



January 9, 2017

By Electronic Submission

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

**CITIZEN PETITION**

Dear Sir or Madam:

The American Herbal Products Association (AHPA) submits this Citizen Petition pursuant to 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to withdraw a proposed rule and issue an Advance Notice of Proposed Rulemaking regarding the declaration of botanical ingredients in dietary supplements by the common or usual name.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products. AHPA is the publisher of both the first (1992) and second (2000) editions of *Herbs of Commerce* and is actively working on development of a third edition.

I. Action Requested

AHPA respectfully requests that the Commissioner of Food and Drugs:

- 1) Withdraw the proposed regulation published at 68 Fed. Reg. 51738 (August 28, 2003) to amend 21 C.F.R. § 101.4(h) in part by replacing the references currently listed in the regulation – the 1992 edition of *Herbs of Commerce* and the 1994 edition of *International Code of Botanical Nomenclature (Tokyo Code)* – with the 2000 editions of the same books; and

- 2) Issue an Advance Notice of Proposed Rulemaking proposing to amend 21 C.F.R. § 101.4(h) to remove the reference to the 1992 edition of *Herbs of Commerce* and suggest a proposed rule to require designation of the common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) be consistent with the *Herbs of Commerce*, 2nd edition (2000) or its revisions, or other authoritative references or their revisions, and inviting input as to what those other authoritative references might be.

## II. Statement of Grounds

A number of plant species used in dietary supplements are not listed in *Herbs of Commerce*, 1st edition (1992), the reference currently incorporated by reference in 21 C.F.R. § 101.4(h) for designation of common or usual names of botanical ingredients. In addition, the established taxonomy of plant species regularly evolves in accordance with the rules of botanical nomenclature, such that some of the species in this reference now have different accepted Latin binomial names than were accepted when this reference was published, and corrections are also sometimes needed to common names. AHPA makes this request to withdraw the proposed regulation and to publish an Advance Notice of Proposed Rulemaking regarding amendments to 21 C.F.R. § 101.4(h) so that dietary supplement ingredients may be referenced against the most current version of *Herbs of Commerce* and other appropriate authoritative references, reflecting the most current taxonomic nomenclature for more of the plant species in commerce as dietary ingredients. As the agency noted in its own proposal to amend 21 C.F.R. § 101.4(h), *Herbs of Commerce*, 2nd edition, added standardized common names for approximately 1,500 more botanicals than were included in the earlier edition, and changed the standardized common names for approximately 140 botanicals listed in the first edition of *Herbs of Commerce*. 68 Fed. Reg. at 51739 (August 28, 2003). Since the proposed regulation was issued in 2003, additional changes have been made to the nomenclature of numerous plants in commerce and there are additional authoritative references that might be included in 21 C.F.R. § 101.4(h). AHPA proposes that FDA issue an Advance Notice of Proposed Rulemaking to assure a robust forum for the exchange of information regarding this subject.

## III. Environmental Impact

Petitioner claims a categorical exclusion from the requirements of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.30.

IV. Economic Impact

An economic impact statement will be submitted if requested by the Commissioner, pursuant to 21 C.F.R. § 10.30(b).

V. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,



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