



November 14, 2023

*Via Electronic Submission*

Division of Dockets Management  
Department of Health and Human Services  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Docket No. FDA-2017-P-0176

**Amendment to American Herbal Products Association Citizen Petition Regarding the Designation of Botanical Ingredients in Dietary Supplements Under 21 C.F.R. § 101.4(h)**

The American Herbal Products Association (AHPA) submits this Citizen Petition amendment pursuant to 21 C.F.R. § 10.30(g) in view of the recent publication of AHPA's *Herbs of Commerce*, 3rd Edition (2023).

***I. Background***

On January 9, 2017, AHPA submitted a Citizen Petition requesting that the U.S. Food and Drug Administration (FDA or Agency) take the following actions:

- 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) to 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.

On February 2, 2018, FDA issued an interim response stating that the Agency “ha[d] not reached decision on your petition due to competing agency priorities” and that the

“petition is currently under active evaluation by our staff.” To AHPA’s knowledge, FDA has not taken any subsequent action in response to this Citizen Petition and FDA’s 2003 proposed rule to amend 21 C.F.R. § 101.4(h) remains pending.

In June 2023, AHPA published the third edition of *Herbs of Commerce*, which added standardized common names for approximately 800 more botanicals than included in the 2nd edition cited in AHPA’s initial Citizen Petition (and over 2,000 more botanicals than included the 1992 edition currently referenced in 21 C.F.R. § 101.4(h)). *Herbs of Commerce*, 3rd Edition, reflects the most current taxonomic nomenclature for botanicals used as dietary ingredients in dietary supplements marketed in the United States.

## ***II. Amended Request***

Pursuant to 21 C.F.R. § 10.30(g), AHPA seeks to amend the second action requested in its January 9, 2017, Citizen Petition. Specifically, AHPA requests that FDA issue a direct final rule to amend 21 C.F.R. § 101.4(h) to remove the reference to the 1992 edition of *Herbs of Commerce* and require that the common or usual name of ingredients in dietary supplements that are botanicals (including fungi and algae) be consistent with the standardized common names in *Herbs of Commerce*, 3rd Edition (2023). In AHPA’s view, this amendment does not involve any controversial regulatory changes as it would merely update the regulation to reflect the most current version of *Herbs of Commerce* with no further substantive changes; FDA should not anticipate receiving any significant adverse comments.

## ***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, as amended, 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.

The remainder of AHPA's initial Citizen Petition request remains unchanged, except AHPA notes the interim change in its mailing address to:

American Herbal Products Association  
8630 Fenton St, Suite 123  
Silver Spring, MD 20910

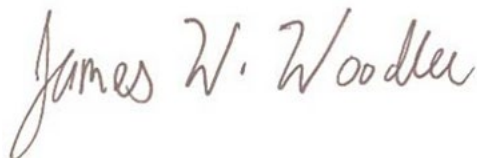
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