HMC monographs provide quality specifications—tests, procedures and acceptance criteria—with validated analytical procedures and allied reference materials that aid in conformity assessment. *HMC* monographs and associated general chapters can help ingredient manufacturers, herbal product manufacturers, regulatory agencies, and other stakeholders to assess conformance of herbal medicinal ingredients with independent public standards and control the quality of articles moving in international commerce. When coupled with sound registration processes and adherence to suitable Good Manufacturing Practices, standards in *HMC* can become an important part of the safety net that helps ensure access to good quality medicines.

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Robust, Public Standards-Setting Process

HMC standards are developed through a public standards-setting process that invites input from all interested parties, and with the collaboration and approval of experts from around the world, via the volunteers who serve on the USP Council of Experts. Proposed monographs on the *HMC* website are initially posted as “*For Development*,” which indicates more information is needed before they can advance to the next stage. Once all the information is complete, monographs are advanced for public comment as “*For Comment*” monographs. After addressing public comments, the standards are authorized by the USP Council of Experts and published as “*Final Authorized*.”

First Ingredients Proposed for Public Input

With today’s launch of *HMC*, USP is proposing the first 23 monographs for comment. These are:

- *Phyllanthus amarus* Aerial Parts
- *Phyllanthus amarus* Aerial Parts Powder
- *Phyllanthus amarus* Aerial Parts Powdered Extract
- *Rhodiola rosea* Root and Rhizome
- *Rhodiola rosea* Root and Rhizome Powder
- *Rhodiola rosea* Root and Rhizome Powdered Extract
- *Rhodiola rosea* Root and Rhizome Tincture
- *Salvia miltiorrhiza* Root and Rhizome
- *Salvia miltiorrhiza* Root and Rhizome Powder
- *Salvia miltiorrhiza* Root and Rhizome Powdered Extract
- *Ganoderma lucidum* Fruiting Body
- *Ganoderma lucidum* Fruiting Body Powder
- *Ganoderma lucidum* Fruiting Body Powdered Extract
- *Lagerstroemia speciosa* Leaf
- *Lagerstroemia speciosa* Leaf Powder
- *Lagerstroemia speciosa* Leaf Powdered Extract
- *Trigonella foenum-graecum* Seed
- *Trigonella foenum-graecum* Seed Powder
- *Trigonella foenum-graecum* Seed Powdered Extract
- *Trigonella foenum-graecum* Seed 4-Hydroxyisoleucine Powdered Extract
- *Panax pseudoginseng* Root and Rhizome
- *Panax pseudoginseng* Root and Rhizome Powder
- *Panax pseudoginseng* Root and Rhizome Powdered Extract

These monographs will be open for a 90-day comment period before they are reviewed and adopted by the USP Council of Experts as authorized monographs. Users will be able to submit comments directly within the website for the USP Council of Experts to consider, and each monograph has an associated discussion forum to allow for real-time exchange among users worldwide. An additional 20 monographs in the *For Development* category also are available on the *HMC* website. After monographs become authorized, comments may still be submitted for consideration by the USP Council of Experts for possible future revisions.

For more information about *HMC*, and to view and comment on the proposed monographs, visit hmc.usp.org. Media inquiries may be directed to mediarelations@usp.org.

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USP – Advancing Health Since 1820

The U.S. Pharmacopeial Convention (USP) is a scientific, nonprofit, standards-setting organization that improves global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP’s standards are used worldwide. For more information about USP visit <http://www.usp.org>. **FY1342**