

C. Updated Books To Be Incorporated by Reference

Herbs of Commerce, 2nd Edition (2000) establishes a “standardized common name,” expressed primarily in English, for each plant used in commerce, including fungi and algae. However, in a few instances, the standardized common name is expressed in another language or is the same as the plant’s Latin binomial name (i.e., genus and species) when that name has become common. For example, the Spanish word “mate” is the standardized common name for the plant “*Ilex paraguariensis* A. St.-Hil.,” and the Latin binomial name “*Phyllanthus amarus*” is the standardized common name for the plant “*Phyllanthus amarus* Schumach.” The standardized common name generally applies to the whole plant, but in some instances it applies to a plant part. For example, the standardized common names “mace” and “nutmeg” pertain specifically to the plant parts “aril” and “seed,” respectively, of the same plant “*Myristica fragrans* Houtt.”

All standardized common names listed in *Herbs of Commerce, 2nd Edition* (2000) are printed in boldface letters. In this book under “Section One: Latin Binomials,” each plant name is listed first alphabetically by its Latin binomial name. The plant’s corresponding standardized common name is stated after the acronym “SCN” on the first indented line of text underneath its Latin binomial name. Under “Section Two: Standardized Common Names,” each plant name is listed first alphabetically by its standardized common name. The plant’s corresponding Latin binomial name is stated on the first indented line of text underneath its standardized common name.

In addition to the standardized common name, *Herbs of Commerce, 2nd Edition* (2000) identifies the currently recognized Latin binomial name and four other categories of common names for each of the plants listed, as applicable. These other categories are:

- “botanical synonym,”
- “Ayurvedic name,”
- “pinyin name,” and
- “other common name.”

The botanical synonym, if any, represents one or more examples of other Latin binomial names that have been broadly used for the plant in the past. The Ayurvedic name, if any, generally represents the plant’s Sanskrit name; however, the Hindi name may be cited if the plant is primarily known by it instead. The pinyin name, if any, may be one or more of the plant’s Chinese

common names. Other common names, if any, represent any additional names frequently used for the plant.

The “standardized common name” is different and distinct from all of the other categories of common names for a plant. There is only one *standardized* common name that is selected for each plant listed in *Herbs of Commerce, 2nd Edition* (2000); however, there may be several names cited within one or more of the other categories of common names that are associated with the same plant.

The *International Code of Botanical Nomenclature (Saint Louis Code) 2000* (the Code) establishes the current internationally accepted rules that govern the scientific naming of plants, including fungi and algae. The scientific name, which identifies the plant’s genus and species, is expressed in Latin and applies to the whole plant without exception. The Latin binomial name of a plant is followed by the name(s) of the person(s) who described and published the plant name in accordance with the Code’s guidelines. The Code refers to such notation about authors as an “author citation.”

II. Direct Final Rule

FDA is revising § 101.4(h) to substitute *Herbs of Commerce, 2nd Edition* (2000) for its 1992 edition, and the *International Code of Botanical Nomenclature (Saint Louis Code) 2000* for its 1994 edition, as books incorporated by reference. Requirements on how these references are to be used for dietary supplement labeling purposes remain the same and are not affected by this direct final rule, with one minor exception.

Currently, § 101.4(h)(2) uses the phrase “such as” when referring to the *International Code of Botanical Nomenclature* as a reference that industry may use to ensure that any Latin binomial name of a botanical ingredient listed on the label of a dietary supplement conforms to the internationally accepted rules of botanical nomenclature. As presently worded, the regulation could be interpreted to allow other references to be consulted for this purpose. We are revising the language in the Code of Federal Regulations (CFR) to make the *International Code of Botanical Nomenclature* the only reference that may be used on the rules for determining and formatting the Latin binomial name of a botanical ingredient for dietary supplement labeling purposes. This book is internationally recognized by botany experts from nations around the world as the foremost authoritative reference on

botanical nomenclature. We are not aware of any comparable reference that comprehensively addresses the rules on the scientific naming of plants and has as broad international support. The *International Code of Botanical Nomenclature* is regulated by the Nomenclature Section of an International Botanical Congress. This group meets under the auspices of the International Union of Biological Sciences, of which the U.S. National Research Council/National Academy of Sciences is a member. The XVI International Botanical Congress brought together more than 4,000 scientists from more than 100 countries at its most recent meeting held in Saint Louis, MO in 1999 when the *International Code of Botanical Nomenclature (Saint Louis Code) 2000* was voted on and adopted. Therefore, to be in harmony with this international cooperation and to be consistent with FDA’s science-based philosophy, this direct final rule is incorporating by reference the *International Code of Botanical Nomenclature (Saint Louis Code) 2000* as the one that industry must follow on the rules to determine and format the Latin binomial names of any botanical ingredients stated on dietary supplement labels.

Some dietary supplements may contain a botanical ingredient that is not listed in the 2000 edition of *Herbs of Commerce* and therefore does not have a standardized common name. Like the former regulation, in such cases the direct final rule is requiring that the common or usual name for that botanical ingredient listed on the label be accompanied, in parentheses, by the Latin binomial name of the plant from which it is derived. When needed to positively identify the botanical ingredient, the direct final rule is continuing to require that the Latin binomial name also must include the author citation, stated in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*.

FDA is aware that there may be instances when a botanical ingredient belongs to a subspecies or variety of a species that is not listed in the 2000 edition of *Herbs of Commerce*. In those cases, the Latin binomial name and author citation alone will not identify the subspecies or variety of that species. Although not a requirement, FDA encourages industry to voluntarily state the following on dietary supplement labels directly after the Latin binomial name when needed to positively identify a botanical ingredient below the species level: The name of any