

applicable subspecies, variety, or other subdivision and its corresponding 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 further revising § 101.4(h) to incorporate statutory restrictions on the use of the term “ginseng” that were imposed by section 10806 of the Farm Bill. Specifically, the direct final rule includes the following statement in § 101.4(h): “The use of the term ‘ginseng’ as a common or usual name (or part thereof) for any dietary supplement or dietary ingredient is limited to those that are derived from a plant classified within the genus ‘*Panax*.’”

Finally, FDA is making minor wording changes in § 101.4(h) to improve the reader’s understanding, consistent with the principles of plain English, or to improve technical accuracy, consistent with internationally accepted botanical terminology. Examples of changes we are making to improve the reader’s understanding are using simpler language throughout, substituting the word “must” for “shall,” and dividing very long sentences into shorter ones. To be more technically accurate, the direct final rule replaces the current wording under § 101.4(h)(2) that refers to the “designation of the author or author(s) who published the Latin name” with the term “author citation” to refer to the “name(s) of the person(s) who described and published the Latin binomial name in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*.” For technical clarity, the direct final rule also adds the notation “(i.e., genus and species)” after the first reference to the term “Latin binomial name” under § 101.4(h).

III. Use of the Incorporated References and Implementation of Pertinent Farm Bill Provisions

Over the years, FDA has received several inquiries from representatives of the dietary supplement industry about the use of *Herbs of Commerce* and the *International Code of Botanical Nomenclature*. These books are references for industry to use in determining the common or usual name of each botanical ingredient or to consult on the rules for determining and formatting any required Latin binomial names corresponding to the botanical ingredients declared on dietary supplement labels. The act of “incorporation by reference,” however,

does not imply that all of the botanicals that have standardized common names listed in *Herbs of Commerce* or that follow the scientific naming rules found in the *International Code of Botanical Nomenclature* are safe for consumption as dietary supplements or other foods by man or other animals. Citation of these books in the CFR is specific and limited to the sole purpose of identifying authoritative references for industry to use to determine the correct plant nomenclature. Neither reference addresses the safety or uses of plants.

This direct final rule focuses only on the naming of botanical ingredients of dietary supplements for labeling purposes. It is the responsibility of manufacturers and distributors to ensure that the particular botanicals they use as ingredients of dietary supplements are safe for human consumption, do not contain contaminants, are properly identified on the label, are legally marketed, and conform to all governing regulations.

In addition, *Herbs of Commerce, 2nd Edition* (2000) does not represent an authoritative compilation of botanical dietary ingredients that were marketed in the United States before October 15, 1994 (i.e., botanicals that are not new dietary ingredients under section 413(c) of the act (21 U.S.C. 350b(c))). The book’s disclaimer explains that the publisher did not verify whether or not the companies that submitted botanical information for inclusion in this reference had valid documentation that supported such marketing. The book’s disclaimer further states: “The listing of a particular species of plant in this work is not, therefore, in and of itself, evidence that such species was marketed in the United States prior to October 15, 1994” (Ref. 3, page xx). This direct final rule does not confer FDA endorsement of *Herbs of Commerce, 2nd Edition* (2000) for any other purpose than to serve as a reference on the common or usual names of botanical ingredients contained in dietary supplements.

In most cases, *Herbs of Commerce, 2nd Edition* (2000) assigns a unique standardized common name to each plant. However, the book indicates that the same standardized common name is given to more than one plant when the plants are used interchangeably in commerce. There are over 100 instances in *Herbs of Commerce, 2nd Edition* (2000) where the same standardized common name applies to two or more different species, subspecies, or varieties of the same genus of plant.

In other cases in *Herbs of Commerce, 2nd Edition* (2000), a name listed under one of the categories of common names

(e.g., Pinyin names) for one botanical may be shared by another botanical from a different genus of plants. For example, the botanical *Ammi majus* L. has the standardized common name bishop’s weed, whereas bishop’s weed is also listed as the other common name for the botanical *Aegopodium podagraria* L. that has the standardized common name ash weed.

Confusion and mistakes in the identity of botanicals can be caused when the ingredients have the same or similar common names. Therefore, it is important that manufacturers know a botanical’s true identity, including its Latin binomial name with author citation and its biological and chemical properties, before substituting one botanical for another as an ingredient of a dietary supplement. It is the responsibility of manufacturers and distributors to ensure that any botanical used as an ingredient of a dietary supplement or other food marketed in the United States is safe for consumption and complies with all applicable requirements of the act.

The “standardized common names” of botanicals listed in both the 1992 and 2000 editions of *Herbs of Commerce* are consistent with the Farm Bill’s definition of the term “ginseng.” However, both editions note that the term “ginseng” has been used as part of “other common names” associated with botanicals from genera other than *Panax*, including blue ginseng, lesser ginseng, prince ginseng, and Siberian ginseng. We remind industry that names that include the term “ginseng” may be used as the common or usual name for a botanical ingredient only if the botanical is derived from the plant genus “*Panax*.”

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

V. Regulatory Impact Analysis

FDA has examined the economic implications of this direct final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The