

USP Dietary Supplements Stakeholder Forum  
Wednesday, June 1, 2016

## Dietary Supplements Nomenclature Guideline

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## 41(6) Stimuli to the Revision Process: GUIDELINE FOR ASSIGNING TITLES TO USP DIETARY SUPPLEMENT MONOGRAPHS

### STIMULI TO THE REVISION PROCESS

Stimuli articles do not necessarily reflect the policies  
of the USPC or the USP Council of Experts

### GUIDELINE FOR ASSIGNING TITLES TO USP DIETARY SUPPLEMENT MONOGRAPHS

USP Dietary Supplement and Herbal Medicines Nomenclature Joint Subcommittee, USP Staff<sup>a</sup>, <sup>b</sup>

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**A BSTRACT** The first publication of the *Pharmacopoeia of the United States* in 1820 included quality monographs of articles that would today be considered dietary supplements, for example, vitamins, minerals, and certain botanicals. Titles for such monographs were crafted to be brief and distinct, and in many instances a single word sufficed if that word was expressive and unambiguous. The 1820 volume discussed a guide for developing botanical monograph titles and indicated that USP would adapt a nomenclature that was simple, with the intent that the monograph title would be brief and explicit, expressing the medical meaning and nothing else. This *Stimuli* article presents a new guideline for formulating titles of dietary supplement monographs. The intent of this article is to initiate a discussion on this new proposed guideline, to solicit public comments, and to invite the participation of interested parties in USP's efforts to develop a nomenclature guideline for dietary supplement monographs. The goal of this effort is to eventually bring existing monograph titles into alignment with a uniform naming convention.

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#### INTRODUCTION

The first publication of the *United States Pharmacopeia (USP)* in 1820 included quality monographs of articles that today are referred to as dietary supplements (DSs), including vitamins, minerals, and certain botanicals. Monographs for some of these articles have been included in the compendium since the 1820 edition. In 1993, in response to the Nutrition Labeling and Education Act (NLEA) of 1990, a separate compendium section titled *Nutritional Supplements* was created to contain monographs for vitamins and mineral combinations. DS monographs were started in 1995 in response to the Dietary Supplement Health and Education Act of 1994 (DSHEA) and included some monographs for botanicals that were originally placed in the *National Formulary (NF)*. The *Nutritional Supplements* section was active through the publication of *USP 26–NF 21* in 2003. In 2004, a new section, *Dietary Supplements*, was introduced into *USP 27–NF 22* to replace the *Nutritional Supplements* section and included monographs for ingredients and dosage forms of DSs as defined by DSHEA. Monographs for botanical DSs originally in the *NF* were also moved to this new DS section. This new DS section is currently published in the *USP–NF*, which combines all of the dietary supplement monographs from the two compendia.

# Dietary Supplement Nomenclature Guidelines

**Historically** since *USP* 1820 volume, monograph titles for substances that could today considered as dietary supplements have been simple- one word was used in many cases and excluded plant parts for botanicals.

Examples: *Aloe*, *Belladonna*, *Elm*, *Ipecac*, *Psyllium*, and *Senna* (plant parts not included in title)

**DSHEA** in 1994 defined dietary supplements to contain- vitamins; minerals; a herb or other botanicals; an amino acids;

**Titles for vitamins;** minerals and amino acids are straightforward,  
**for botanicals** much more complex due to innovations in industry

**The *Guideline*** creates a naming convention so that USP DS monograph titles are crafted in a manner that fulfils regulatory labeling requirements and also creates uniformity in USP DS monograph titles.

**Today:** Simple, single name approach does not meet the many innovations in the DS industry, e.g., Saw Palmetto

**To differentiate these articles need additional descriptors, e.g.,**  
**plant part, preparation, type of extract**

## Article

## Monograph Name

- |  |   |
|--|---|
| 1) Partially dried ripe fruit                  | Saw Palmetto Partially Dried Fruit              |
| 2) Fruit powder                                | Saw Palmetto Fruit Powder                       |
| 3) Fruit hexane extract                        | Saw Palmetto Fruit Lipophilic Soft Extract      |
| 4) Fruit hydroalcoholic extract                | Saw Palmetto Fruit Hydroalcoholic Dry Extract   |
| 5) Fruit supercritical CO <sub>2</sub> extract | Saw Palmetto Fruit CO <sub>2</sub> Soft Extract |

Furthermore, each article can be incorporated into different finished dosage forms, e.g., Saw Palmetto Capsules

## Dietary Supplements

### Botanical Ingredients

(includes plant, fungal, algal, and certain bacterial materials)

**Complex articles of botanical origin**  
e.g., botanical materials and extracts

### Non-Botanical Ingredients

**Complex articles of animal origin,**  
other complex dietary substances,  
**Single chemical entity articles**  
e.g., isolated substances, vitamins,  
minerals, amino acids, enzymes

## Dietary Supplement Dosage Forms



# Monograph Types

## DIETARY INGREDIENTS

### Titles for Monographs of **Complex Articles of Botanical Origin**

- Botanical Materials (e.g. Plants including fungi, mushrooms, etc.)
- Botanical Products (e.g. gum, latex, resin, etc.)
- Botanical Processed Forms (plant powder, extracts)

### Titles for Monographs of **Complex Articles of Animal Origin** (*Krill Oil* )

### Titles for Monographs of **Other Complex Dietary Substances** (*Probiotics e.g. Lactobacillus johnsonii*)

### Titles for **Single Chemical Entity** Monographs (vitamins, mineral nutrients, amino acids, enzymes, and isolated or synthetic substances )

## DIETARY SUPPLEMENTS (*Chondroitin Sulfate Sodium Tablets*) [Dosage forms]

# Botanical Dietary Ingredient Monograph Titles

As per the Dietary Supplement Health and Education Act of 1994 (DSHEA) and Code of Federal Regulations Title 21 section 101.4(h), the label of a DS must include common or usual names of botanical dietary ingredients and these names shall be consistent with names standardized in American Herbal Products Association's publication *Herbs of Commerce* (1992 edition is specified in 21 CFR 101.4(h) but current edition (2000) is used in practice)

USP botanical dietary ingredient monograph titles include current edition of *Herbs of Commerce* Standardized Common Name (SCN) unless that creates ambiguity, in which case an Other Common Name (OCN) will be used if available.

One Hundred Third Congress  
of the  
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Tuesday,  
the twenty-fifth day of January, one thousand nine hundred and ninety-four*

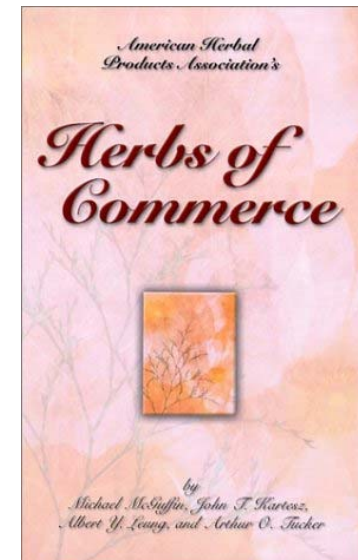
An Act

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled.*

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Dietary Supplement Health and Education Act of 1994”.



## Unambiguous example:

SCN: **Feverfew** for *Tanacetum parthenium* (L.) Sch.Bip.



## Ambiguous example:

SCN: **Labrador tea** is the same for two different subspecies,  
so

OCN: **Bog Labrador tea** for *Ledum palustre* L. subsp.  
*groenlandicum* (Oeder) Hultén (synonym *Ledum*  
*groenlandicum* Oeder)

OCN: **Marsh Labrador tea** for *Ledum palustre* L. subsp.  
*decumbens* (Aiton) Hultén







# Monographs: Complex Articles of Botanical Origin

Current Examples	Proposed Examples
<b>Botanical Materials</b>	
Andrographis	Andrographis Stem and Leaf
Capsicum	Capsicum Species Fruit
<b>Botanical Products</b>	
Aloe	Aloe Species Latex
Castor Oil	Castor Seed Oil
<b>Botanical Processed Forms</b>	
<i>Powdered Andrographis</i>	Andrographis Stem and Leaf Powder
<i>Powdered Andrographis Extract</i>	Andrographis Stem and Leaf Dry Extract
NA	<i>Capsicum</i> Species Fruit Oleoresin
<i>Black Cohosh Fluidextract</i>	Black Cohosh Root and Rhizome Fluidextract
	Cranberry Fruit Juice



# Complex Articles of Animal Origin & Others

Current Examples	Proposed Examples
<b>Processed Animal Articles</b>	
Cod Liver Oil	Cod Liver Oil
Omega-3 Acid Triglycerides	Fish Oil Omega-3 Acid Triglycerides
<b>Single Chemical Entity</b>	
<i>Alanine</i>	<i>Alanine</i>
<i>Ergocalciferol</i>	<i>Ergocalciferol</i>
<b>Dosage Forms</b>	
<p><b>[DIETARY INGREDIENT NAME] {RELEASE CHARACTERISTIC} [DOSAGE FORM]</b></p> <p>Asian Ginseng Root Powder Capsules  <i>Calcium Carbonate Lozenges</i></p>	

# Dietary Supplement Monograph Naming Theme

Whole Botanical Material



Turmeric Rhizome

Powdered Botanical Material



Turmeric Rhizome Powder

Native Extract<sup>1</sup>



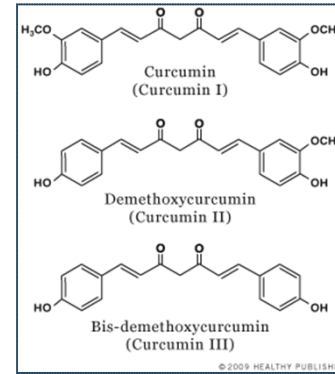
Turmeric Rhizome Dry Extract

Additionally Processed Extract



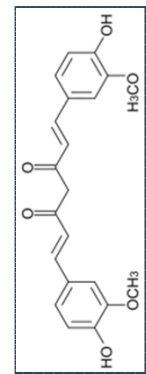
Turmeric Rhizome Curcuminoid Extract

Isolated Class of Compounds



Curcuminoids

Purified Single Chemical



Curcumin

## Degree of Complexity

Intact plant material

→ Single chemical entity

## Degree of Purification

<sup>1</sup> Extract with no added inert substances and no processing beyond extraction (*USP38 <565>*)

Does not include terms for plant (or fungal, algal, bacterial, or animal) materials that are defined in standard textbooks

It focuses on terms specific to DS products and ingredients whose definitions are not so readily available elsewhere or that have been defined differently in various sources, e.g.:

- ▶ **Plant processed forms:** Plant material that has been subjected to processing, e.g., grinding to powder. Examples of processed plant forms include juices, powders, extracts, and fractions, but not isolated pure compounds
- ▶ **Extract:** Preparations with liquid, solid, or semisolid consistency obtained from plant material using solvents to separate constituents of interest from the plant. Excipients may be included except for native extracts, which contain no constituents that were not native to the plant from which the extract was made
- ▶ **Dry extract:** Solid preparations obtained by evaporation of the solvent used in their production
- ▶ **Dry juice:** Dry material obtained by, for example, freeze drying or spray drying juice, often onto a carrier



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Improved Health

A light gray world map is centered in the background of the slide, showing the continents of North America, South America, Europe, Africa, Asia, and Australia.

# Discussions



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# Thank You