Upcoming Events

USP Open Forum Multi-Ingredient Dietary Supplement Products: Development of Quality Tests May 6, 2021 • 10:00am-12:00pm ET Virtual Meeting

USP Open Forum: Multi-Ingredient Dietary Supplement Products: Development of Quality Tests

May 6, 2021 | Virtual

Let your voice be heard! USP will be hosting a Multi-Ingredient Dietary Supplement Products -Development of Quality Tests Open Forum on Thursday, May 6, 2021 from 10-12 ET. Please join us for this virtual discussion to help contribute to the future of USP standards. Click here to <u>register</u> – it's free, and advance registration is required.

Many marketed dietary supplement products are not covered by existing monographs due to the broad diversity of possible dietary ingredient combinations. USP's proposed General Chapter <2800> Multi-ingredient Dietary Supplement Products - Development of Quality Tests is intended to provide guidance on the development of quality tests for assessing adherence to established specifications for multi-ingredient products. The Open Forum is being held by USP to discuss the proposed content of the chapter with stakeholders and learn what additional information might be useful to include in the chapter to improve the quality and relevance of the chapter before it is posted in *Pharmacopeial Forum* for public comment. Topics to be discussed at the Open Forum include, but are not limited to:

Development of Identification Tests

- Development of Strength (Assay) Procedures
- Impurities Testing Dosage Form Performance Testing
- The 6th International qNMR Summit (virtual)

Preliminary dates: October 5-7 2021 A definitive, broadly international event concerning every aspect of qNMR theory and practice, its

compendial and industrial implementation, and future development perspectives. Now, virtual and free! Registration details will be available shortly. Please keep an eye on the USP Events Calendar, qnmrsummit.com, or send an email to Anton Bzhelyansky (anb@usp.org) for further details. **Dietary Supplements Compendium Online**



most relevant public USP standards and auxiliary information from both the United States Pharmacopeia-National Formulary (USP-NF), and the Food Chemicals Codex (FCC), along with exclusive supplemental information, images and data. The second annual update to the USP Dietary Supplements Compendium (DSC) Online will be available this summer. New monographs, admission evaluation summaries, illustrations with

chromatograms, chemical structures and photomicrographs are being added to further enhance the user experience and improve understanding of compendial analysis. New illustrations include those for: Pyrroloquinolone Quinone (PQQ) Disodium Salt

- Terminalia chebula Fruit Bitter Orange Flavonoids Dry Extract
- D-chiro-Inositol, Citicoline Calcium Magnesium Citrate
- As always, we invite you to provide feedback and help us prioritize the work for upcoming DSC

Online editions. Please direct your comments to Anton Bzhelyansky (anb@usp.org). DSC Online continues to provide in-depth, comprehensive information for all phases of development and manufacturing of quality dietary supplements including quality control, quality assurance, and regulatory/compendial affairs. For more information or to order a DSC Online subscription for only \$150 per year, please

Publications in Peer-reviewed Journals

The Case of a Bisdesmosidic Triglycoside as Withania somnifera Aerial Parts Marker

Open Access

NMR-Based Quantum Mechanical Analysis Builds Trust and Orthogonality in Structural Analysis:

click here.

Sitaram Bhavaraju, David Taylor, Matthias Niemitz, David C. Lankin, Anton Bzhelyansky, Gabriel I. Giancaspro, Yang Liu, and Guido F. Pauli* Publication Date: February 24, 2021 View the publication in the *Journal of Natural Products* here.

Past Events

January 22, 2021



An Open Forum about Elderberry Standards Development was hosted by USP on January 22, 2021. More than 100 participants attended the virtual event, where they provided their input,

USP Elderberry Standards Development Forum

perspectives, and feedback about issues involving quality standards for Elderberry. Main topics discussed included: Adulteration concerns, taxonomy for different species, manufacturing processes, ingredient specifications and testing methodologies.

Pyrrolizidine alkaloids (PAs) are heterocyclic organic compounds

Testing carried out by stakeholders according to the current USP monograph reveals that the main concerns about adulteration are substitution with Black Rice extract, addition of synthetic dyes and species mislabeling. Stakeholders supported the development of new USP speciesspecific monographs for both European and American Elderberry for the different categories of ingredients. For more details about the outcomes of the event and next steps, please see the

Executive Summary. USP Open Forum: Pyrrolizidine Alkaloid Contaminants January 29, 2021

synthesized by a variety of plant species. Many PAs exhibit hepatotoxic, genotoxic, carcinogenic and mutagenic activities and are known to contaminate foods as well as herbal products and teas, thereby posing a serious threat to human health. An

Open Forum about Pyrrolizidine Alkaloid Contaminants was hosted by USP on January 29, 2021. This virtual event had more than 150 attendees, including stakeholders from industry, academia, and regulatory agencies such as the U.S. Food and Drug Administration. At the Open Forum, subject matter experts presented the latest information on PA contaminants in agricultural crops and foods. Main topics discussed included: Test methods, approach to reference standards, current regulations in different countries, dietary intake and health effects of PA exposure. USP sought input and feedback from attendees regarding the two General Chapters related to PA contaminants: <567> Analysis of Contaminant Pyrrolizidine Alkaloids (PAs) and <1567> Pyrrolizidine Alkaloids as Contaminants that are in development. For more details about the outcomes of the event and next steps, please see the **Executive Summary**. Society of Toxicology Annual Meeting, March 2021

USP participated in the Society of Toxicology Annual Meeting, presenting on USP Probiotic Quality Activities at a session entitled "Establishing Quality, Safety, and Regulatory Principles for

Probiotics: More Than Just a Gut Check." The talk centered on the difference between evaluating living micro-organisms rather than chemical entities from a toxicological point of view, covering challenges with identification, dose (enumeration) and the appropriate tests for evaluating safety since most standard toxicology tests are not relevant. **Be Part of the Standards Development Process!**

sponsoring monographs or General Chapters and their supporting Reference Standards. USP doesn't charge fees

Help shape standards specifications and test methods by

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:



Botanical Dietary Supplement Ingredients Acai Cuminum cyminum

Dandelion Root

- Hops Horehound
- Melissa officinalis Moringa Leaf Skullcap aerial parts
- Yarrow aerial parts **Non-Botanical Dietary Supplement Ingredients:**

Glucuronolactone Histidine Lactobacillus plantarum 299v

- Levocarnitine Tartrate Lutein esters
- L-Ornithine Lysine

Zeaxanthin preparation

 Pantethine Phosphatidylserine Salmon Oil (wild and farmed) Soy Protein

Non-Botanical Dosage Forms (Finished Dietary Supplements): Cyanocobalamin capsules Glucosamine, Chondroitin Sulfate Sodium capsules

- Magnesium Citrate capsules Menaquinone 4 tablets and capsules Pyrroloquinoline Quinone Disodium Capsules (or other dosage forms)
- Methylcobalamin orally disintegrating tablets • Omega-3-Triglyceride chewable gels (gummies) Plant Sterol tablets
- Plant Sterols and Stanols Ester Capsules S-Adenosyl-L-Methionine Disulfate Tosylate tablets (or other dosage forms) • S-Adenosyl-L-Methionine Disulfate 1,4-Butanedisulfonate tablets (or other dosage forms) • Omega-3-Acid Triglycerides with Vitamin D capsules
- 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 development of a quality standard for a dietary ingredient is considered, it must undergo

For more information on how to donate and a complete list of requested monographs, please

a USP Admission Evaluation, performed by the USP Dietary Supplements Admission Evaluations and Labeling Expert Committee (DSAEL EC). The DSAEL EC reviews information related to the ingredient's safety, relevance in the market, regulatory status, 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 DSAEL EC held a working meeting via WebEx on Wednesday, January 13, 2021. Members

deliberated on and admitted Feverfew Leaf Dry Extract for monograph development. The DSAEL

EC also met on Monday, April 12, 2021, to deliberate on Black Cumin Seed Oil, Siler Root, and

Palm Oil Tocotrienols and Tocopherols. All three were moved into Class A for monograph

For more information, please contact Hellen Oketch-Rabah, Ph.D., or Emily Madden, Ph.D., <u>DABT</u>. **Nomenclature of Dietary Supplements**

<u>Updates from the Dietary Supplements and Herbal Medicines (DSHM) Nomenclature Joint</u>

The DSHM Nomenclature Joint Subcommittee met on January 20, 2021 and recommended the following monograph titles to the USP Nomenclature and Labeling EC for approval:

Subcommittee (DSHM Nom JSC)

 American Elder Berry Powder • European Elder Berry Powder American Elder Berry Liquid Extract

- American Elder Berry Juice Concentrate European Elder Berry Juice Concentrate American Elder Berry Juice European Elder Berry Juice
- American Elder Berry Dry Juice European Elder Berry Dry Juice • Lactiplantibacillus plantarum (changed from Lactobacillus plantarum) • Ligilactobacillus salivarius (changed from Lactobacillus salivarius)
- Lacticaseibacillus casei (changed from Lactobacillus casei) • Lacicaseibacillus paracasei (changed from Lactobacillus paracasei; previously changed from Lactobacillus paracasei (LCP-37). • Japanese Sophora Flower Bud

Japanese Sophora Flower Bud Powder

American Elder Berry Liquid Extract

DSHM Nom JSC will be considering the following titles at future meetings. Any information on their nomenclature is welcome. Bromelain

 Bitter Orange Young Fruit Bitter Orange Immature Fruit

Pea Protein

development.

- Coptis chinensis Rhizome Granules for Oral Solution European Elder Berry Aqueous Dry Extract Phosphatidylserine Bergamot Orange Fruit Dry Extract
- Blood Orange Fruit Dry Extract Wild Salmon Oil Farmed Salmon Oil Red Yeast Rice Powder
- DSHM Nom JSC revised the Guideline for Assigning Titles to USP Dietary Supplement *Monographs* available <u>here</u>. For more information on dietary supplements nomenclature, please

contact Hellen Oketch-Rabah, Ph.D.

Products & Services

New Dietary Supplements Reference Standards

Herbal Medicines/ Botanical **Dietary Supplements**

- Paeoniflorin • Paeonia lactiflora Peeled
- Root Dry Extract • Jujuboside A
- Cullen corylifolium Fruit **Dry Extract** • <u>Egeline</u>
- Marmelosin
- Reference Standards in development: **Botanicals**
- Aegle marmelos Fruit Dry Extract
- Angelica sinensis Root Powder Azadirachta indica Seed
- Azadirachta indica Leaf Dry Extract • Broccoli Seed Dry Extract
- Black Cumin Seed Thymoguinone Oil
- Carvacrol • Chrysanthemum indicum
- Flower Dry Extract • Chrysanthemum x
- morifolium Flower Dry Extract
- Cranberry Fruit Juice Dry Extract
- 4-cymene • Ginger Rhizome Carbon
- Dioxide Soft Extract Glucoraphanin Isochlorogenic Acid A
- Ligusticum chuanxiong Rhizome Powder
- Linarin Pomegranate Fruit Dry
- Extract
- Procyanidin A2
- Punicalagin
- Senkyunolide A
- Z-Ligustilide Cimifugin • 5-O-Methylvisamminoside
- Saposhnikovia divaricate Root Dry Extract Dextrose
- Malic Acid Aloeverose Aloin B
- Non-Botanicals Choline Citrate

Hydroxocobalamin

Inositol Niacinate

- L-Ornithine Hydrochloride Lysine Tocopherols
- Palm Oil Tocotrienols and N-Acetylornithine <u>Monographs</u>

Standards Open for Public

Comment until May 31, 2021

The standards below were published in PF 47 (2) for public comment on March 1, 2021 and will accept public feedback until May 31, 2021. To comment,

New Monographs/General

<u>Chapters</u> Sichuan Lovage Rhizome Sichuan Lovage Rhizome

please visit Pharmacopeial Forum.

- Cranberry Fruit Dry Juice Lactobacillus acidophilus
- Revised Monographs/General <u>Chapters</u> Lactobacillus paracasei
- **Omissions**
- Lactobacillus acidophilus
- Lactobacillus acidophilus

Standards to be published in PF 47 (3) The standards below will be published in PF 47 (3) on May 1, 2021 and public feedback will be

accepted until July 31, 2021. To comment, please visit Pharmacopeial Forum New Monographs/General <u>Chapters</u>

- Dong Quai Root Dong Quai Root Powder Cranberry Fruit Juice Dry
- **Extract Capsules** Streptococcus thermophilus Ligilactobacillus salivarius
- Lactiplantibacillus plantarum Revised Monographs/General
- Omega-3 Acids Capsules Fish Oil Containing Omega-3 Acids Delayed-

Fish Oil Containing

<u>Chapters</u>

 Fish Oil Containing Omega-3 Acids Krill Oil Capsules

Release Capsules

- Krill Oil Delayed-Release Capsules Omega-3 Acids Triglycerides
- Fish Oil Omega-3 Acid Ethyl Esters Concentrate Krill Oil Omega-3 Free Fatty Acids
- Omega-3-Acid Ethyl Esters Calcium Ascorbate • Conjugated Linoleic Acid –
- Free Fatty Acids Dexpanthenol Preparation New Monographs Under
- **Development Botanicals**
- Bitter Orange Young Fruit Bitter Orange Young Fruit
- Black Cumin Seed Oil Thymoquinone Capsules Cinnamomum cassia Bark
- Cinnamomum cassia Bark Powder • Cinnamomum verum Bark
- Cinnamomum verum Bark • Coptis chinensis Rhizome
- Aqueous Dry Extract Elder Berry Juice (American and European) Elder Berry Juice
- Concentrate (American and European)
- Elder Berry Dry Juice (American and European) Elder Berry Liquid Extract
- (American and European) Elder Berry Aqueous Dry Extract (American and
- European) Elder Berry Fruit Powder
- (American and European) Feverfew Leaf Extract
- Gastrodia rhizome Gastrodia rhizome Powder
- Gastrodia rhizome Dry Extract Green Tea Leaf Dry
- Extract • Inula racemosa Root Inula racemosa Root
- Powder Inula racemosa Root Dry Extract
- Maca Root Powder Maca Root Gelatinized Powder Maca Root Extract
- Neem Leaf Neem Leaf Powder Neem Leaf Dry Extract Red Clover Tablets
- Red Yeast Dry Extract Red Yeast Rice Powder Non-Botanicals
- Apigenin Astaxanthin Biomass beta-Hydroxy-beta-
- Bacillus subtilis Bromelain • Calcium beta-hydroxybeta-methylbutyrate (Ca-

methylbutyric acid (HMB)

- HMB) GABA
- Hydrolyzed Collagen Hydrolyzed Keratin Inositol Niacinate
- Levocarnitine Tartrate Lutein Esters
- Lysine Mineral Ascorbates Mineral Bisglycinates
- Native Collagen Oil-soluble Vitamins Preparation Pea Protein
- Phosphatidylserine Phytosterol Esters Plant sterols
- Rice protein Salmon oil (farmed and
- Streptococcus thermophilus Soy Protein Zeaxanthin Preparation
- <u>Development</u> <582> Water-Soluble Vitamins Assay by Liquid Chromatography—Mass

New General Chapters Under

Spectrometry • <2800> Multi-ingredient Dietary Supplement

Products - Development of

Quality Tests <1567> Pyrrolizidine Alkaloids as Contaminants <567> Analysis of Contaminant Pyrrolizidine

Alkaloids

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