New Online Dietary Supplements Compendium Coming Soon!

**Dietary Supplements Compendium 2019 Edition**

To align with user needs and expectations, the Dietary Supplements Compendium (DSC) 2019 Edition will be an online platform, similar to the USP-NF Online. The redesigned, intuitive interface will give users access to the most comprehensive collection of quality standards for dietary supplements. Click here for more details.

The new edition of the DSC will be available summer of 2019. Please check back and sign up for the latest information about upcoming enhancements and availability!

In addition to selected new and revised monographs and General Chapters from the USP-NF and Food Chemicals Codex issued over the last three years, the DSC 2019 will feature:

- 72 new monographs
- 24 additional General Chapters
- 59 new, updated and supplementary sets of High-Performance Thin-Layer Chromatographic (HPLC) data for the botanical monographs in full color and high resolution.
- 24 new and 45 revised Admission Evaluations documents
- 21 new and 12 revised sets of data in support of the dietary supplement monographs with dozens of new chromatograms and color photomicrographs
- A new edition of the USP Dietary Supplements Verification Program (DSVP) manual
- Revised and updated dietary intake comparison tables
- New and updated guidance documents contributed by dietary supplements industry associations
- An extensive collection of FDA documents relevant to the dietary supplements industry

**USP Dietary Supplements Verification Program on “CBS This Morning”!**

On February 22, 2019, USP was highlighted by Dr. David Agnus in a segment on **CBS This Morning**.

Dr. Agnus, discussed supplement regulation and recommended consumers look for the USP Verified mark to ensure they are getting a quality supplement. View the full segment and learn why the USP Verified Mark is important to health.

Americans spent more than $40 billion on supplements last year, and three out of four Americans regularly take a supplement. The FDA plans to strengthen its oversight of the dietary supplement market. This is an important development and USP is a leading change agent to help ensure quality supplements.

For more information, visit [www.USPverified.org](http://www.USPverified.org).

**Upcoming Events and Meetings**

**Products and Services**

**New Dietary Supplements Reference Standards**

Below is a list of newly released reference standards.

**Herbal Medicines/ Botanical Dietary Supplements**

- Negundoside
- Vitex negundo Leaf Dry Extract
- Baicalein
- Baicalein 7-O-Glucuronide
- Scutellaria Baicalensis Root Dry Extract

**Non-Botanicals**

- Docosahexaenoic Acid
- Eicosapentaenoic Acid
- Omega-3 Free Fatty Acids
- L-alpha-Glycerophosphorylethanolamine
- L-alpha-Glycerylphosphorylcholine
- beta-Glycerylphosphorylcholine

**Monographs**

**Standards Open for Public Comment until May 31, 2019**

The standards below were published in PF 45(2) for public comments on March 1, 2019 and will receive and consider feedback until May 31, 2019. To comment, please visit: [USP-NF Pharmacopeial Forum](http://www.uspnf.org)

**New Monographs/General Chapters**

- Citicoline
- Oil- and water-soluble vitamins with minerals Chewable Gels

**Revised Monographs/General Chapters**

- Saw Palmetto Capsules
- Saw Palmetto Extract
- Lactase
Let your voice be heard!

Please join us on May 15 for the Dietary Supplements Stakeholder Forum on-site or online. This is a free event and USP encourages manufacturers, organizations, service providers, and other interested parties who work with dietary supplements to attend, share perspectives and provide direct feedback on priority standards issues. Stakeholder topics submitted so far include hemp, pesticide residues, food allergens and label content claims. Click here to view agenda and for more details. Register Today!

Past Events

Botanical, Non-Botanical and Joint Dietary Supplements Expert Committee Annual Meetings
March 26-28, 2019 | Rockville, MD

The Botanical Dietary Supplements and Herbal Medicines Expert Committee (BDSHM EC) and Non-Botanical Dietary Supplements Expert Committee (NBDS EC) had their annual joint face-to-face meetings at USP's Rockville site this past March. In their separate meetings, the ECs received updates from their Expert Panels and Subcommittees, reviewed upcoming ballot items for USP43-NF38, and received updates on other ongoing projects.

In their joint meeting, they received updates from Joint Subcommittees, discussed topics of mutual interest, and received updates from USP staff. The Chair and Vice Chair from the Food Ingredients Expert Committee also attended and led discussions on ongoing and potential collaborative activities between the Foods and Dietary Supplements groups. Executive Summaries from these meetings are scheduled to be posted to the EC's respective work plan pages on USP.org by mid-May:

- Expert Committee Work Plan for Botanical Dietary Supplements,
- Expert Committee Work Plan for Non-Botanical Dietary Supplements.

Natural Products Expo West
March 5 – 9, 2019 | Anaheim California

About 86,000 natural ingredient and product suppliers descended upon the Anaheim Convention Center in March for Natural Products Expo West. Products that were of particular interest at the show included Hemp/CBD and probiotics. Discussions about potential changes to DSHEA, the regulatory/legal status of CBD-containing products, the definition of non-GMO, and synthetic biology were held during the scientific sessions. USP experts met with attendees and responded to questions about monographs, sponsoring monographs, dietary ingredient and dietary supplement verification programs and GMP audits.

Be Part of the Standards Development Process!

Help shape standards specifications and test methods by sponsoring monographs or general chapters and their supporting Reference Standards. USP doesn't charge fees to develop monographs – all you need is a willingness to collaborate with us to help safeguard the supply chain for supplements and ingredients. USP standards for dietary ingredients and dietary supplements are a resource for public specifications and scientifically valid methods that can help in GMP compliance and in safeguarding the supply chain for supplements and ingredients. USP is seeking donations for the following monographs:

Non-Botanical Dietary Supplement Ingredients:
- Undenatured Collagen Type II
- Gluconolactone
- Gamma amino butyric acid (GABA)
- Keratin
- Bifidobacterium Infantis
- Lactobacillus plantarum 299v
- Lutein esters
- L-Ornithine
- Pantethine

Reference Standards Coming Soon:

Botanicals
- Bitter Orange Fruit Flavonoid Dry Extract
- Coptis chinensis Rhizome Dry Extract
- Coptisine Chloride
- Epicatechin
- Guarana Seed Dry Extract
- Procyanidin B2

Non-Botanicals
- Annatto Seed Tocotrienols Extract
- beta-Glycerylphosphorylcholine
- Hydroxocobalamin Chloride

Standards Open for Public Comment until September 31, 2019

The standards below will be published in PF 45(4) for public comment on July 1, 2019 and will receive and consider feedback until September 31, 2019. To comment, please visit: USP-NF Pharmacopeial Forum

New Monographs/General Chapters
- Calcium Magnesium Citrate
- D-chiro-Inositol
- Fish Oil Omega-3 Acid Ethyl Esters Concentrate
- Pummelo Peel
- Pummelo Peel Powder
- Pummelo Peel Flavonoids Dry Extract

Revised Monographs/General Chapters
- Asian Ginseng Root and Rhizome
- Asian Ginseng Root and Rhizome Powder
- Asian Ginseng Root and Rhizome Dry Extract
- American Ginseng Root and Rhizome
- American Ginseng Root and Rhizome Powder
- American Ginseng Root and Rhizome Dry Extract

New Monographs under Development

Botanicals
- Ajowan Fruit
- Ajowan Fruit Powder
- Ajowan Fruit Dry Extract
- Broccoli Seed Dry Extract
- Cranberry Fruit Juice Dry Extract
Non-Botanical Dosage Forms (Finished Dietary Supplements):

- Cyanocobalamin capsules
- Glucosamine, Chondroitin Sulfate Sodium capsules
- Magnesium Citrate capsules
- Menaquinone 4 tablets or capsules
- Methylcobalamin orally disintegrating tablets
- Omega-3-Triglyceride chewable gels (gummies)
- Plant Sterol tablets
- S-Adenosyl-L-Methionine Disulfate Tosylate tablets

For more information on how to donate and a complete list of requested monographs, please visit USP Dietary Supplements and Herbal Medicines Standards Development Process or contact DietarySciStaff@USP.org.

USP Admission Evaluations of Articles Prior to Monograph Development

Before a dietary ingredient is considered for the development of quality standards, it must undergo a USP Admission Evaluation, performed by the USP Dietary Supplements Admission Evaluations Joint Standard Setting Subcommittee (DSAE JS3). The DSAE JS3 reviews information related to the ingredient’s safety, relevance in the market, regulatory status, and presence in other pharmacopeias and whether the article poses a serious health risk when used as a dietary supplement.

If the article does not pose a serious health risk or poses a minor safety concern that can be mitigated by a label caution statement in the monograph, the article is placed in class A and is admitted for monograph development. If the article poses a serious health risk, it is placed in class B and is not admitted for monograph development.

The DSAE JS3 met via Webex on Tuesday, March 19th, 2019, to deliberate on Indian Barberry Stem, Coptis Species Rhizome and Terminalia chebula fruit. Comments on the safety of these ingredients are welcome.

For more information, please contact Hellen Oketch-Rabah, Ph.D., at HAO@usp.org or Emily Madden, Ph.D. at Emily.Madden@usp.org.

Nomenclature of Dietary Supplements

Updates from the Dietary Supplements and Herbal Medicines (DSHM) Nomenclature Subcommittee

DSHM Nom JSC met on February 26th, 2019 and recommended the following monograph titles for approval:

- Magnolia Species Bark
- Magnolia Species Bark Powder
- Moringa Leaf Dry Extract

DSHM Nom JSC is revising the Guideline for Assigning Titles to USP Dietary Supplement Monographs. To view the Guideline, click here: Guideline for Assigning Titles to USP Dietary Supplement Monographs. This process will continue for the next 6 months. Any comments on the guideline are welcome. For more information on dietary supplements nomenclature, please contact: Hellen Oketch-Rabah, Ph.D., at HAO@usp.org.

USP Answers Your Questions

Q. How are various Temperature and Storage conditions defined by USP?
A. Freezer: A place in which the temperature is controlled between −25° and −10° (−13° and 14° F). It is noted that, in some instances, articles may have a recommended storage condition between −20° (−4° F). In such cases, the temperature of the storage location should be controlled to ±10°.

Refrigerator: A cold place in which the temperature is controlled between 2° and 8° (36° and 46° F).

Cold: Any temperature not exceeding 8° (46° F).

Cool: Any temperature between 8° and 15° (46° and 59° F). [Note—An article for which storage in a cool place is directed may, alternatively, be stored and shipped as refrigerated, unless otherwise specified by the individual monograph.]

Room temperature (also referred to as Ambient temperature): The temperature prevailing in a working environment.

Controlled room temperature: The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°–25° (68°–77° F). The following conditions also apply:
• Mean kinetic temperature not to exceed 25°. Excursions between 15° and 30° (59° and 86° F) that are experienced in pharmacies, hospitals, and warehouses, and during shipping are allowed. Provided the mean kinetic temperature does not exceed 25°, transient spikes up to 40° are permitted if they do not exceed 24 h. Spikes above 40° may be permitted only if the manufacturer so instructs.
• Articles may be labeled for storage at “controlled room temperature” or at “20°–25°”, or other wording based on the same mean kinetic temperature [see also Good Storage and Distribution Practices for Drug Products (1079), Quality Management System, Environmental Management System, Mean Kinetic Temperature (MKT) Calculation].
• An article for which storage at Controlled room temperature is directed may, alternatively, be stored and shipped in a cool place or refrigerated, unless otherwise specified in the individual monograph or on the label.

Warm: Any temperature between 30° and 40° (86° and 104° F).

Excessive heat: Any temperature above 40° (104° F).

Dry place: A place that does not exceed 40% average relative humidity at 20° (68° F) or the equivalent water vapor pressure at other temperatures. The determination may be made by direct measurement at the place. Determination is based on NLT 12 equally spaced measurements that encompass either a season, a year, or, where recorded data demonstrate, the storage period of the article. There may be values of up to 45% relative humidity provided that the average value does not exceed 40% relative humidity. Storage in a Container validated to protect the article from moisture vapor, including storage in bulk, is considered a Dry place.

Protect from freezing: The Container label will bear an appropriate instruction to protect the article from freezing in cases where freezing exposes an article to loss of strength or potency or to destructive alteration of its characteristics. These risks are present in addition to the risk that the Container may break if exposed to freezing temperatures.

Protect from light: Where light subjects an article to loss of strength or potency or to destructive alteration of its characteristics, the Container label bears an appropriate instruction to protect the article from light. The article must be packaged in a light-resistant Container.

Non-Botanicals
• Calcium Magnesium Citrate
• Choline Citrate
• Conjugated Linoleic Acids–Triglycerides
• D-chiro-Inositol
• Pinitol
• Pyrroloquinoline quinone
• L-Ornithine Hydrochloride
• S-Adenosyl-L-Methionine
• 1,4-Butanedisulfonate

Isorhamnetin–3–O–Rutinoside
• Ligusticum chuanxiong Rhizome Powder
• Linarin
• Maca root
• Maca root extract
• Marmelosin
• Palmatine Chloride
• Pomegranate Fruit Dry Extract
• Procyanidin A2
• Punicalagin
• Senkyunolide A
• Rhoifolin
• Terminalia chebula Fruit Dry Extract
• Z-Ligustilide

Click here to Find a Reference Standard
To Suggest a Reference Standard, click here.