To: ANSI Goldenseal Task Group  
From: Roy Upton  
Re: Overview of Development of AHP Compliance Monographs  

March 31, 2009

Introduction
This communication is to introduce the ANSI Goldenseal Task Group to the process by which the American Herbal Pharmacopoeia (AHP) compliance monographs were developed. Each AHP Compliance Monograph is derived from the more complete AHP monograph on the specific botanical. In developing each of the sections, the primary scientific literature has been extensively reviewed, drafted by individuals with the requisite academic training and expertise, and subjected to peer review of others with the requisite skills. All writers and reviewers are cited in the original monograph. Following are specific details about the development of each of the sections of the Compliance Monograph.

Nomenclature
The botanical nomenclature provided reflects the formal botanical treatment of the botanical according to the International Code of Botanical Nomenclature (ICBN). The common name provided, in rare exceptions, is taken from Herbs of Commerce (HOC), the officially recognized text of common nomenclature for botanical ingredients. In those rare exceptions where AHP writers and reviewers consider the HOC citation to be incorrect, AHP has inserted the name we feel is correct and have also maintained the name provided by HOC.

Definition
The Definition outlines the minimum criteria that constitute a AHP-compliant botanical ingredient. In most cases, AHP definitions are harmonized with the pharmacopoeial Definition standards of either the European (EP) or United States (USP) pharmacopoeias.

Macroscopic Identification and Organoleptic Characterization
The Macroscopic Identification and Organoleptic Characterizations given were developed and compared against multiple authentic samples and compared against the primary pharmacognosy literature. Specific attention is given to ensure the materials characterized are representative of materials in trade, including the describing of different forms and grades, if applicable, and are in compliance with pharmacopoeial standards for purity. Characterizations for whole, semi-whole, and powdered materials are provided.

Microscopic identification
Complete microscopic descriptions of sections and powdered materials are given. When appropriate, differentiating information about potential adulterants will be given. As in
Macroscopic Descriptions, all descriptions are generated from authentic samples and compared against the primary microscopy literature.

Spot Tests
When applicable, spot tests (e.g., colorimetric tests) are verified and provided.

High Performance Thin Layer Chromatography (HPTLC)
When developing the HPTLC characterizations, multiple authentic samples are used to ensure the profile provided is representative of material in trade and is of acceptable quality. The primary compounds of interest are those considered to be most correlated with pharmacological activity or qualitative markers, when known. Methods are gathered from the primary literature with an emphasis given to compendial methods when available. If necessary, comparative analyses of a variety of methods are performed to determine which method is most appropriate for characterization of authentic material. Also included in the analysis will be primary products including, when applicable, those subjected to clinical studies for utility with a variety of matrices.

Quantitative Analyses
When applicable, the most appropriate quantitative analytical method is provided. The primary goal of the method(s) is to provide a method whose utility has been verified by a formal AHP single- or multi-lab verification process. The compounds used are the most correlated with pharmacological activity or qualitative markers as determined by the primary pharmacological literature, constituent declaration in product labeling, and a survey of experts. Primary factors for considering a method as appropriate include accuracy of the findings, speed, basic ruggedness, applicability to a large segment of the manufacturing community, and avoidance of the use of toxic reagents and solvents. In an attempt to promote harmonization, primary consideration is given to those methods that are already accepted in official pharmacopoeias. When necessary, comparative tests are conducted to determine which of the available method(s) is most appropriate. The validation process minimally includes: standard precision, linearity, sample precision using replicate samples, sample linearity, selectivity (co-elution, sensitivity to analyte degradation), retention times, and limits of detection.

Qualitative Standards
Each monograph shall include standards of purity including as appropriate: Foreign organic matter, total ash, acid-insoluble ash, water insoluble extractives, loss of moisture on drying, and, when available, specific qualitative markers such as allowable percentages of defective material (e.g. percentage of defective fruits of cranberry). The methods used to determine these values shall be provided or fully referenced.

Storage
General and/or specific Storage information is provided as is available.
American Herbal Pharmacopoeia®

Any questions or further details about this process can be provided upon request.
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