



## Guideline for Assigning Titles to *USP* Dietary Supplement Monographs

Approved by the Nomenclature & Labeling Expert Committee on August 19, 2019

### INTRODUCTION

The purpose of this Guideline is to provide a systematic approach to the development of monograph titles for dietary ingredients and dietary supplement (DS) dosage forms admitted to the *United States Pharmacopeia–National Formulary (USP–NF)* and *Dietary Supplements Compendium (DSC)* published by the United States Pharmacopeial Convention (USP). There are many considerations when naming monographs for dietary ingredients and DSs. These considerations include, but are not limited to, available scientific conventions, existing products in commerce and the practices of the DS industry, USP's historical and scientific practices, international aspects of products, their common names originating from traditional medicine, environmental and agricultural practices, regulatory status, and the labeling requirements of applicable federal regulations. This Guideline complements *USP* General Chapter <1121> *Nomenclature* and the *Nomenclature Guidelines* cited therein (1).

This DS Guideline describes how either common names or scientific names of articles are selected for use in the monograph title. For complex articles of botanical or animal origin, the DS Guideline will explain which details should be in the monograph title versus in the *Definition* section with regard to species and subspecies or variety names and common synonyms, the part of the organism and its processed form, type of extract, and composition of partially purified natural complexes. The DS Guideline will also discuss assignment of titles for single chemical entity monographs and for monographs describing the article in a particular finished oral dosage form. The examples provided herein are drawn from monographs in the *USP–NF* and proposed Guideline monograph titles that illustrate the results of applying this guidance. However, it should be noted that this Guideline applies to *USP* DS monograph titles and not to *NF* or other non-DS monograph titles.

Each monograph shall have a title that is consistent with its *Definition* section and that avoids ambiguity as much as possible yet is concise. A DS monograph title must accurately identify the article whose quality specifications it describes. If the title is not reflective of how the article is best known in commerce, that can be clarified in the *Definition*. The DS monograph title should help guide manufacturers in meeting the identity aspects of labeling for dietary ingredients and finished DS products.



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Many DS monograph titles were adopted before the establishment of the current title formats and nomenclature policies. Many of these existing monograph titles are aligned with current nomenclature practices, but those existing monograph titles that are not aligned with current nomenclature practices should not be interpreted as precedents for future monograph titles. Furthermore, it is preferable that existing monograph titles that do not follow the DS Guideline should be revised only on an as-needed, case-by-case basis.

In this Guideline, *USP–NF* monograph titles are distinguished from other text by being in **bold font**. Hypothetical DS monograph titles illustrating the application of these guidelines are in bold and enclosed in quotation marks to distinguish them from titles of existing monographs or approved titles of monographs currently under development. Titles of monographs currently in the *Food Chemicals Codex (FCC)* or *Herbal Medicines Compendium (HMC)* are not in bold to reduce the chance of confusion between the different compendia.

The DS Guideline was developed by the USP Dietary Supplements and Herbal Medicines Nomenclature Joint Subcommittee (DSHM Nomenclature JS) with input from the USP Nomenclature and Labeling Expert Committee (NL EC), the Botanical Dietary Supplements and Herbal Medicines Expert Committee (BDSHM EC), and the Non-Botanical Dietary Supplements Expert Committee (NBDS EC). All titles of dietary ingredient monographs and DS monographs have been approved by the Nomenclature and Labeling EC with the concurrence of the appropriate EC, based on USP staff research and the best scientific judgment of the ECs.

### GENERAL CONSIDERATIONS

#### Historical Practice

The first *Pharmacopoeia of the United States of America*, published in 1820 (2), included monographs of articles that today may be marketed as DSs. These articles include some minerals (medicinal and nutritional) and many botanicals. During its first 100 years, from 1820 through 1920, around 875 botanical monographs were published in the *USP*. Vitamin monographs were incorporated later – the USP established a Vitamin Advisory Board in 1932, and the very first USP reference standards distributed were Vitamins A & D in Cod Liver Oil. 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 minerals. 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

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were originally placed in the *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. The *Dietary Supplements* section includes monographs for ingredients and dosage forms of DSs as defined by DSHEA. Some monographs for botanical articles originally in the *NF* were also migrated to this new DS subsection of the *USP*. However, many monographs for articles that continue to have excipient purposes remain as *NF* monographs, e.g., Peppermint, Peppermint Oil, and Peppermint Water; Licorice Root Fluidextract; and Cardamom, Cardamom Oil, and Cardamom Tincture.

It should be noted, however, that other botanical articles in the *USP–NF* are not necessarily DSs. They may be classified as drugs (prescription or non-prescription), medical devices, or excipients. For example, **Aloe**, **Belladonna Leaf**, **Digitalis**, **Elm**, **Ipecac**, **Opium**, **Podophyllum**, **Psyllium Husk**, **Rauwolfia Serpentina**, **Senna Leaf**, and **Senna Pod** remain in the drug section of the *USP* [Note: Monograph titles are indicated in bold font]. There is a *USP* monograph for **Gutta Percha**, which is used as a medical device material for endodontic (root canal) treatment. Other articles for purposes such as flavors, fragrances, and other excipients, e.g., **Rose Oil**, are placed in the *NF*.

The creation of monograph titles for vitamin and mineral articles is more straightforward than for botanical articles. Vitamin and mineral articles are mostly comprised of single ingredients with titles formulated in a manner similar to those for drugs. Guidance to develop botanical monograph titles was provided in the first *USP* in 1820, in which the guideline approach was to adopt a nomenclature to "...be conformable to the present language of science, divested of as much of its prolixity as can be done consistently with clearness and distinctness. It is conceded that the essential properties of names ought to be expressiveness, brevity and dissimilarity." The intent was that the monograph title "...expresses the medicine, and nothing else; ...needed to be short and explicit, and does not require to be mutilated in practical use, as long names will inevitably be" (2). Thus, a monograph title was to be brief and distinct; a single word sufficed if that word was expressive and unambiguous.

### DS Monograph Titles and DS Product Label Regulatory Requirements

Paragraph 3(a) of DSHEA states that a DS shall be deemed to be a food (i.e., neither an over-the-counter nor prescription drug) within the meaning of this Act. The Act defines a DS as: "(1) a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B)

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a mineral; (C) a herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).”<sup>1</sup> The Act also requires the label of a DS to identify the name of each ingredient.

As set out in the Code of Federal Regulations Title 21 (21 CFR) section 101.4 (h)<sup>2</sup>, the “common or usual names of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in *Herbs of Commerce*, 1992 edition” (*HoC1*) (3).

Although DS monograph titles are not subject to DSHEA and federal product labeling requirements, to make the monographs as useful as possible to stakeholders, USP is assigning titles to DS monographs in a manner as consistent as possible with DSHEA and *HoC*. This includes the use of *HoC* Standardized Common Names (SCNs) of botanicals utilized in North American commerce and the use of common or usual names appearing in commerce when there is no SCN or *HoC* Other Common Name (OCN). It should be noted that USP’s DS monograph titles are required on labels of products purporting to be USP grade, but other titles may be used on labels of products not purporting to be USP grade as long as they are compliant with the federal regulations.

Since the incorporation of *HoC1* by reference into 21 CFR 101.4 (h), a second edition, *HoC2*, was published in 2000 (4). Some changes from *HoC1* to *HoC2*, beyond the addition of more herbs of commerce, include revisions to common names and Latin binomials and the dropping of hyphens from Pinyin Names (Pinyin is the standard system of Romanized spelling for transliterating Chinese). The revisions in *HoC2* and any subsequent editions will be taken into consideration for the creation of monograph titles for botanicals.

The intent set out in *HoC1* was that there should be only one SCN for a plant, and that name should apply to only one taxon. However, certain exceptions were noted.

Where a commodity is represented by more than one taxon in an official compendium such as the *USP*, the *European Pharmacopoeia (Ph. Eur.)*, or the *European Medicines Agency (EMA)* monographs, the SCN could apply to all of the species in that one monograph. For example, *HoC1* has only one species associated with the SCN “devil’s

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<sup>1</sup> See § 201(ff) of DSHEA, 108 Stat. 4325, Public Law 103-471, 103<sup>rd</sup> Congress (1994) for additional details of the definition of a dietary supplement. These provisions are now codified in the Federal Food, Drug, and Cosmetic Act at 21 United States Code § 321(ff).

<sup>2</sup> Electronic Code of Federal Regulations since it is updated regularly: <https://gov.ecfr.io/>  
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claw”, *Harpagophytum procumbens*, but a second species, *Harpagophytum zeyheri*, is included in the monographs of the *Ph. Eur.* and the *EMA*. Therefore, in the title for a potential monograph including both species (as in the proposed USP *Herbal Medicines Compendium* monograph entitled *Harpagophytum Species Root*<sup>3</sup>) the SCN could be used, i.e., “**Devil’s Claw Root**,” with the Latin binomials of the two species set out in the *Definition*. In commerce, batches of Devil’s Claw may be composed of either *H. procumbens* or *H. zeyheri* or, in some cases, mixtures of both species. Thus, a product could have either species or a mixture of both species present and be compliant with such a “**Devil’s Claw Root**” monograph.

In cases where the plant has an established common name in the U.S. but it is imported from a country where a different common name is officially recognized, *HoC1* proposed that the foreign common name could follow in parentheses after the English common name. For example, the SCN for *Astragalus membranaceus* is “astragalus” but it is well known in the Traditional Chinese Medicine trade as “huang qi.” Thus, in the monograph **Astragalus Root**, the monograph’s *Definition* could provide the Pinyin common name “huang qi” and the article could be listed on a product label as “astragalus (huang qi).” Most DS articles have different names in other languages. The selection of one or more foreign names of an article to appear in the *Definition* is based primarily on how common or usual they are in U.S. trade.

The third exception noted in *HoC1* was that more than one SCN could be used for a single taxon if that plant produces more than one commodity in commerce. For example, *Myristica fragrans* has the SCN “nutmeg” for the seed and “mace” for the aril surrounding the seed, because they are used as separate spices and as distinct herbal medicinal ingredients in the Indian systems of traditional medicine.

As a second example more applicable to monograph titles, *Siraitia grosvenorii* has the *HoC1* SCN “luo-han-guo” (without hyphens in *HoC2*), which is the common name best known for the article when used in Traditional Chinese Medicine. Thus, the title for its monograph should be “**Luo Han Guo**.” However, when used as a natural low-calorie sweetener (i.e., meeting the exception set out in *HoC1* when the article represents a different commodity), *Siraitia grosvenorii* is better known as “monk fruit.” Therefore, an *NF* monograph (i.e., for the sweetening agent purpose) could have the title “**Monk Fruit**.” This would make it clear to the reader that “**Luo Han Guo**” is the DS monograph title and “**Monk Fruit**” is the *NF* monograph title. Even though the two monographs are describing the same botanical raw material and will both have the same Latin binomial in the monographs’ *Definition* section, the DS and *NF* monographs may have differences in their specifications.

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<sup>3</sup> <https://hmc.usp.org/monographs/harpagophytum-species-root-0-1>  
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It must be noted that editions of *HoC* produced after the first are not legally binding for labels. Therefore, guidance for monograph titles will also be taken from the U.S. regulations' general principles for the naming of non-standardized foods, 21 CFR 102.5 (a). This paragraph states: "The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods."

An example of a common or usual name of a DS ingredient used in a monograph title when there is no SCN or OCN in *HoC* yet is **Banaba Leaf**. This common name for *Lagerstroemia speciosa* is well established in commerce.

Common names used in commerce change over time. For example, *Euterpe oleracea* had no SCN in *HoC1* but it has the SCN "cabbage palm" in *HoC2*. That ingredient is now better known as "açai" berry. In these cases, using the most appropriate common name in the monograph title will facilitate the monograph's use by industry. The relationship between names can be clarified by adding other well-established common names and the Latin binomial to the monograph's *Definition* and compendium *Index*. Potential revisions to monograph title names and *Definition* synonyms that change over time will be considered as needed by the DSHM Nomenclature JS.

In some cases, two or more plant species may have the same SCN but can be distinguished from each other in the monograph title, if necessary, to meet the requirements of the monograph. This can be done by using an OCN provided in *HoC2* in the monograph title. For example, "Labrador tea" was not included in *HoC1* but in *HoC2* it is the SCN for both *Ledum groenlandicum* (accepted name: *Rhododendron groenlandicum*) and *Ledum palustre* subsp. *decumbens* (accepted name: *Rhododendron tomentosum* subsp. *decumbens*). To have a separate monograph for each species, the OCNs "bog Labrador tea" and "marsh Labrador tea," respectively, could be used in the monograph titles. *HoC2* explicitly noted the need for flexibility in the use of the exact SCN, giving the example of the SCN "common bean" for *Phaseolus vulgaris* but noting that specific naming of articles such as "kidney bean," "pinto bean," "green bean," and "snap bean" is appropriate whenever such modifiers are applied accurately.



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In cases where more than one species of a genus is represented in a single monograph, the genus name shall be used followed by the word “Species”<sup>4</sup> in the monograph title unless there is one SCN for all the included species and, for the purposes of the monograph, there is no need to distinguish among them. For example, *HoC2* has a separate SCN for each of 11 different species of willow, but in commerce, the barks of various species of *Salix* are used alone or mixed to make “willow bark” or “willow bark extract” supplements. Due to substantial anatomical and chemical similarities and hybridization between species, distinguishing them by microscopic, chemical, or genetic tests is neither feasible nor necessary. Because use of any one “willow” SCN in the monograph title will not accurately reflect the composition of the article of commerce, the more appropriate title is ***Salix* Species Bark**.

### Monograph Titles and Latin Binomial Names

The Latin binomial (i.e., the genus and specific epithet) of a botanical article is provided in the *Definition* and either in the monograph title or in the monograph’s *Labeling* section. This provides scientific clarity for identity and also aids manufacturers in complying with the same requirement for DS labeling as stated in 21 CFR 101.4 (h)(2) for plants and other organisms that are not yet listed in *HoC*, and thus have not been assigned an SCN. A good example is *Pelargonium sidoides*. While several species of *Pelargonium* have an SCN, this medicinal species of geranium does not. Similarly, *HoC* has many SCNs for *Citrus* species but not for *C. maxima*, the pummelo (also spelled “pomelo” or “pumelo”). If the SCN applies to more than one species and there are no OCNs provided in *HoC* to distinguish between those species, and a distinction is necessary for the purposes of the monograph, then the Latin binomial or the common name well established in commerce will be used in the monograph title.

Any Latin binomial shall be in accordance with internationally accepted rules on nomenclature, such as those in the *International Code of Nomenclature for algae, fungi, and plants* (5), the *International Code of Zoological Nomenclature* (6), and the *International Code of Nomenclature of Prokaryotes* (7). For example, Latin binomials and subspecies or variety names (and Family names in the *Definition*; they do not appear in monograph titles) should be italicized. The *International Code of Nomenclature for algae, fungi, and plants* “sets no binding standard in this respect, as typography is a matter of editorial style and tradition, not of nomenclature. Nevertheless,

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<sup>4</sup> The Latin term “Species” with an uppercase S has a different meaning in monograph titles of some other currently valid national pharmacopeias, e.g., the pharmacopeias of Austria (ÖAB), Switzerland (PhHelv), and Hungary (PhHg) as well as *Formulae Normales* (FoNo), wherein the term Species is used as a synonym for the German term Teegemische, meaning herbal teas composed of multiple species. G01.17-01



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scientific names, irrespective of rank, are consistently printed in italic type in the *Code* and its authors suggest that editors and authors, in the interest of international uniformity, may wish to consider adhering to the practice exemplified by the *Code*, which has been well received in general and is followed in a number of botanical and mycological journals” (8). Family names that have not been italicized in current USP monographs will be reformatted during a subsequent revision.

Inclusion of the variety or subspecies in the title of a monograph depends on whether it is relevant for an accurate definition of the article of commerce. Phytochemical and/or safety differences, which may arise in different ecotypes or chemotypes of the same species from different geographic regions, and traditional use differences at the variety or subspecies level, should be evaluated to determine whether the variety or subspecies should be included in the monograph title. For example, the *Ziziphus jujuba* var. *spinosa* Seed HMC monograph<sup>5</sup> title includes the variety name. This variety name is important because only *Ziziphus jujube* var. *spinosa* (Bunge) Hu ex H.F.Chow is accepted as the source for the seeds that are the compendial article. Since the HoC2 SCN “jujube” applies to both the species as a whole, *Ziziphus jujube*, and the variety *Ziziphus jujube* var. *spinosa*, to reflect accurately the botanical source, the title for a monograph for the same article as described in the HMC would need to be “**Ziziphus jujuba** var. **spinosa** Seed.” The relationship of the article to the material with the SCN “jujube” would be explained in the *Definition*. When a variety or subspecies is not relevant to the article’s definition and characterization, it should not be used in the title of the monograph.

An example of a monograph title that includes the subspecies is ***Bifidobacterium animalis*** subsp. ***lactis***. Where a subspecies is included in the monograph title, the preferred abbreviation will be “subsp.” rather than “ssp.” This abbreviation is in accordance with the *International Code of Nomenclature of Prokaryotes* (7), as it is for plant, fungal, and algal subspecies according to the *International Code of Nomenclature for algae, fungi, and plants* (4).

### Use of Synonyms in Monograph Titles vs. *Definitions*

Both common names and Latin binomials may have synonyms used in commerce and in the literature on DSs. Use of well-established common name synonyms set out in HoC as OCNs has been discussed above. A brief review of synonyms is conducted by the DSHM Nomenclature JS as part of the process for monograph title selection.

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<sup>5</sup> <https://hmc.usp.org/monographs/ziziphus-jujuba-var-spinosa-seed-0-1>  
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In the monograph title, the Latin binomial most widely known in commerce may be used even if it does not represent currently accepted taxonomic nomenclature. For example, if a monograph were to be developed for the article *Sceletium tortuosum* aerial parts (which is currently an article in the *HMC*), the title would be the same, ***Sceletium tortuosum* Aerial Parts**. In this example, the article is not listed in *HoC* and there is no SCN or OCN or a common name well known in commerce. According to the authoritative Kew Medicinal Plant Names Services (9), the accepted scientific name for this plant is *Mesembryanthemum tortuosum* L., but since the Latin binomial *Sceletium tortuosum* (L.) N.E. Br. is a synonym well established in commerce, it is the more appropriate choice for the monograph title. By providing appropriate details of synonymy in the monograph's *Definition*, the connection is maintained between the article of commerce and its accepted Latin binomial, which is always subject to revision by taxonomists.

The botanical term "synonym" is abbreviated "syn." In some current monographs, a botanical synonym is less precisely indicated by "also known as," e.g., *Curcuma longa* L., also known as *C. domestica* Val. in the **Turmeric** (Guideline title: "**Turmeric Rhizome**") monograph. In botany, the term synonym is used with specific adjectives to describe more precisely the relationship between Latin binomials (5). The term "also known as" may be used elsewhere for non-scientific synonyms. For an article of commerce, it is important to be pragmatic in selecting which other synonyms should be included to clarify the article's identity. Considering the example of the monograph for **Aloe** (Guideline title: "**Aloe Species Leaf Latex**"), it includes in the *Definition* several species, just one of which is *Aloe vera*, which has at least 17 scientific synonyms but only one of those is used commonly in commerce. Thus, it is indicated in the *Definition* as follows: *Aloe vera* (L.) Burm.f. (syn. *Aloe barbadensis* Mill.). Taxonomic websites can be consulted for a reasonably comprehensive list of Latin binomial synonyms, so it will not be necessary to duplicate all of that information in a monograph. Kew's *Medicinal Plant Names Services* (9), the U.S. Department of Agriculture, Agricultural Research Service's *Germplasm Resources Information Network (GRIN)* online database (10), and *The Plant List* (11, the product of a collaboration between several Botanical Gardens) are the main sources used by USP. In the event of conflicting information from these sources, the BDSHM EC or other sources of botanical expertise are consulted.

With regard to single chemical entities, synonyms have been provided in the *Definition*, sometimes in parentheses, e.g., Ubidecarenone (Coenzyme Q<sub>10</sub>). However, the more standard approach that has been used commonly in monographs and general chapters is to preface the substance synonym with "also known as," e.g., acacia (also known as gum arabic). This approach could also be used to indicate common acronyms, e.g., S-Adenosyl-methionine, also known as SAME.



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The following criteria may be helpful to members of the relevant EC in deciding which, if any, Latin binomial synonyms to select for inclusion in the monograph *Definition* in cases where a particular Latin binomial has been selected for the title:

1. If the Latin binomial selected for use in the monograph title or associated with the monograph title's SCN is a synonym according to the current nomenclature set out in *Kew's Medicinal Plant Names Services* (9) or the USDA *GRIN* database (10), then clarification of the synonymy should be included in the monograph *Definition*. For example, *Polygonum multiflorum* Thunb. is the Latin binomial associated with the SCN "fo-ti," but it is a synonym for the accepted name *Reynoutria multiflora* (Thunb.) Moldenke. Both this synonym and the accepted Latin binomial would be included in the *Definition* section of a monograph for this article, e.g., "**Fo-Ti Root**." As another example, in its current monograph, ***Garcinia cambogia*** (Guideline title: "***Garcinia cambogia* Pericarp**"; SCN "garcinia") is a synonym used in the title; in the *Definition*, both *Garcinia cambogia* (Gaertn.) Desr. and *Garcinia gummi-gutta* (L.) N. Robson are included, although the author N. Robson has since been revised to Roxb. To determine which synonyms are well established in commerce, references to consult include key compendia or pharmacopeias from authoritative sources (e.g., monographs published by the *European Medicines Agency*, Health Canada's Natural and Non-prescription Health Products Directorate, *Food Chemicals Codex*, *European Pharmacopoeia*, *Pharmacopoeia of the People's Republic of China*, or the *HMC*).
2. Where key compendia or pharmacopeias from authoritative sources provide multiple synonyms, the presence of a synonym in two or more compendia/pharmacopeias may be evidence that it is well known enough to cite in the monograph *Definition*. For example, in a "**Lo Han Guo Fruit**" monograph, *Momordica grosvenorii* Swingle and *Thladiantha grosvenorii* (Swingle) C. Jeffrey could be provided as commonly cited synonyms for *Siraitia grosvenorii* (Swingle) C. Jeffrey ex A.M.Lu & Zhi Y.Zhang. It is likely that not all synonyms are used in commerce. Setting a criterion that synonyms must be found in two or more references may help avoid listing terms that are not used frequently. This criterion can be revisited if too long a list is obtained in too many cases.
3. If a synonym is not listed in one of these official compendia but other peer-reviewed literature suggests there is a risk of confusion, then this synonymy should be included in the monograph text. For example, the botanical article with the SCN of "calamus," used in both Traditional Chinese Medicine and in Ayurvedic medicine, has the Latin binomial *Acorus calamus* L. In North American traditional medicine, the related native plant is described in the literature either as *Acorus calamus* L. or as *Acorus americanus* (Raf.) Raf. The latter Latin binomial does not appear in most



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major compendia. The accepted Latin binomial for the North American plant is *Acorus calamus* var. *americanus* Raf. Belonging to the species *Acorus calamus*, the SCN applies so the monograph title should be “**Calamus Rhizome**.” However, there are phytochemical differences between the North American and Eurasian materials based on established genotypic differences at the variety level that may be relevant to standard setting for safety and quality. For that reason, a monograph setting standards for the North American plant material should include this variety synonymy in the *Definition* to clarify its relationship to “calamus.”

### Exclusion of Latin Binomial Authors and Families from Monograph Titles

The citation of the author or authors who validly published the Latin binomial, and the Family to which it belongs, are key parts of the scientific name of an organism. For brevity, however, it is not necessary to include the author citation of a Latin binomial or the Family in the monograph title; they will be provided in the *Definition*.

Author names follow directly after the Latin binomial. For example, in the **Andrographis** monograph (Guideline title: “**Andrographis Stems and Leaves**”), the article’s scientific name is given as *Andrographis paniculata* (Burm.f.) Nees, followed by the Family, italicized, in parentheses, e.g., *Andrographis paniculata* (Burm.f.) Nees (Family *Acanthaceae*). The Latin binomial needs to be followed by the author citation in the *Definition* because the author citation helps in locating the original published plant description. This approach helps determine the “nomenclatural type”, i.e., the plant specimen to which the name is permanently assigned and from which the original description was created, and the date of publication (and hence priority) of that name. These points are key criteria used to determine the correct name for a particular species.

The author citation also helps with tracing changes in names. For example, the author citation for the plant name *Andrographis paniculata* (Burm.f.) Nees indicates that Christian Gottfried Daniel Nees von Esenbeck (internationally standardized abbreviation, “Nees”) transferred this species to the genus *Andrographis*. He made this transfer after he re-examined and reclassified the same type of specimen whose description was the basis for the original name *Justicia paniculata* Burm.f. That name was published by Nicolaas Laurens Burman (“f.” stands for *filius* because he was the son of another botanist, Johannes Burman, whose standardized abbreviation is “Burm.”).

The author citation becomes critical in tracing the source of the Latin binomial to prevent confusion over duplicate names and confirm the correct nomenclature of an article. A

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good example of this is the case of two different species that have been described in the literature with the same Latin binomial, *Illicium anisatum*. Only the author distinguishes the two names: *Illicium anisatum* L. is the correct Latin binomial for toxic Japanese star anise, and *Illicium anisatum* Lour. is an incorrect Latin binomial for edible Chinese star anise, for which the accepted Latin binomial in the *NF* monograph **Anise Oil** (which permits use of either true anise or star anise) is *Illicium verum* Hook.f. (Family *Illiciaceae*, since revised to *Schisandraceae*).

Correct nomenclature will be an issue on a product label, on a raw material order form, or in a master formula. Thus, the level of detail in the monograph *Definition* section will be consistent with the labeling regulations that require inclusion of the designation of the author or authors who published the Latin name.

A detailed explanation of how authors are cited and the meaning of terms such as “ex” or “in” found within the author citation is provided in Chapter VI of the *International Code of Nomenclature for algae, fungi, and plants* (5).

Family names are also useful in the *Definition* because there are phytochemical similarities between species within the same Family. Thus, the Family name can alert scientists to potential phytochemical markers of identity, quality, and potential safety issues. The previously used abbreviation “Fam.” is being expanded to “Family” for clarity in the *Definition* section.

### Use of Plant Parts in Monograph Titles

The 1820 edition of the *USP* deliberately omitted the plant part except where two parts of the plant had different uses, not just for brevity but because the names of botanical drugs and medicines were well known to be associated with a specific plant part (2). Thus, plant parts were not included previously in *USP* botanical monograph titles except where multiple monographs were developed for different plant parts of the same species, in which case the plant part was included to distinguish the monographs from each other by title.

*USP* followed this format when creating monograph titles until the enactment of DSHEA in 1994. Current regulations, i.e., 21 CFR 101.4(h)(1), require the DS label to list the part of the plant (e.g., root, leaf) from which the dietary ingredient is derived, such as “Garlic bulb” or “Garlic (bulb)”. There is a great diversity of both botanical species and parts finding use in modern DSs. Therefore, in the DS monograph title, the name of the plant part (in singular form unless including multiple plant parts) follows the name (common or Latin binomial) of the article. For example, ***Echinacea purpurea* Aerial**

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**Parts** is a separate monograph from *Echinacea purpurea* Root. Further examples are provided below.

The name of the part of the plant shall be expressed in English (e.g., “flower”) rather than in Latin (e.g., “flos”), as is used in some pharmacopeias.

An exception to including multiple plant parts in the monograph title may be made where that would result in a monograph title that is not brief. Generally, when there are three or more plant parts, it may be preferable to use in the monograph title the part best known to industry or used in monograph titles of other pharmacopeias, or alternatively, leaving the listing of plant parts to the *Definition*. For example, the current edition of the *Ph. Eur.* has a monograph for **Valerian Root (Valerianae radix)** for which the *Definition* is: “Dried, whole or fragmented underground parts of *Valeriana officinalis* L. *s.l.*, including the rhizome surrounded by the roots and stolons.” Therefore, rather than creating a monograph title “**Valerian Rhizome Root and Stolon**” that will become very cumbersome when extract types and dosage forms are added, it can be shortened to the internationally accepted “**Valerian Root**” with the additional plant parts set out in the *Definition*. As another example, “**Norway Spruce Lignans**” may be obtained from multiple parts of the Norway spruce tree, and the necessary details of plant parts will be included in the monograph’s *Definition*.

Where several plant parts are included in the monograph title, the order of the plant parts is simply the order in which they are listed in the monograph’s *Definition*. This may or may not be in order of descending quantity in the article. While the latter would be a logical order that could be followed for titles of new monographs, it would be too labor intensive to try to verify this information for existing monographs. Where it exists, a collective term such as “aerial parts” or “flowering top” that accurately reflects the composition of the article should be used rather than listing plant parts separately, which could make monograph titles too cumbersome. For example, the article **Hawthorn Leaf with Flower** consists of the dried tips of the flower-bearing branches up to 7 cm in length. While this article will also contain some stem and stem bark material, the *Definition* limits the amount by specifying the terminal 7-cm portion of the branch. Therefore, “Leaf with Flower” is sufficiently descriptive for the parts of the plant that are important for characterization of the article. On the other hand, the article **Echinacea purpurea Aerial Parts** consists of all plant parts above ground level, as described in the *Specific Tests – Botanic Characteristics – Macroscopic* section, and it would be too cumbersome to name them all in the title, so the use of a collective term is appropriate.



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### Organization of this Guideline

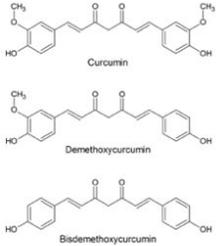
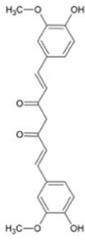
In order to provide organization and a logical flow to this guidance on assigning titles to monographs, the information is presented in a progression from the most complex articles to more purified articles. This approach is accomplished within the following categories: complex articles of botanical origin (including plants, fungi, and algae); complex articles of animal origin; complex articles of bacterial origin; single chemical entities or combinations of single chemical entities, including vitamins, minerals, and amino acids; and finished oral dosage form articles.

For example, a family of monographs that would reflect this progressive level of refinement (and thus a decrease in complexity) would be assigned names as follows. **Turmeric** (“**Turmeric Rhizome**”) is the unprocessed botanical raw material article, which when ground will produce the article **Powdered Turmeric** (“**Turmeric Rhizome Powder**”), which can be extracted with aqueous ethanol to make the extract article **Powdered Turmeric Extract** (“**Turmeric Rhizome Dry Extract**”). This extract could be subject to additional processing to make a partially purified natural complex article “**Turmeric Rhizome Curcuminoids Extract**,” from which the **Curcuminoids** class of compounds is isolated as another article. This could be further purified to provide “**Curcumin**” as a single, isolated chemical entity article. Any of the preceding articles, except the unprocessed raw material, could be formulated into a finished oral dosage form article such as “**Turmeric Rhizome Powder Capsules**” or “**Curcumin Tablets**” (see *Figure 1*).



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### Articles of Botanical Origin

Whole Botanical Material	Powdered Botanical Material	Native Extract <sup>1</sup>	Additionally Processed Extract	Isolated Class of Compounds	Purified Single Chemical
					
Turmeric Root	Turmeric Root Powder	Turmeric Root Dry Extract	Turmeric Root Curcuminoids Extract	Curcuminoids	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  
(*USP* General Chapter <565> *Botanical Extracts*)

**Figure 1. A family of DS monographs**

### DIETARY INGREDIENT MONOGRAPH TITLES

A “dietary ingredient,” as defined by DSHEA, is a substance intended for use in the manufacture of DS finished dosage forms. Dietary ingredient monographs define and characterize plant, fungal, and algal materials, some of which may in fact be raw materials (“crude herb” is a synonymous term) as described in the *USP* General Chapter <563> *Identification of Articles of Botanical Origin*. There may also be dietary ingredients used directly in the manufacture of DSs.

Some dietary ingredient monographs describe botanical raw materials that have been processed to a limited extent, such as by drying and milling (which involves cutting,



## Guideline for Assigning Titles to *USP* Dietary Supplement Monographs

sifting, particle sizing, and density adjustment). Other dietary ingredient monographs describe complex botanical extracts, extracts subjected to additional processing, partially purified natural complexes, single chemical entities, and mixtures of single chemical entities.

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

Articles of botanical origin in this Guideline include plant, fungal, algal, and cyanobacterial articles. Each monograph shall have a title that is consistent with its *Definition* and *Identification* sections. The monograph title shall include the SCN (or OCN in the cases explained above) from *HoC1* or its subsequent editions, or the Latin binomial where necessary (in the cases explained above). The organism's name will be followed by the name of the botanical part(s), except in the case of single-celled or colonial organisms such as yeasts (e.g., "***Saccharomyces cerevisiae***," "**Red Yeast**"), certain algae (e.g., "**Chlorella**"), and cyanobacteria (also known as blue-green algae, e.g., **Spirulina**) that have no parts. The part name is followed, where applicable, by the processed form. The botanical part or material name and processed form name shall be written in English and in singular form unless multiple parts are included (e.g., aerial parts to represent all of the above-ground parts of the plant including the stems, leaves, and flowers).

Additional information about the article that is the subject of the monograph – such as the Latin binomial(s) with their corresponding author(s) and the family, other common name(s), identity, strength (range of ratios of crude plant material to extract), composition (range of concentration of one or more marker compounds), and extraction solvent – shall generally be included under its *Definition*.

Below are examples indicating how monograph titles shall be developed for the different types of complex dietary ingredients of botanical origin, including raw botanical materials and various types of botanical processed forms. By following this Guideline, one can give a family of monographs a consistent title format. An example of such a monograph family includes a botanical raw material monograph for **Gymnema** ("**Gymnema Leaf**") (in *Table 1*), a processed botanical material monograph for **Powdered Gymnema** ("**Gymnema Leaf Powder**") (in *Table 2*), a botanical dry extract monograph for **Native Gymnema Extract** ("**Gymnema Leaf Dry Extract**") (in *Table 3*) and an additionally processed botanical extract monograph for **Purified Gymnema Extract** ("**Gymnema Leaf Gymnemic Acids Dry Extract**") (in *Table 7*).

A few particularly complicated cases are described below to provide further guidance on how monograph titles are assigned.

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“Kelp” is the SCN for various species of brown algae: *Alaria marginata*, *Ascophyllum nodosum*, *Laminaria digitata*, *L. hyperborea* (syn. *L. cloustonii*), *L. setchellii*, *L. sinclairii*, and *Macrocystis pyrifera*. Not all of these species have assigned OCNs. Another species, *L. saccharina*, has “sugar kelp” as the SCN. Kelp is defined in 21 CFR 172.365 as the dehydrated, ground product prepared from *Macrocystis pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni* [sic] for special dietary and nutritional additives as a source of the essential mineral iodine. Therefore, using the SCN in a monograph title, Kelp (an existing *FCC* and *DSC* monograph) might be interpreted to capture only three of the four species set out in 21 CFR 172.365, and could include other genera and species not permitted as “kelp” under the conditions set out in this regulation. To resolve this rare exception to the general approach, a monograph entitled “**Kelp Thallus**” could specify the four species from 21 CFR 172.365 in the *Definition*, while a monograph for *Ascophyllum nodosum* could have the title “**Kelp (*Ascophyllum nodosum*) Thallus**” to include the SCN and be distinguishable from the other monograph.

The article **Spirulina** (“**Spirulina Species**”) consists of the dried, whole, cyanobacterium (blue-green microalgae) *Arthrospira platensis* (syn. *Spirulina platensis*); *Arthrospira maxima* (syn. *Spirulina maxima*); or *Arthrospira fusiformis* (syn. *Spirulina fusiformis*). Although all three species of *Arthrospira* have a *Spirulina* synonym, only the first two of these species have the SCN “spirulina.” They constitute most of the article on the market, so using the synonym “**Spirulina Species**” in the title rather than the accepted name *Arthrospira* in the title, is a compromise that allows the monograph title to use the SCN that industry and consumers are very familiar with. The *Definition* section provides details needed to understand the article’s composition. In some cases, the monograph will also include a labeling requirement related to these additional details.

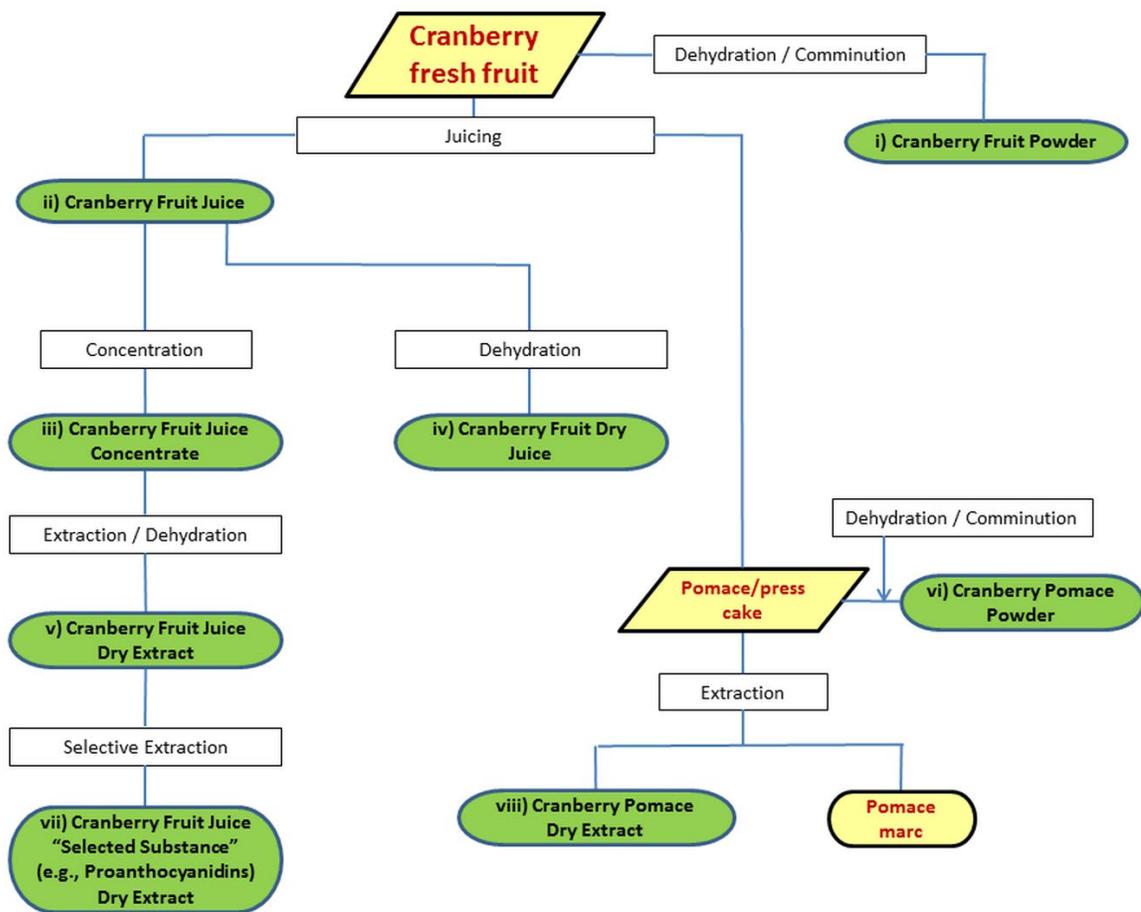
The particularly complicated example of naming various commercial complex articles of botanical origin prepared from cranberry is illustrated in Figure 2. “Cranberry” is the SCN for the whole plant of *Vaccinium macrocarpon* Aiton as well as the common name for the fruit. “Cranberry” is recognized in 21 CFR 102.33 for food common or usual names and 101.30 for the juice, plus Title 7 (Agriculture), Title 15 (Commerce and Foreign Trade), Title 19 (Customs Duties), and Title 40 (Protection of the Environment) regarding pesticide residues, etc. Since cranberry leaf, cranberry seed, and cranberry seed oil are also DS articles, and 21 CFR 101.4(h)(1) requires the DS label to list the part of the plant from which the dietary ingredient is derived, DS monograph titles will contain the plant part even when it appears to be redundant. For example, “**Cranberry Fruit Dry Extract**” will be the title, since omitting “Fruit” because “berry” is already in the title would lead to ambiguity if a monograph were to be developed for “**Cranberry Leaf**

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**Dry Extract.** The same approach will apply in other similar cases, e.g., “**Bilberry Fruit Dry Extract**” instead of the existing **Powdered Bilberry Extract** to contrast with a potential monograph for “**Bilberry Leaf Dry Extract.**” As a slightly different case, in the Oxford and Merriam-Webster dictionaries, “elderberry” is spelled as one word, but the SCN for the plant is “elder” with an adjective for each species, e.g., “American elder” (*Sambucus canadensis* L.) or “European elder” (*Sambucus nigra* L.). In this case, the monograph title **European Elder Berry Dry Extract** with a space captures the SCN and the plant part.



**Figure 2. Naming cranberry-derived articles** (items in yellow not likely to be dietary supplement articles)



## Guideline for Assigning Titles to *USP* Dietary Supplement Monographs

### *Titles for Botanical Material Monographs*

Botanical materials include the whole plant or a specific part of the plant (or fungus or alga), with the exception noted above for single-celled or colonial organisms. Botanical materials also include some natural gums, resins, oleo-gum-resins, mucilages, and latexes that occur as exudates of the plant, e.g., **Aloe** (“**Aloe Species Leaf Latex**”) or **Guggul** (“**Guggul Oleo-gum-resin**”). Other examples of these materials are obtained by extraction, e.g., **Guar Gum**, **Capsicum Oleoresin** (“**Capsicum Species Fruit Oleoresin**”), and “**Marshmallow Root Mucilage**.” In either case, these terms are descriptive of the article, so to keep the monograph title concise, the details will be captured in the *Definition*.

The examples provided in *Table 1* illustrate how titles for botanical material monographs will be derived when following the new Guideline, compared to how current monograph titles were derived.

**Table 1. Current and Guideline Nomenclature Formats for Botanical Material Monograph Titles**

Current Examples	Guideline Examples <sup>a</sup>
{SCN} OR {LATIN BINOMIAL W/O AUTHORITY} <sup>b</sup> {BOTANICAL MATERIAL(S)}	{SCN} OR {LATIN BINOMIAL W/O AUTHORITY} [BOTANICAL MATERIAL(S)]
Aloe	“ <b>Aloe Species Leaf Latex</b> ”
NA <sup>c</sup>	“ <b>Aloe Vera Leaf Juice</b> ”
Andrographis	“ <b>Andrographis Stem and Leaf</b> ”
Asian Ginseng	“ <b>Asian Ginseng Root</b> ”
<i>Boswellia serrata</i>	“ <b>Indian Frankincense Oleo-gum-resin</b> ”
Capsicum	“ <b>Capsicum Species Fruit</b> ”
<i>Centella asiatica</i>	“ <b>Gotu Kola Aerial Parts</b> ”
Chamomile	“ <b>Chamomile Flower</b> ”
NA	“ <b>Clubmoss Spore</b> ”
Cranberry Liquid Preparation <sup>d</sup>	“ <b>Cranberry Fruit Juice</b> ” <sup>e</sup>
NA	“ <b>Echinacea purpurea Aerial Parts Juice</b> ”
NA	“ <b>European Elder Fruit Dry Juice</b> ”



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Current Examples	Guideline Examples <sup>a</sup>
[[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] <sup>b</sup> {BOTANICAL MATERIAL(S)}	[[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)]
<b>Ganoderma Lucidum Fruiting Body</b>	“ <b>Reishi Fruiting Body</b> ”
<b>Guggul</b>	“ <b>Guggul Oleo-gum-resin</b> ”
<b>Gymnema</b>	“ <b>Gymnema Leaf</b> ”
<b>NA</b>	“ <b>Kelp Thallus</b> ”
<b>NA</b>	“ <b>White Pine Pollen</b> ”
<b><i>Rhodiola rosea</i></b>	“ <b><i>Rhodiola rosea</i> Root and Rhizome</b> ”
<b>Senna Leaf</b>	<b>Senna Leaf</b>
<b>Senna Pods</b>	“ <b>Senna Pod</b> ”
<b>Spirulina</b>	“ <b><i>Spirulina</i> Species</b> ”
<b>Valerian</b>	“ <b>Valerian Root</b> ”
<b>Wheat Bran</b>	<b>Wheat Bran</b>

<sup>a</sup> Examples in quotes are hypothetical, solely to show what the new titles would look like.

<sup>b</sup> Items within brackets [ ] are required, whereas those within braces { } are to be used as appropriate (i.e., one should use {SCN} where an unambiguous SCN is provided in *Herbs of Commerce* but use {Latin binomial} in other cases as explained above).

<sup>c</sup> **NA**: title not available because currently no USP monograph exists for this article.

<sup>d</sup> Use of the term “Preparation” is discussed below.

<sup>e</sup> The **Cranberry Liquid Preparation** Monograph’s *Definition* allows for two species, *Vaccinium macrocarpon* or *Vaccinium oxycoccus*, but both have the same SCN “cranberry” and there is no need to distinguish between them in the monograph, so the title “**Cranberry Fruit Juice**” follows the Guideline format.

### ***Titles for Botanical Processed Form Monographs***

Articles referred to as plant (or fungal, algal, or cyanobacterial) processed forms include plant powders, dry extracts, soft extracts, liquid extracts, juices (liquid or dry), other liquid articles such as fixed oils and essential oils, and fractions of extracts, but do not include isolated pure compounds. The examples provided below illustrate how titles for plant processed-article monographs will be derived following this Guideline, compared to how current monograph titles were derived.

#### *Titles for Botanical Powder Monographs:*



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The term “powder” indicates that the botanical material has been milled (comminuted) into a powder. Some materials such as spores and pollen are powder-sized, but spores and pollen are botanical parts so their monograph titles will follow the format and examples shown in *Table 1*. Examples of botanical powders are provided in *Table 2*. Botanical powders are not meant to include other botanically derived articles that may be powdered or present in powder form, such as dry extracts and dry juices, the title formats for which are discussed below.

**Table 2. Current and Guideline Nomenclature Formats for Botanical Powders**

Current Examples	Guideline Examples
{PROCESS} [{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] {BOTANICAL MATERIAL(S)}	[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)] [POWDER]
Powdered <i>Andrographis</i>	“ <i>Andrographis</i> Stem and Leaf Powder”
Powdered Ashwagandha Root	“Ashwagandha Root Powder”
Powdered Black Cohosh	“Black Cohosh Rhizome and Root Powder”
NA	“Cranberry Fruit Powder”
NA	“Cranberry Pomace Powder”
Powdered <i>Centella asiatica</i>	“Gotu Kola Aerial Parts Powder”
Powdered Garlic	“Garlic Bulb Powder”
Powdered Gymnema	“Gymnema Leaf Powder”
Powdered Hawthorn Leaf with Flower	“Hawthorn Leaf with Flower Powder”
Powdered Horse Chestnut	“Horse Chestnut Seed Powder”

### *Titles for Botanical Extract Monographs:*

For botanical extracts, monograph titles are derived from several factors: the raw material identity, whether the raw material was fresh or dried, the physical state or consistency of the extract, and which extraction solvent was used. This last factor allows for differentiation between similar articles based on their chemical profiles due to the extraction solvent used (see General Chapter (565) *Botanical Extracts*). Examples



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of the physical state or consistency of the extract include liquid (e.g., fluid extracts, tinctures), semisolid (e.g., soft extracts, oleoresins), and dry extracts (e.g., powders, granules, or flakes). The examples provided in *Tables 3, 4, and 5* illustrate how titles for botanical extract monographs will be derived when following the Guideline compared to how current monograph titles were derived.

For clarity, in the following tables the format terms: **[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)]** used above to describe botanical materials and powders will be simplified to **[SOURCE MATERIAL]**, which incorporates all of the above terms.

**Table 3. Current and Guideline Nomenclature Formats for Botanical Dry Extracts**

<b>Current Examples</b>	<b>Guideline Examples</b>
<b>[{PROCESS} {TYPE}] [SOURCE MATERIAL<sup>a</sup>] [EXTRACT]</b>	<b>[SOURCE MATERIAL {FRESH}<sup>b</sup>] [{TYPE}<sup>c</sup> DRY EXTRACT]</b>
<b>Powdered Andrographis Extract</b>	<b>“Andrographis Stem and Leaf Dry Extract”</b>
<b>Powdered Asian Ginseng Extract</b>	<b>“Asian Ginseng Root Dry Extract”</b>
<b>Aztec Marigold Zeaxanthin Extract</b>	<b>“Aztec Marigold Zeaxanthin Dry Extract”<sup>d</sup></b>
<b>NA</b>	<b>“Cranberry Fruit Juice Dry Extract”</b>
<b>NA</b>	<b>“Cranberry Pomace Dry Extract”</b>
<b>Powdered <i>Centella asiatica</i> Extract</b>	<b>“Gotu Kola Aerial Parts Dry Extract”</b>
<b>NA</b>	<b>“Broccoli Seed Glucoraphanin Dry Extract”<sup>d</sup></b>
<b>Powdered Goldenseal Extract</b>	<b>“Goldenseal Root and Rhizome Dry Extract”</b>
<b>Native Gymnema Extract</b>	<b>“Gymnema Leaf Dry Extract”</b>
<b>NA</b>	<b>“Oat Fresh Seed Dry Extract”</b>
<b>Rosemary Leaf Dry Aqueous Extract</b>	<b>“Rosemary Leaf Aqueous Dry Extract”</b>
<b>NA</b>	<b>“Rosemary Leaf Hydroalcoholic Dry Extract”</b>
<b>Saw Palmetto Extract (in part)<sup>e</sup></b>	<b>“Saw Palmetto Fruit Hydroalcoholic Dry Extract”</b>
<b>Yeast Extract</b>	<b>“Yeast Dry Extract”</b>

<sup>a</sup> Source material refers to the unprocessed botanical material used to prepare an extract or other processed botanical materials, the naming of which is outlined in *Tables 1 and 2*.



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Current Examples	Guideline Examples
[ <b>{PROCESS}</b> <b>{TYPE}</b> ] [ <b>SOURCE MATERIAL<sup>a</sup></b> ] [ <b>EXTRACT</b> ]	[ <b>SOURCE MATERIAL {FRESH}<sup>b</sup></b> ] [ <b>{TYPE}<sup>c</sup> DRY EXTRACT</b> ]
<p><sup>b</sup> If fresh plant material is used to prepare the extract, the word <b>Fresh</b> is included after the SCN or Latin binomial and before the plant part. Otherwise, dry material is assumed.</p> <p><sup>c</sup> <b>TYPE</b> is an additional term that further identifies the article. The solvent is specified when two or more articles need to be differentiated based on their chemical profile due to the solvent used.</p> <p><sup>d</sup> “<b>Aztec Marigold Zeaxanthin Dry Extract</b>” and “<b>Broccoli Seed Glucoraphanin Dry Extract</b>” are derived from cultivars naturally rich in the target class of compounds and thus differ from extracts subjected to further processing to become enriched in the target class of compounds. This can be specified in the <i>Definition</i>, e.g., “from the flowers of <i>Tagetes erecta</i> L., grown from seeds of varieties of the Scarletade cultivar rich in zeaxanthin”; “from seeds of <i>Brassica cretica</i> Lam. of the Hopkins cultivar [or to be less restrictive, of cultivars] rich in glucoraphanin.”</p> <p><sup>e</sup> The current <b>Saw Palmetto Extract</b> monograph describes extracts obtained by extraction with hydroalcoholic mixtures, hexane, or supercritical carbon dioxide. In the future, this may be divided into three separate monographs, one for the dry extract and two for the soft extracts, due to the differences in physical form and composition of the extracts produced by using different extraction solvents.</p>	

**Table 4. Current and Guideline Nomenclature Formats for Botanical Soft Types of Extracts**

Current Examples	Guideline Examples
[ <b>SOURCE MATERIAL</b> ] [ <b>EXTRACT</b> ]	[ <b>SOURCE MATERIAL {FRESH}</b> ] [ <b>{TYPE}</b> ] [ <b>{SOFT EXTRACT}</b> ] OR [ <b>{MUCILAGE}</b> ] OR [ <b>{OLEORESIN}</b> ]
Capsicum Oleoresin	“ <b>Capsicum Species Fruit Oleoresin</b> ”
NA	“ <b>Turmeric Rhizome Ethanol Oleoresin</b> ”
NA	“ <b>Ginger Rhizome Carbon Dioxide Soft Extract</b> ”
NA	“ <b>Lemon Balm Leaf Soft Extract</b> ”
NA	“ <b>Marshmallow Root Mucilage</b> ”
Saw Palmetto Extract (in part) <sup>a</sup>	“ <b>Saw Palmetto Fruit Lipophilic Soft Extract</b> ” “ <b>Saw Palmetto Fruit Carbon Dioxide Soft Extract</b> ”
NA	“ <b>Valerian Fresh Root Soft Extract</b> ”
<p><sup>a</sup> The current <b>Saw Palmetto Extract</b> monograph describes extracts obtained by extraction with hydroalcoholic mixtures, hexane, or supercritical carbon dioxide. In the future, this may be divided into three separate monographs, one for the dry extract and two for the soft extracts, due to the differences in physical form and composition of the extracts produced by using different extraction solvents.</p>	



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**Table 5. Current and Guideline Nomenclature Formats  
for Botanical Liquid Types of Extracts**

Current Examples	Guideline Examples
[SOURCE MATERIAL] [EXTRACT]	[SOURCE MATERIAL {FRESH}] [LIQUID EXTRACT]
<b>Aromatic Cascara Fluidextract</b>	“ <b>Cascara Sagrada Bark Aromatic<sup>a</sup> Fluidextract</b> ”
<b>Black Cohosh Fluidextract</b>	“ <b>Black Cohosh Rhizome and Root Fluidextract</b> ”
<b>Garlic Fluidextract</b>	“ <b>Garlic Bulb Fluidextract</b> ”
<b>Ginger Tincture</b>	“ <b>Ginger Rhizome Tincture</b> ”
<b>Licorice Fluidextract<sup>b</sup></b>	“ <b>Licorice Root Fluidextract<sup>b</sup></b> ”
<b>NA</b>	“ <b>Oat Fresh Seed Tincture</b> ”
<b><i>Rhodiola rosea</i> Tincture</b>	“ <b><i>Rhodiola rosea</i> Root and Rhizome Tincture</b> ”
<b>Valerian Tincture</b>	“ <b>Valerian Root Tincture</b> ”

<sup>a</sup> See the Glossary for an explanation of “aromatic.”

<sup>b</sup> **Licorice Fluidextract** is currently an *NF* monograph, but if a DS monograph were to be created, the Guideline title would apply. This would help to distinguish between the two monographs since a DS monograph could have different standards than an *NF* monograph derived from the same botanical material because the articles have different purposes.

### *Titles for Botanical Fatty Oil and Essential Oil Monographs:*

Articles such as fatty (fixed) oils, essential (volatile) oils, essential oil spirits, and essential oil waters may be obtained by solvent extraction as described in General Chapter <565> *Botanical Extracts*. However, these materials may also be obtained by other methods such as expression (e.g., cold pressed, expeller pressed, or pressed with heating) of fatty oils and steam distillation of essential oils. The type of oil (e.g., fatty vs. essential) and the method of manufacturing (e.g., expression or extraction) are not differentiated in the monograph title, but instead are specified in the *Definition*.

Examples of monograph titles for botanical fatty oil and essential oil articles that may be obtained by extraction or by expression are provided in *Table 6*.



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**Table 6. Current and Guideline Nomenclature Formats for Botanical Fatty Oils and Essential Oils**

Current Examples	Guideline Examples
[SOURCE MATERIAL] [{OIL} OR {SPIRIT} OR {WATER}]	[SOURCE MATERIAL {FRESH}] [{OIL} OR {OIL SPIRIT} OR {OIL WATER}]
Castor Oil	“Castor Seed Oil”
Aromatic Castor Oil	“Castor Seed Aromatic <sup>a</sup> Oil”
<i>Cryptocodinium cohnii</i> Oil	<i>Cryptocodinium cohnii</i> Oil
Evening Primrose Oil	“Evening Primrose Seed Oil”
Flax Seed Oil	Flax Seed Oil
NA	“Olive Oil”
Peppermint Oil <sup>b</sup>	“Peppermint Leaf Oil”
Peppermint Spirit	“Peppermint Leaf Oil Spirit” <sup>a</sup>
Peppermint Water <sup>b</sup>	“Peppermint Leaf Oil Water” <sup>a</sup>
Schizochytrium Oil	“ <i>Schizochytrium</i> Species Oil”

<sup>a</sup> See the Glossary for an explanation of terms such as “aromatic,” “aromatic oil water,” and “spirit.”

<sup>b</sup> These are currently *NF* monographs, but if DS monographs were to be created, the Guideline titles would apply.

### Use of the Term “Native Extract” in Monograph Titles:

General Chapter <565> states that certain botanical extracts are “native extracts.” Native extracts are “extracts with no added inert substances and no processing beyond the extraction” (except for solvent removal in the case of dry or soft extracts). The only monographs with the word “native” in the title currently are **Native Guggul Extract** (Guideline title: “**Guggul Oleo-gum-resin Soft Extract**”) and **Native Gymnema Extract** (Guideline title: “**Gymnema Leaf Dry Extract**”).

Most other botanical extract monographs indicate in the *Definition*, rather than by use of the term “native” in the title, whether suitable inert substances may be added. One example is the mention of carriers in the monograph for **Powdered Holy Basil Leaf Extract**, Guideline title: “**Holy Basil Leaf Dry Extract**”). In another example, the *Definition* may say nothing about the presence or absence of added substances, e.g., in the monograph for **Maritime Pine Extract** (Guideline title: “**Maritime Pine Stem Bark Dry Extract**”). Note that many aspects of product formulation are not specified in the G01.17-01



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*Definition* of botanical extract articles, such as the use of excipients as diluents for producing normalized or standardized content extracts or the use of flow agents in powders such as dry extracts.

Since the *Definition* is an appropriate location to describe the acceptability of the use of certain excipients in the article, for example to dilute a native extract in order to standardize quantified content, there is no need to add qualifiers to monograph titles denoting that the article is excipient free, e.g., “native.” Monographs that currently have “native” in the title will be reviewed and any appropriate changes will be made as part of the routine monograph revision cycle.

### *Titles of Monographs for Botanical Extracts Subjected to Additional Processing*

Some extracts are subjected to additional processing that increases the content of characterized constituents, decreases the content of unwanted constituents, or both.

In a processed extract, the percentage of characterized or unwanted constituents may vary. The result will be specified in the *Definition* of the article. For example, the current **Powdered Garcinia Hydroxycitrate Extract** monograph (Guideline title: “**Garcinia Pericarp Hydroxycitrate Dry Extract**”) specifies not less than (NLT) 40% (-)-hydroxycitric acid.

In cases where there are monographs for both native extracts and additionally processed extracts of the same botanical raw material, the term “purified” has been used in monograph titles to identify and describe the article that resulted from additional processing. For complex botanical articles, the term “purified” is not sufficiently descriptive, therefore, the DS Guideline approach is to name the characterized constituent or class of compounds in the monograph title.

For example, the **Native Gymnema Extract** (Guideline title: “**Gymnema Leaf Dry Extract**”) is defined as having a ratio of plant material to extract of about 8:1 and containing NLT 5.0% of gymnemic acids, calculated as gymnemagenin on the dried basis. In contrast, the **Purified Gymnema Extract** (Guideline title: “**Gymnema Leaf Gymnemic Acids Dry Extract**”) monograph is defined as having a ratio of plant material to extract of about 25:1, with NLT 90.0% and not more than (NMT) 110.0% of the labeled amount of gymnemic acids, calculated as gymnemagenin on the dried basis. Note that the specifications in the *Definition* of this article are based on a labeled amount rather than a concentration in the extract as was defined for the **Powdered Garcinia Hydroxycitrate Extract** monograph (Guideline title: “**Garcinia Pericarp Hydroxycitrate Dry Extract**”).

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**Native Guggul Extract** (Guideline title: “**Guggul Oleo-gum-resin Soft Extract**”) has a ratio of plant material to extract of approximately 9:1 and contains NLT 5.0% of guggulsterones E and Z, calculated on the anhydrous basis as guggulsterone Z. The monograph for **Purified Guggul Extract** (Guideline titles: “**Guggul Oleo-gum-resin Guggulsterones Soft Extract**” and “**Guggul Oleo-gum-resin Guggulsterones Dry Extract**”) does not mention an extract ratio but specifies NLT 90.0% and NMT 110.0% of the labeled amount of the sum of guggulsterones E and Z calculated as guggulsterone Z. The article is described in the *Definition* as a “semisolid extract” with no added substances or a “powder extract” containing suitable added substances. While both types of extracts are currently included in a single monograph, the DS Guideline approach is generally to have separate monograph titles that distinguish between these articles. This approach will be a topic for future discussion by the DSHM Nomenclature JS and the associated Expert Committees.

**Powdered Decaffeinated Green Tea Extract** (Guideline title: “**Green Tea Leaf Decaffeinated Dry Extract**”) serves as an example of a current monograph for an article subjected to additional processing to reduce the level of a constituent, in this case caffeine, with a specification of NMT 0.1%. Note that the order of terms in the monograph title should follow the standard pattern set out in *Table 7*; it is not intended to reflect the order in which steps in the processing of the article are done. For example, decaffeination of green tea may be done by extraction of the leaf material with supercritical carbon dioxide. Alternatively, water may be used at a high temperature for a short extraction time followed by carbon filtration to remove most of the caffeine; the filtered water with the remaining flavor ingredients can then be reused for preparation of the extract. Extraction of the caffeine may also be done with organic solvents such as methylene chloride or ethyl acetate. The decaffeinated leaf material is then used in the production of the dry extract rather than the green tea leaf extract being subsequently decaffeinated. Another potential example of reduction of the level of a constituent would be “**Licorice Root Deglycyrrhizinized Soft Extract**”, which has been processed to remove glycyrrhizin (glycyrrhizic acid or glycyrrhizinic acid).



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**Table 7. Current and Guideline Nomenclature Formats for Botanical Extracts Subjected to Additional Processing**

Current Examples	Guideline Examples
[[{PROCESS} {TYPE}]] [SOURCE MATERIAL] [[{CONSTITUENT OR CLASS OF COMPOUNDS} {EXTRACT}]]	[SOURCE MATERIAL] [CONSTITUENT OR CLASS OF COMPOUNDS] [{TYPE} {DRY EXTRACT} OR {SOFT EXTRACT} OR {LIQUID EXTRACT} OR {OIL}]
<b>Powdered Garcinia Hydroxycitrate Extract</b>	<b>“Garcinia Pericarp Hydroxycitrate Dry Extract”</b>
<b>Powdered Decaffeinated Green Tea Extract</b>	<b>“Green Tea Leaf Decaffeinated Dry Extract”</b>
<b>Purified Guggul Extract</b>	<b>“Guggul Oleo-gum-resin Guggulsterones Soft Extract” and “Guggul Oleo-gum-resin Guggulsterones Dry Extract”<sup>a</sup></b>
<b>Purified Gymnema Extract</b>	<b>“Gymnema Leaf Gymnemic Acids Dry Extract”</b>
<b>NA</b>	<b>“Licorice Root Deglycyrrhizinated Soft Extract”</b>
<b>Powdered Soy Isoflavones Extract</b>	<b>“Soy Seed Isoflavones Dry Extract”</b>
<b>Tomato Extract Containing Lycopene</b>	<b>“Tomato Fruit Lycopene Soft Extract”</b>
<sup>a</sup> The current monograph’s <i>Definition</i> describes both the soft extract and a dry extract produced by the addition of excipients. See discussion in the text above.	

At a higher level along the continuum of refinement, in some current monographs, the specification in the monograph’s *Definition* is for a class of compounds isolated as a fraction from a particular botanical material’s extract. For example, ***Centella asiatica* Triterpenes** (Guideline title: **“Gotu Kola Aerial Parts Triterpenes”**) is described as a fraction that contains NLT 90.0% *Centella asiatica* triterpene derivatives. Another example, **Grape Seeds Oligomeric Proanthocyanidins** (Guideline title: **“Grape Seed Oligomeric Proanthocyanidins”**), is described as a fraction that contains NLT 75.0% oligomeric proanthocyanidins.

Since triterpenes and oligomeric proanthocyanidins are both diverse and widespread classes of compounds, it is necessary to include the source botanical material in the monograph title. *Table 8* provides some examples of current and Guideline monograph titles for articles that consist of classes of compounds obtained as fractions of botanical material extracts.



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**Table 8. Current and Guideline Nomenclature Formats for Classes of Compounds Obtained as a Fraction of a Botanical Material Extract**

Current Examples	Guideline Examples
[[{PROCESS} {TYPE}]] [SOURCE MATERIAL] [CONSTITUENT OR CLASS OF COMPOUNDS]	[SOURCE MATERIAL] [CONSTITUENT OR CLASS OF COMPOUNDS]
<i>Centella asiatica</i> Triterpenes	“Gotu Kola Aerial Parts Triterpenes”
Grape Seeds Oligomeric Proanthocyanidins	“Grape Seed Oligomeric Proanthocyanidins”
Psyllium Hemicellulose	“Psyllium Seed Husk Hemicellulose”

There are also monographs that set standards for “partially purified natural complexes” as opposed to the processed/semi-purified extracts and fractions just described. The format for monograph titles for partially purified natural complexes is simply **[CLASS OF COMPOUNDS]**. For example, **Sennosides** is defined as a partially purified natural complex of anthraquinone glucosides isolated from senna leaf and/or senna pod as the calcium salts. The specifications are for NLT 90.0% and NMT 110.0% of the labeled amount of sennosides, and the labeled amount of sennosides should be NLT 60.0% (weight for weight, w/w), calculated on the dried basis. **Curcuminoids** is defined as a partially purified natural complex of diaryl heptanoid derivatives isolated from turmeric, with NLT 95.0% curcuminoids, calculated on the dried basis, as a sum of curcumin (70.0%–80.0%), desmethoxycurcumin (15.0%–25.0%), and bisdesmethoxycurcumin (2.5%–6.5%). Note that the name for the class of compounds is sufficiently distinctive that the source botanical material does not need to be in the monograph title, only in the *Definition*.

With regard to extracts subjected to additional processing to be enriched with or depleted in a particular substance vs. fractions of extracts vs. partially purified natural complexes, it would be arbitrary to set any numerical concentration threshold to distinguish between them. Note that the current monograph for **Sennosides** specifies an amount NLT 60% whereas the “**Gotu Kola Aerial Parts Triterpenes**” monograph specifies NLT 90.0% *Centella asiatica* triterpene derivatives, so the concentration ranges overlap; they are all complex articles along a continuum of refinement.

In practice, while the degree of purification of natural complexes may overlap with that of extracts subjected to additional processing, the intent of a monograph for a partially purified natural complex is to provide quality specifications for a complex article that is



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more akin to a single chemical entity than a botanical extract. The characterized constituents may be isolated as salts or other derivatives not found in the source plant material. In addition, ratios of the congeners may be very different from what is found in the source plant material. The *Definition* section of each monograph provides the necessary details.

These general principles may help to distinguish monograph titles that specify the name of the source plant material as well as the class of compounds from those that mention only the class of compounds. However, the decision on how to title these very similar categories of monographs will have to be made on a case-by-case basis with input from the appropriate Expert Committees.

### Titles for Monographs of Complex Articles of Animal Origin

Monograph titles for dietary ingredients of animal origin should follow the directives in 21 CFR 101.4 *Food; designation of ingredients*, which is consistent with DSHEA with respect to the requirement to use common or usual English names where available. Nomenclature at the appropriate level of detail will be provided in the article's *Definition*. For example, **Krill Oil** is extracted primarily from a single species of Antarctic krill identified in the monograph's *Definition* as *Euphausia superba* Dana.

The general nomenclature convention for titles of monographs of complex articles of animal origin is **[ANIMAL NAME] [{ANIMAL ORGAN(S)} {ANIMAL MATERIAL}]**. Current examples include **Cod Liver Oil** and **Krill Oil**, and potential examples could be "**Oyster Shell**" and "**Shark Cartilage**."

Just as with botanical material extracts subjected to additional processing to increase the content of characterized constituents, decrease the content of unwanted constituents, or both, an example of a complex article of animal origin subject to further processing is the **Fish Oil Containing Omega-3 Acids** monograph (Guideline title: "**Fish Oil Omega-3 Acids**"). Note that the several families of fish that can be used to produce fish oil omega-3 acids (families *Engraulidae*, *Carangidae*, *Clupeidae*, *Osmeridae*, *Scombroidae*, and *Ammodytidae*) are listed in the **Fish Oil Containing Omega-3 Acids** monograph's *Definition* because it is not feasible to identify each individual species in the monograph title or *Definition*.

**Omega-3 Acid Triglycerides** is an example of a monograph for an article of animal origin that sets standards for a "partially purified natural complex." Its *Definition* specifies that the omega-3 acids must come from fish body oil and sets out the families of fish that are acceptable sources of the body oil, and the omega-3 acids that comprise the

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triglycerides. It specifies that the article contains NLT 58.0% of total omega-3 acids expressed as triglycerides and NLT the labeled amount of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) expressed as the free fatty acids. The format for monograph titles for partially purified natural complexes from animal source materials, as with that type of botanical monograph title, is simply **[CLASS OF COMPOUNDS]**. Another example is the **Pancreatin** monograph, in which the source material name (hog pancreas or ox pancreas) is provided in the *Definition* and can be specified in labeling to allow consumers to make informed choices with respect to kosher or halal products.

### Titles for Monographs of Complex Articles of Bacterial Origin

Monographs for complex articles of bacterial origin such as probiotics should follow the format **[LATIN BINOMIAL W/O AUTHORITY] [STRAIN IDENTIFIER]**. For example, there are *USP* monographs for ***Lactobacillus acidophilus* La-14**, ***Lactobacillus acidophilus* NCFM**, ***Lactobacillus paracasei* LPC-37**, and ***Lactobacillus rhamnosus* HN001**.

The monograph for ***Bifidobacterium animalis* subsp. *lactis*** sets out in the *Definition* three acceptable strains: Bi-07 (ATCC SD5220), Bi-04 (ATCC SD5219), and HN019 (ATCC SD5674). This flexible approach accommodates in one monograph multiple strains that meet the same specifications.

### Titles for Single-Chemical Entity Monographs

The nomenclature for single-chemical entities, including single vitamins, minerals, and phytochemicals, is the same as for drug substances, as described in the *USP Nomenclature Guidelines (1)* cited in *USP* General Chapter <1121> *Nomenclature*.

Single-chemical entity monographs typically have a chemistry section following the title that provides a figure of the chemical structure as well as the molecular formula, molecular weight, systematic chemical name, and if available, common synonym(s), the Chemical Abstracts Service (CAS) Registry Number, and the Unique Ingredient Identifier (UNII). The UNII is a non-proprietary, free, unambiguous, non-semantic, alphanumeric identifier linked to a substance's molecular structure or descriptive information by the Substance Registration System (SRS) of the U.S. Food and Drug Administration (FDA) and USP.

Examples of single-chemical entity monograph titles include **N-Acetylglucosamine**, **Glutathione**, **Lycopene**, **Melatonin**, **Quercetin**, and **Rutin**.



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### *Titles for Vitamin and Mineral Monographs*

**Ascorbic Acid, Cholecalciferol, Cyanocobalamin, and Ergocalciferol** are examples of single-chemical entity vitamin monographs where the title uses an established drug nonproprietary name<sup>6</sup> as per the *Nomenclature Guidelines* (1), and not “Vitamin C,” “Vitamin D<sub>3</sub>,” “Vitamin B<sub>12</sub>,” and “Vitamin D<sub>2</sub>,” respectively.

The **Vitamin A** monograph is a more complex example where the article must possess NLT 95.0% of the vitamin A activity declared on the label, but it may consist of retinol or esters of retinol formed from edible fatty acids, principally acetic and palmitic acids. Similarly, the **Vitamin E** monograph includes alpha-tocopherol and its alpha-tocopheryl acetate or alpha-tocopheryl acid succinate derivatives, and it may be the *RRR*- (previously referred to as *d*-) isomer or the all-racemic (*d,l*-) form. Other tocopherols and tocotrienols are not included in the **Vitamin E Definition**—a potential separate monograph could cover mixed tocopherols and tocotrienols.

The source of the vitamin may be included, where relevant. For example, there are specific quality requirements established in the monograph for ***Bacillus subtilis* subsp. subtilis Menaquinone-7 Extract**, which is a complex supercritical carbon dioxide extract consisting of a brown oil, consisting mainly of fat (> 97%), that contains NLT 1.5% and NMT 5.0% of menaquinone-7, and NLT 0.014% and NMT 0.15% of menaquinone-6.

Most mineral DS ingredients are single-chemical entity articles of high purity, e.g., **Calcium Ascorbate, Chromium Picolinate, and Magnesium Citrate**. Some monographs describe more complex articles. For example, the main constituent described in the **Ground Limestone** monograph is calcium carbonate (NLT 94.0% and NMT 100.5% CaCO<sub>3</sub>). This main constituent is accompanied by trace minerals such as magnesium and alkali salts and fluoride.

### *Titles for Carbohydrate Monographs*

The titles of monographs for carbohydrates use an established name. This name may be a drug nonproprietary name, e.g., **Acacia, Agar, Alginate Acid, or Inulin**. Otherwise, a name that is common in commerce is used, e.g., **Guar Gum, “Gum Ghatti,” Locust Bean Gum, Pectin, or Tragacanth**. The *Definition* provides a CAS Registry Number, if

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<sup>6</sup> Types of nonproprietary drug names include: USAN – United States Adopted Name, INN – International Nonproprietary Name, BAN – British Approved Name, and JAN – Japanese Accepted Name.  
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available, for greater clarity. An example is 9002-18-0 for Agar, which suffices given that the complexity of polysaccharides generally makes providing a systematic chemical name following the International Union of Pure and Applied Chemistry (IUPAC) rules impractical as well as unnecessary.

### *Titles for Protein Monographs*

The titles of monographs for proteins use an established name, which may be a drug nonproprietary name if available or a name that is common in commerce. For example, the **Lactase** monograph uses the official USP drug substance name in the title and then provides more specificity in the *Definition*, i.e.,  $\beta$ -D-galactoside galactohydrolase. “**Soy Protein Isolate**” would be an example of a potential monograph title name based on a name established in commerce. In some but not all cases, a CAS Registry Number is available and is provided in the monograph text for greater clarity, e.g., “**Gluten**,” CAS RN 8002-80-0. The IUPAC systematic chemical name is not practical in most cases due to its length and complexity.

### *Stereochemistry in Monograph Titles*

With regard to stereochemistry, per the United States Adopted Name (USAN) system the monograph titles for amino acids assume the L- isomer, e.g., **Alanine**. The chemistry section specifies L-alanine (the “L” written in small caps font). Amino acid derivative monograph titles also follow USAN where available, e.g., **Glutathione**, which provides the stereochemistry within the chemistry section: *N-(N-L- $\gamma$ -Glutamyl-L-cysteinyl)glycine*. Title names may be stereo-specific, e.g., **S-Adenosyl-L-methionine Disulfate Tosylate**, **L-Alanyl-L-glutamine**, **Glycyl-L-glutamine**, **Glycyl-L-tyrosine**, and **5-Hydroxy-L-tryptophan**. Certain amino acid derivatives have stereochemistry built into the USAN name, e.g., **Levocarnitine** instead of L-carnitine. As with amino acid derivatives, a USAN name for articles in other chemical classes may specify the isomer in the monograph title, e.g., **Calcium L-5-Methyltetrahydrofolate**; **Dexpanthenol**, which is an alcoholic analog of D-pantothenic acid; and **meso-Zeaxanthin**, for which the *Definition* specifies that the article consists chiefly of the 3*R*,3'*S* *meso* isomer of zeaxanthin.



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### Titles for Monographs of DS Manufacturing Intermediates

In DS monograph titles, the term “preparation” will be used to describe premixes of articles, in some cases with excipients, which are intended to be incorporated into a finished dosage form. These are not articles that are already in a finished dosage form.

This use of the term “premix” should be distinguished from uses in allied fields. For example, USP <1152> *Animal Drugs for Use in Animal Feeds* notes that “Animal drugs approved for further manufacture into medicated animal feeds may be in either dry or liquid form. They are sometimes referred to as premixes. The term ‘premix’ is no longer used for animal drugs for use in animal feeds but is still used in some older drug monographs. Animal drugs in feeds are regulated as Type A medicated articles and Type B and Type C medicated feeds.” The term “premix” does not appear in any USP monograph titles.

In the DS industry, some of the ingredients used for manufacturing DSs are preparations containing active substances and excipients. These mixtures are intended to increase uniformity in the dosage forms prepared with them. This may be necessary in several situations: 1) where ingredients are included in minute (e.g., microgram) quantities, 2) to help increase dispersibility of lipophilic substances in water for better dissolution profiles, or 3) to increase the stability of some substances that are known to interact with other ingredients and thus require protection.

The term “Preparation” appears in the titles of DS monographs for mixtures of one or more dietary ingredients with suitable excipients. These articles are used as manufacturing intermediates (premixes) rather than finished products. The first example occurred when the vitamin E family of monographs was created. It became necessary to distinguish pure vitamin E substances from different articles containing vitamin E forms such as the acetate or the succinate that were used as ingredients for the Vitamin E capsules. Following the recommendation of the American Pharmacists Association, the term “Preparation” was introduced to accomplish this purpose.

Subsequently, use of the term “Preparation” was extended to botanical ingredients. It has been applied to nine current DS monograph titles to distinguish ingredients from more complex articles incorporating that ingredient. However, these extended uses of this term were not consistent with the original intention that a “Preparation” is a premix. For example, the current DS monograph **Cranberry Liquid Preparation** (Guideline title: “**Cranberry Fruit Juice**”) specifies cranberry juice and no added substances, so the term “Preparation” in the title is not necessary. Many current DS monographs that do not contain the word “Preparation” in the title include provisions in the *Definition* section that allow for the addition of “suitable added substances” (such as excipients,

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e.g., **Powdered Andrographis Extract**, Guideline title: “**Andrographis Stem and Leaf Dry Extract**”). Some DS monographs allow for the addition of “suitable antioxidants” (e.g., ***Cryptocodinium cohnii* Oil**).

The term “Preparation” in future DS monograph titles will be consistent with the intent of identifying a premix, as it continues to be used in monograph titles for vitamins and carotenoids. For example, **Dexpanthenol Preparation** contains NLT 94.5% and NMT 98.5% of dexpanthenol, and NLT 2.7% and NMT 4.2% of pantolactone as ingredients. In this case, there are no separate **Dexpanthenol** or **Pantolactone** monographs.

**Vitamin A Oral Liquid Preparation** consists of an emulsion, suspension, or solution that contains either retinyl acetate or retinyl palmitate in an amount equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of vitamin A as retinol. In contrast, the **Vitamin A** monograph defines the article as a suitable form of retinol (retinol itself or esters of retinol formed from edible fatty acids, principally acetic and palmitic acids) that may be diluted with edible oils; incorporated in solid, edible carriers, or excipients; and it may contain suitable antimicrobial agents, dispersants, and antioxidants. The tolerance limit is set to vitamin A activity equivalent to NLT 95.0% of that declared on the label.

**Vitamin E Preparation** combines a single form of vitamin E (*d*- or *dl*-alpha tocopherol or their acetate or succinate esters) with one or more inert substances in a liquid or solid form. It contains NLT 95.0% and NMT 120.0% of the labeled amount of vitamin E. In contrast, in the **Vitamin E** DS monograph, the article is one of the above forms of vitamin E that contains NLT 96.0% and NMT 102.0% of that form of vitamin E. Thus, there are specific and narrow quantitative tolerances for the purity of the ingredient set out in the **Vitamin E** monograph compared to broader tolerances for the labeled amount in the **Vitamin E Preparation** monograph.

Similarly, **Menaquinone-7 Preparation**, **Beta Carotene Preparation**, **Lutein Preparation**, **Lycopene Preparation**, and **meso-Zeaxanthin Preparation** DS monographs describe a combination of the ingredient with one or more inert substances and/or antioxidants. The “Preparation” monographs specify tolerance limits for the labeled amount of DS ingredients, while the related but separate DS ingredient monographs describe the article as a substance with tolerance limits for the content of that ingredient.

With regard to international pharmacopoeial harmonization, note that USP’s use of the term “Preparation” for DS monographs is different from how the term is used in some other pharmacopoeias. For example, the *European Pharmacopoeia* defines “herbal drug preparations” as “homogeneous products obtained by subjecting herbal drugs to treatments such as extraction, distillation, expression, fractionation, purification,

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concentration, or fermentation. Herbal drug preparations include, for example, extracts, essential oils, expressed juices, processed exudates, and herbal drugs that have been subjected to size reduction for specific applications, for example herbal drugs cut for herbal teas or powdered for encapsulation.” The *European Pharmacopoeia* defines “pharmaceutical preparations” as “medicinal products generally consisting of active substances that may be combined with excipients, formulated into a dosage form suitable for the intended use, where necessary after reconstitution, presented in a suitable and appropriately labelled container.”

### TITLES FOR DIETARY SUPPLEMENT MONOGRAPHS

Dietary supplements are finished dosage forms for the oral route of administration only, manufactured to include dietary ingredients. Most commonly, DS dosage forms include tablets, capsules, liquid extracts (e.g., fluidextracts and tinctures), juices, syrups, teas for infusion, and powders to be reconstituted for ingestion or sprinkled on food. DS dosage form nomenclature typically follows the same rules as those for drug products (see the *Nomenclature Guidelines (1)* and General Chapter <1151> *Pharmaceutical Dosage Forms*).

Some examples are provided below (note that some examples are hypothetical and are provided only to illustrate how titles should be derived). For the sake of clarity, the terms: **[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}]** **[{BOTANICAL MATERIAL(S)} {FRESH}]** **[{TYPE} {DRY EXTRACT} OR {SOFT EXTRACT} OR {OLEORESIN} OR {LIQUID EXTRACT} OR {JUICE} OR {DRY JUICE} AND/OR {CONSTITUENT OR CLASS OF COMPOUNDS}]** used above to describe botanical materials (or animal materials) and the processed form will be simplified to **[DIETARY INGREDIENT]**, which incorporates all of the above terms.

The general form is as follows: **[DIETARY INGREDIENT] {RELEASE CHARACTERISTIC} [DOSAGE FORM]**

#### *Capsules:*

**American Ginseng Capsules (“American Ginseng Root Powder Capsules”), Cod Liver Oil Capsules, Fish Oil Containing Omega-3 Acids Delayed-Release Capsules (“Fish Oil Omega-3 Acids Delayed-Release Capsules”), Krill Oil Delayed-Release Capsules, Milk Thistle Capsules (“Milk Thistle Fruit Dry Extract Capsules”)**

#### *Lozenges:*

**Calcium Carbonate Lozenges, Zinc and Vitamin C Lozenges**



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### *Tablets:*

**Black Cohosh Tablets (“Black Cohosh Rhizome and Root Fluidextract Tablets”), Cat’s Claw Tablets (“Cat’s Claw Stem Bark Dry Extract Tablets”), Chondroitin Sulfate Sodium Tablets, Glucosamine Tablets, “Gymnema Leaf Dry Extract Tablets,” Methylsulfonylmethane Tablets, Niacin Extended-Release Tablets**

### *Oral emulsions:*

**Castor Oil Emulsion**

### *Oral solutions:*

**Ascorbic Acid Oral Solution, Cholecalciferol Solution, Oil-Soluble Vitamins with Minerals Oral Solution, Water-Soluble Vitamins with Minerals Oral Solution, Oil- and Water-Soluble Vitamins with Minerals Oral Solution, Zinc Acetate Oral Solution**

### *Oral suspensions:*

**Calcium Carbonate Oral Suspension**

### *Powders for oral suspension:*

**Psyllium Hydrophilic Mucilloid for Oral Suspension**

## DRUG VERSUS DIETARY SUPPLEMENT NAMES FOR ARTICLES

In the United States, drugs and DSs conform to different standards and require different testing procedures for identity, purity, strength, and composition. Occasionally, the same substance is used in a drug and in a DS. When used in a drug, the substance is given a USAN name or International Nonproprietary Name (INN), but when the same substance is used in a DS, it may be referred to by a different scientific name, SCN, or another common name. Because the articles (drug vs. DS) may have to meet different standards, the use of different names may be important. *Table 9* provides some examples of such multiple names.

**Table 9. USAN Names vs. DS Names**

<b>USAN Name</b>	<b>DS Name</b>
Ademetionine	<b>S-Adenosyl-L-methionine</b>
Ubidecarenone	<b>Coenzyme Q<sub>10</sub></b>



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USAN Name	DS Name
Sinecatechins (topical drug)	<b>“Green Tea Leaf Catechins Extract”</b>

The number of cases in which a product that has a USAN as a drug ingredient is also a DS ingredient is limited by the regulations governing DSs. For example, the plant with the *HoC2* SCN “dragon’s blood croton” (*Croton lechleri* Müll.Arg., Family *Euphorbiaceae*) is the source of a red latex article with the USAN name Crofelemer (trade name Fulyzaq), which has been approved in the U.S. as a prescription botanical drug for the treatment of diarrhea associated with anti-HIV drugs. According to the FDA’s *Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues (12)*, an ingredient that has been approved as a new drug or licensed as a biologic can be a dietary ingredient for use in a DS if, and only if, prior to such approval or licensing the ingredient was marketed as a DS or as a food. Conversely, an article that has been authorized for investigation as a new drug or as a biologic before being marketed as a food or as a DS cannot be marketed as a DS if substantial clinical investigations of the article have begun and the existence of such investigations has been made public.

Nevertheless, there are many botanicals with a long history of use as both DSs and as over-the-counter or prescription drug ingredients, which may also lead to differences in names. For example, “elm bark” is the name for the demulcent ingredient from the plant *Ulmus rubra* Muhl. (Family *Ulmaceae*) in the FDA’s Oral Health Care drug products monograph (13), while the current DS monograph title is **Elm** and the Guideline title based on the SCN is **“Slippery Elm Inner Bark.”**

### GLOSSARY

This glossary 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. Readers are also encouraged to consult *USP* General Chapters <563> *Identification of Articles of Botanical Origin* and <565> *Botanical Extracts* for additional information on DS terminology. Dosage form terminology standards are set out in the *Nomenclature Guidelines (1)* and General Chapter <1151> *Pharmaceutical Dosage Forms*.

**Aqueous extract:** An article prepared by extracting materials with water.



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**Aromatic:** An aromatic botanical article is created by the addition of essential oils to the extract (e.g., **Aromatic Cascara Fluidextract**, Guideline title: “**Cascara Sagrada Bark Aromatic Fluidextract**”) or other type of article (e.g., **Aromatic Castor Oil**, Guideline title: “**Castor Seed Aromatic Oil**”) as flavoring agents, so the DS monograph title follows the Guideline format with the addition of the adjective **Aromatic**.

**Aromatic oil water:** A clear, saturated, aqueous solution of essential oils or other aromatic or volatile substances. For example, **Peppermint Water** (“**Peppermint Leaf Oil Water**”) is prepared as a clear, saturated solution of **Peppermint Oil** (“**Peppermint Leaf Oil**”) in **Purified Water**.

**Concentrate:** A liquid article derived from a starting material also in liquid state after a process of partial removal of the liquid vehicle, resulting in a higher concentration of some of the constituents compared to the original material. The article has not been taken to dryness and redissolved. This applies to animal articles (e.g., Fish Oil Omega-3 Acids Ethyl Esters Concentrate) as well as plant articles (e.g., Aloe Juice Concentrate). USP General Chapter <1151> *Pharmaceutical Dosage Forms* states that, “In veterinary medicine, a powder that needs to be reconstituted prior to administration has been called a concentrate (e.g., drug products administered via drinking water). Such use of the term ‘concentrate’ is no longer preferred.” The Glossary to <1151> provides the following definition: “Concentrate (not a preferred term for human or veterinary drug products): The current use is for drug substances that are not intended for direct administration to humans or animals. The use in drug product nomenclature is being phased out.”

**Dry extract:** Solid articles obtained by evaporation of the solvent used in their production. Excipients such as carriers or flow agents may be needed in some cases to prepare a dry extract.

**Dry juice:** Dry material obtained by, for example, freeze-drying or spray drying plant juice into a 100% juice solids form or diluted with use of excipients such as carriers or flow agents.

**Essential oil:** Natural aromatic complex mixtures of compounds (there may be 200 or more in one essential oil) belonging mainly to two chemical classes: 1) terpenoids (e.g., monoterpenoid ketones, alcohols, hydrocarbons, and esters such as carvone, menthol,  $\alpha$ -pinene, and thymol acetate; sesquiterpenoids such as  $\alpha$ -bisabolol and caryophyllene; and less commonly, diterpenoids such as phyllocladene and (+)-kaurene); and 2) phenylpropanoids (e.g., anethole, cinnamaldehyde, coniferyl alcohol). However, there may also be other volatile compounds such as phenols (e.g., methyl salicylate or vanillin), non-terpene alcohols, non-terpene alkanes, alkenes, alkynes, spiro-ethers,

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coumarin, sulfur-containing compounds such as allyl isothiocyanate in mustard oil, or aldehydes such as benzaldehyde in bitter almond essential oil. They are liquid at room temperature and generally immiscible in water but are soluble in alcohol or other organic solvents, so they act like oils. They are called “essential” because they represent the “essence” of the plant in terms of fragrance. Since they evaporate when exposed to the air at room temperature, they are also called volatile oils or ethereal oils. They may be present in the leaf, seed, bark, stem, root, flower, and other plant parts, and may be obtained by steam distillation, extraction using various solvents, or other techniques.

**Extract:** An article with liquid, solid, or semisolid consistency in which the constituents of interest are completely or partially separated from other components with the aid of water, alcohol, alcohol-water mixtures, or other suitable solvents. This extraction process involves the removal of the desired constituents from the plant matter with suitable menstrua, the evaporation of all or nearly all of the solvent, and the adjustment of the residual fluids, masses, or powders to the prescribed standards. Suitable inert substances may be added as carriers or diluents to improve physical characteristics. Suitable antimicrobials and other preservatives may be added to preserve the integrity. Extracts may be subjected to processes that increase the content of characterized constituents, decrease the content of unwanted constituents, or both. Extracts with no added inert substances and no processing beyond the extraction are called native extracts. In some articles, the plant matter may be pretreated by inactivation of enzymes and microbial contaminants, grinding, defatting, or a similar procedure. Types of extracts are *Dry extract*, *Soft extract*, and *Liquid extract*; each is defined in this *Glossary*.

**Fluidextract:** A type of *Liquid extract* of plant matter, containing ethanol as a solvent or as a preservative, or both, made such that each 1 mL contains the extracted constituents of 1 g of the crude dry material that it represents, unless otherwise specified (e.g., 1:2) in the individual monograph.

**Fraction:** Extracts subjected to additional processing to produce an article that may consist of one or more specific classes of compounds. Single chemical class examples include sennosides from Senna, oligomeric proanthocyanidins from Grape Seed, and triterpenes from Gotu Kola (*Centella asiatica*), while multiple classes are included in “**Saw Palmetto Fruit Lipophilic Soft Extract**,” which contains a combination of fractions of fatty acids, sterols, and long-chain alcohols.

**Granules:** As defined in General Chapter <1151>, granules are solid dosage forms that are composed of agglomerations of smaller particles. These multicomponent compositions are prepared for oral administration and are used to facilitate flexible

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dosing regimens as granules or as suspensions, address stability challenges, allow taste masking, or facilitate flexibility in administration (for instance, to pediatric or geriatric patients). A marketed product example would be encapsulated granules of pancreatin. Note that some DS raw materials may also be in the form of granules.

**Gum:** A water-soluble carbohydrate derivative in the form of a hydrocolloid comprised of an anionic or nonionic polysaccharide or salts of polysaccharides. Some, such as tragacanth, acacia (also known as gum arabic), karaya (sterculia gum, a common adulterant of tragacanth), and gum ghatti are exudate gums obtained by tapping (wounding) the plant, while guar gum and locust bean (carob) gum are extractive gums obtained from seeds, and xanthan gum is obtained by bacterial fermentation of glucose, sucrose, or lactose.

**Latin binomial:** A system of nomenclature for animals, plants, and other life forms (developed by Linnaeus) that assigns a two-part Latinized name, the generic and specific epithets, to each species, such as *Urtica dioica* and *Urtica urens* for the two species of Stinging Nettle that are included in the current **Stinging Nettle** monograph. Following the new system (Guideline) for monograph titles, it would be named "**Urtica Species Root and Rhizome**," since the two species have different SCNs in *HoC2*.

**Latin binomial authority:** The author of the Latin binomial, i.e., the individual(s) who first named or later revised the name of the plant and validly published that binomial. The author information immediately follows the specific epithet, e.g., *Arthrospira platensis* (Nordstedt) Gomont, *Arthrospira maxima* Setchell & Gardner, and *Arthrospira fusiformis* (Voronichin) J. Komarek & J.W.G. Lund, the three species included in the **Spirulina ("Spirulina Species")** monograph.

**Liquid extract:** Liquid articles prepared from plant matter containing ethanol, water, vinegar, vegetable oil, or glycerin (or a mixture, e.g., aqueous ethanol) as a solvent or vehicle. The term liquid indicates a material that is pourable and conforms to its container at room temperature.

**Native extract:** An extract that contains only those constituents that are native to the botanical material from which the extract was made, with no added inert substances and no processing beyond the extraction and solvent removal.

**Oleo-gum-resin:** A naturally occurring exudate obtained by incision or by spontaneous exudation, e.g., myrrh, frankincense, and guggul. The term "oleo-gum-resin" reflects their complex composition.



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**Plant processed forms:** Plant material that has been subjected to processing, e.g., comminution to a powder. Examples of processed plant forms include powders, juices, extracts, and fractions, but not isolated pure compounds.

**Preparation:** A premix of one or more articles, in some cases with excipients, intended to be incorporated into a finished dosage form; these are not articles that are already in a finished dosage form.

**Resin:** An amorphous, complex mixture of resin acids, resin alcohols, resinotannols, esters, and resins, usually hard and transparent or translucent at room temperature and insoluble in water, e.g., rosin, guaiac, and mastic.

**Soft extract:** Soft extracts are articles with consistencies in between those of liquid extracts and those of dry extracts. Soft extracts are obtained by partial evaporation of the solvent (e.g., alcohol, or hydroalcoholic mixture) used for extraction. Soft, thickly viscous extracts can also be produced by supercritical carbon dioxide extraction.

**Spirit:** A spirit is created by the addition of alcohol to essential oils or other aromatic substances. For example, **Peppermint Oil Spirit** is a *USP* article created by adding ethanol to peppermint leaf oil and the alcohol extract produced from peppermint leaf powder that was macerated in water, strongly expressed, then macerated in alcohol and filtered. **Compound Orange Spirit** is an *NF* article prepared by adding alcohol to a combination (compounding) of orange oil, lemon oil, coriander oil, and anise oil.

**Camphor Spirit** is a *USP* article consisting of alcohol added to the monoterpenoid substance camphor. **Aromatic Ammonia Spirit** is a *USP* article for which alcohol is added to ammonia and ammonium carbonate.

**Tincture:** Tinctures are liquid articles usually prepared by extracting plant materials with alcohol or hydroalcoholic mixtures by maceration or percolation. Traditionally, tinctures of potent articles of botanical origin represent the activity of 1 g of the plant material in each 10 mL of tincture, but tinctures with other ratios (e.g., 1:5) are also prepared.

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This *Guideline* supersedes any previous guideline issued by USP on assigning titles to dietary supplement monographs.

### Summary of Changes for this Revision

SUMMARY OF CHANGES	RATIONALE FOR CHANGE
<b>G01.17-01</b>	
Clarified how family is represented in the monograph Definition to set a standard of spelling it out and writing the family name in Italics	Currently in the Description monographs family is written in different styles, some spell it while others abbreviate.
Included examples for the following ingredients: carbohydrates, protein, amino acids, cranberry derived ingredients	These examples were missing in previous version
Clarified how to name specialized extract e.g. Broccoli Seed Glucoraphanin Extract and other extracts processed to increase specific constituents	These were not well articulated in the previous version
Note the update to the 2018 International Code of Nomenclature for algae, fungi, and plants available here: <a href="https://doi.org/10.12705/Code.2018">https://doi.org/10.12705/Code.2018</a>	To include a 2018 update on the International Code of Nomenclature which, for example now allow the use of alternative family names for 8 plant families, some classical names in use even prior to 1753.
Defines how to use concentrate and preparation	To clarify how/when these terms can be used in monograph titles