

our priorities in content and features implementation. What features would you like to see implemented? What would be on the top of your list of improvements? Please forward your Powder comments to Anton Bzhelyansky (anb@usp.org). DSC Online continues to provide in-depth, • Linarin comprehensive information for all phases of development and manufacturing of quality dietary supplements including quality control, quality assurance, and regulatory/compendial affairs. Marmelosin Some of the advantages of DSC Online include: Paeoniflorin Annual content updates to ensure access to the most current information Extract • Customizable alerts to notify you of changes to bookmarked documents • An intuitive interface to facilitate quick and easy navigation Procyanidin A2 A customizable workspace with bookmarks, alerts and a viewing history • Punicalagin · Convenient, anytime, anywhere access with common browsers Senkyunolide A In addition to selected new and revised monographs and General Chapters from the USP-*NF* and *Food Chemicals Codex* issued since the previous edition, the *DSC 2020* features: Extract Spinosin

 33 new General Chapters • 80 new dietary ingredient and dietary supplement monographs • 35 sets of supplementary information for botanical and nonbotanical DS, including chemical structures, chromatograms, and photomicrographs 45 new Admission Evaluation summaries • 59 updated botanical HPTLC plates • Revised and updated dietary intake comparison tables for use by nutritionists and Updated Dietary Supplement Verification Program manual • Links to the latest industry guidances and regulatory information

For more information or to order the 2019 online DSC please click here. **USP** in the News **Build Trust by Being a Quality Leader**

In case you missed it, read Ron Piervincenzi's article, Build Trust in Your Products and with

action urges us all to continue to work to ensure the public's trust in the quality of dietary

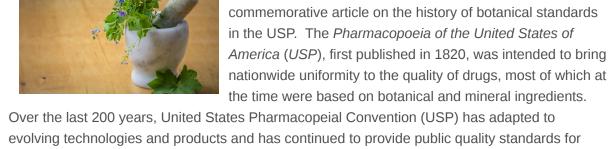
Consumers by Being a Quality Leader, published in Nutrition Industry Executive. This call to

Quality Standards for Botanicals-The Legacy of USP's 200 Years of Contributions. Josef Brinckmann, Robin Marles, Paul Schiff, Hellen Oketch-Rabah, Geeta Tirumalai, Gabriel Giancaspro, Nandakumara Sarma in *Herbalgram*, 126, 50-65, 2020

Publications in Peer-reviewed Journals

and feature article here.

As USP celebrates its 200 anniversary, USP Expert Committee members and USP staff published a commemorative article on the history of botanical standards in the USP. The Pharmacopoeia of the United States of



botanical, chemical, and biological medicines. This article examines the history of the evolution

of botanical quality standards, as well as the current status of botanical monographs for drugs,

in which the USP anticipates adapting to rapid changes in technologies. *Read <u>full article here</u>*

herbal medicines, dietary supplements, and excipients. It also provides an outlook for the future,

Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes. Sarma ND, Waye A, ElSohly MA, Brown PN, Elzinga S, Johnson HE, Marles RJ, Melanson JE, Russo E, Deyton L, Hudalla C, Vrdoljak GA, Wurzer JH, Khan IA, Kim NC, Giancaspro GI. J Nat Prod. 2020 Apr 24;83(4):1334-1351. There is an active and growing interest in cannabis (Cannabis sativa) female inflorescence for medical

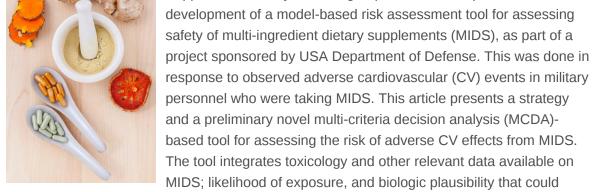
purposes. Defining its quality attributes can help mitigate

substandard, or adulterated products and support sound and

public health risks associated with contaminated,

reproducible basic and clinical research. As cannabis is a heterogeneous matrix that can contain a complex secondary metabolome with an uneven distribution of constituents, ensuring its quality requires appropriate sampling procedures and a suite of tests, analytical procedures, and acceptance criteria to define the identity, content of constituents (e.g., cannabinoids), and limits on contaminants. As an independent science-based public health organization, United States Pharmacopeia (USP) has formed a Cannabis Expert Panel, which has evaluated specifications necessary to define key cannabis quality attributes. Continue reading more here..

Multi-Criteria Decision Analysis Model for Assessing the Risk from Multi-Ingredient **Dietary Supplements (MIDS).** Oketch-Rabah, H. A., Hardy, M. L., Patton, A. P., Chung, M., Sarma, N. D., Yoe, C., Ayyadurai V.A.S, Fox M.A., Jordan, S.A., Mwamburi, M., Mould, D. R., Osterberg, R.E, Hilmas, C, Tiwari, R., Valerio, L., Jones, D., Deuster, P.A., Giancaspro, G.I. (2020). *J Diet Suppl.* 2020 Apr 22:1-23. doi: 10.1080/19390211.2020.1741485 In 2013, the US Pharmacopeia (USP) established a Dietary Supplements Safety Modelling Expert Panel to explore the



United States Pharmacopeia (USP) comprehensive review of the hepatotoxicity of green

Navarro, V., ... & Gurley, B. et al., (2020). Toxicol Rep. 2020 Feb 15;7:386-402. doi:

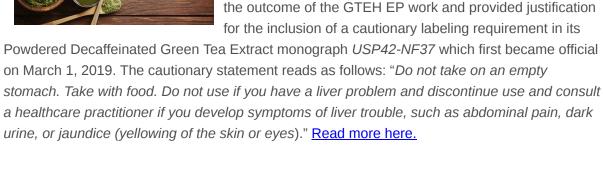
tea extracts. Oketch-Rabah, H. A., Roe, A. L., Rider, C. V., Bonkovsky, H. L., Giancaspro, G. I.,

contribute to specific aspects of risk. Read full article here.

10.1016/j.toxrep.2020.02.008.

Continue reading more here.

Following the United States Pharmacopeia's publication on safety of green tea extracts (GTE) in 2008, USP continued to monitor the literature for news of hepatotoxicity due to GTE. In 2016, USP established the Green Tea Extract Hepatotoxicity Expert Panel (GTEH EP). This publication is



Regulatory landscape of dietary supplements and herbal medicines from a global perspective. Thakkar S, Anklam E, Xu A, Ulberth F, Li J, Li B, Hugas M, Sarma N, Crerar S, Swift S, Hakamatsuka T, Curtui V, Yan W, Geng X, Slikker W, Tong W. Regul Toxicol Pharmacol. 2020 Apr 16:104647. doi: 10.1016/j.yrtph.2020.104647. Online ahead of print. The number of Individuals that use dietary supplements and herbal

medicine products continue to increase in many countries. The context of usage of a dietary supplement varies widely from country to country; in some countries supplement use is limited to general health and well-being while others permit use for medicinal purposes. To date, there is little consensus from country to country on the scope, requirements, definition, or even the terminology with which dietary supplement and herbal medicine categories could be classified. Transparent science-based quality standards for the ingredients across these regulatory frameworks/definitions becomes even more important given the international supply chain.

Past Events 2020 USP Convention Meeting A Virtual Success Convention

USP is governed by three bodies composed entirely of volunteers from around the world:

the <u>USP Convention membership</u>, and the <u>Board of Trustees</u>, and the <u>Council of Experts</u> and its

Expert Committees, which are elected every 5 years by the Convention Membership. On May 4-

6, 2020, Convention Member Delegates and Observer Representatives met for the first-ever

virtual USP Convention Meeting. They shared valuable input and perspectives, elected the

Council of Experts and Board of Trustees for USP's 2020-2025 cycle, approved 15 resolutions

that will guide USP's work, and approved bylaws-amendments that will help USP continue to evolve as it enters its third century. Through these contributions and others, the USP Convention helps improve public health, patient safety, and access to quality medicines for people around the world. Of note for the readers of this eNewsletter, the Convention elected the following chairs for 2020-2025 expert committees in the area of USP dietary supplements and herbal medicines: • Botanical Dietary Supplements and Herbal Medicines Expert Committee: Robin Marles, Ph.D., M.Sc., B.Sc. • Non-Botanical Dietary Supplements Expert Committee: Guido F. Pauli, FAPA, Ph.D., • Admission Evaluation and Labeling Expert Committee: Tieraona Low Dog, M.D. Several of the Convention resolutions provide mandate and directions for setting public standards for dietary supplements and herbal medicines. Specifically, the Convention approved

mandate to USP to develop scientific resources and solutions in the area of cannabis and hemp. Additional information is available here. **USP Stakeholder Forum**

Dietary Supplements

Resolution #10 Cannabis: USP will leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions that

will help address quality-related concerns as well as support additional scientific research on

cannabis, cannabis-derived products, and cannabis-related compounds. This resolution provides

Stakeholder Forum May 28, 2020 | Now Virtual More than 250 stakeholders participated in the 2020 USP Dietary Supplements Stakeholder Forum held for the first time as a virtual meeting, due to the COVID-19 pandemic. The Stakeholder Forum Chair was Holly Johnson, Ph.D., Chief Science Officer of the American Herbal Products Association, who also moderated discussion on agenda topics and panel discussions. The agenda and briefing information is available here. First on the agenda was the COVID-19 crisis and the challenges it has brought to the dietary

supplement (DS) community. Panelists from five national trade associations for the DS industry

shared their members' experiences, needs and priorities. All five associations reported that the

experienced sudden spikes in consumer demand for certain products related to immune health, putting a strain on production capacity. Supply chain problems have complicated the situation.

primary concern of many member companies is protecting the safety of their employees and

after that, meeting the regulatory requirements. Companies indicated that they have also

USP shared its commitment during these extraordinary times to provide support to

manufacturers to help ensure the quality of dietary supplements (https://www.usp.org/dietarysupplements-herbal-medicines). In addition to COVID-related topic discussions, speakers shared important updates about hemp and CBD standards and evidence-based safety information; background information and experiences with pyrrolizidine alkaloids as contaminants; consumer interest in "clean label," and how the DS industry interprets USP standards. Throughout the meeting, USP staff emphasized that stakeholder feedback is always a top priority. Despite the virtual format, attendees were able to participate actively by sending in their

questions and comments via live chat. USP provides quality standards, resources, and information to make an impact on DS quality while meeting the needs of DS manufacturers,

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

 Cuminum cyminum Dandelion Root Hops Horehound Melissa officinalis Moringa Leaf

Non-Botanical Dosage Forms (Finished Dietary Supplements):

• Omega-3-Acid Triglycerides with Vitamin D capsules

seeking donations for the following monographs:

Botanical Dietary Supplement Ingredients

Acai

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

regulators, consumers, and academia.

Non-Botanical Dietary Supplement Ingredients: Glucuronolactone Histidine Lactobacillus plantarum 299v

 Skullcap aerial parts Yarrow aerial parts

 Lutein esters L-Ornithine Pantethine Salmon Oil

Soy Protein

 Cyanocobalamin capsules Glucosamine, Chondroitin Sulfate Sodium capsules Magnesium Citrate capsules Menaquinone 4 tablets and capsules

Zeaxanthin preparation

 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

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 <u>DietarySciStaff@USP.org</u>.

Before development of a quality standard for a dietary ingredient is considered, 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, 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 held a working meeting via Webex on Thursday March 12th, 2020. Members deliberated on and admitted S-Adenosyl-L-Methionine (SAMe) 1,4-Butanedisulfonate, Sour Jujube Seed and White Peony Root for monograph development. The committee recommended that the USP monograph for S-Adenosyl-L-Methionine 1,4-Butanedisulfonate include a cautionary labeling statement stating as follows "Label finished products containing this ingredient with the statement: Consult your physician or healthcare provider before use if you

have bipolar (manic) depression, are taking prescription antidepressant medications or are pregnant or nursing. Discontinue use if you experience increased agitation, mood swings, or

USP Admission Evaluations of Articles Prior to Monograph Development

decreased sleep while taking this product and consult your physician or healthcare provider." The DSAE JS3 met via Webex on Thursday May 26th, 2020, to deliberate on Aloe Vera Leaf Juice, Broccoli Seed Extract, Bifidobacterium longum subsp. infantis Bi-26, Lactobacillus casei Lc-11, and *Bacillus clausii* UBBC07. 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., DABT, at Emily.Madden@usp.org.

• Ligusticum chuanxiong Rhizome

Maca root extract

• Paeonia lactiflora Peeled Root Dry Pomegranate Fruit Dry Extract

• Sophora japonica Flower Dry

• Trachyspermum ammi Fruit Oil • Ziziphus jujuba var. spinosa Seed

Dry Extract Z-Ligustilide

Non-Botanicals • 1,4-Butanedisulfonic acid Calcium Magnesium Citrate • Choline Citrate

Hydroxocobalamin Chloride

 Inositol Niacinate • L-Ornithine Hydrochloride Lysine

Citicoline

• Palm Oil Tocotrienols and Tocopherols • S-Adenosyl-L-Methionine 1,4-Butanedisulfonate

Monographs Standards Open for Public Comment until July 31, 2020 The standards below were published in PF 46(3) for public comment on May 1, 2020

31, 2020. The deadline for comments on all proposals published in PF 46(2) has also been extended to July 31, 2020, see announcement available at https://www.uspnf.com/notices/delayedimplementation-comment-covid-response-To comment, please visit:

http://www.usp.org/usp-nf/pharmacopeial-

and will accept public feedback until July

New Monographs/General Chapters Choline Citrate

• S-Adenosyl-L-methionine 1,4-Butanedisulfonate Revised Monographs/General Chapters Levocarnitine <2750> Manufacturing Practices for Dietary Supplements -published in PF 46(2)

Standards Open for Public Comment

The standards below will be published in PF 46 (4) for public comment on July 1,

until September 30, 2020

2020 and will accept public feedback until September 30, 2020. To comment, please visit: http://www.usp.org/usp-New Monographs/General Chapters Red Asian Ginseng Root and Rhizome

Red Asian Ginseng Root and

Revised Monographs/General Chapters

Rhizome Powder

• Pyrroloquinoline Quinone Disodium (PQQ) Annatto Seed Oil Tocotrienols • Ferrous Fumarate Tablets Standards to be published in PF 46 (5)

The standards below will be published in

PF 46 (5) on September 1, 2020 and will

2020. To comment, please

accept public feedback until November 30,

visit: http://www.usp.org/uspnf/pharmacopeial-forum New Monographs/General Chapters • Astaxanthin Esters Capsules Bacillus clausii • Bifidobacterium longum subsp

 Cranberry Fruit Juice Dry Extract Capsules • Cranberry Fruit Dry Juice Lactobacillus casei Gastrodia rhizome · Gastrodia rhizome Powder • Gastrodia rhizome Dry Extract Siler Root Siler Root Powder Siler Root Dry Extract • Black Cumin Seed Thymoquinone • Palm Oil Tocotrienols and

Tocopherols • Aloe vera Leaf Juice • Aloe vera Leaf Juice Concentrate • Aloe vera Leaf Dry Juice **Revised Monographs/General Chapters** Feverfew Leaf

 Milk Thistle Powdered Milk Thistle Powdered Milk Thistle Extract Milk Thistle Capsules Milk Thistle Tablets American Ginseng Capsules American Ginseng Tablets Asian Ginseng Tablets Calcium Pantothenate Bacillus coagulans **New Monographs under Development** <u>Botanicals</u> Ajowan Fruit • Ajowan Fruit Powder

Feverfew Leaf Powder

Sennosides

 Ajowan Fruit Oil Aloe Vera Leaf Juice Concentrate · Green Tea Leaf Dry Extract Feverfew Leaf Extract Maca root powder

 Maca root gelatinized powder Maca root extract Neem Leaf Neem Leaf Powder Neem Leaf Dry Extract Red Clover Tablets • Cinnamomum cassia Bark • Cinnamomum cassia Bark Powder • Cinnamomum verum Bark · Cinnamomum verum Bark Powder Non-Botanicals • *beta-*Hydroxy*-beta-*methylbutyric

• Calcium beta-hydroxy-betamethylbutyrate (Ca-HMB) GABA Hydrolyzed Collagen Inositol Niacinate • Levocarnitine Tartrate Lutein Esters Lysine Mineral Ascorbates • Mineral Bisglycinates Native Collagen

• Oil-soluble Vitamins Preparation

 Phytosterol Esters Plant sterols · Rice protein • Salmon oil (farmed and wild) • Zeaxanthin Preparation Hydrolyzed Keratin • Streptococcus thermophilus • Lactobacillus salivarius • Lactobacillus plantarum New General Chapter under Development • <582> Water-Soluble Vitamins Assay by Liquid Chromatography— Mass Spectrometry

• <2800> Multi-ingredient Dietary Supplement Products -Development of Quality Tests <2740> Manufacturing Practices for **Dietary Ingredients** Find a Reference Standard Suggest a Reference Standard Download the free USP Reference Standards and Resources App from the Apple Store (https://apps.apple.com/us/app/usp-

resources/id1161490610) or Google Play

id=com.usp.rs app) and easily access,

(https://play.google.com/store/apps/details?

track and receive information and alerts on

the USP Reference Standards of interest to

reference-standards-and-

you from your device.

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

DSHM Nom JSC met in December 2019 and in February 2020 and recommended the following monograph titles to USP Nomenclature and

 Palm Oil Tocotrienols and Tocopherols Rice Bran Oil Tocotrienols and Tocopherols Cranberry Fruit Juice Dry Extract Capsules Apigenin Black Cumin Seed Thymoquinone Oil Ajowan Fruit Oil

 Hydrolyzed Keratin Rice Protein Streptococcus thermophilus Lactobacillus salivarius Lactobacillus plantarum Salmon Oil

Labeling EC for approval:

Annatto Seed Oil Tocotrienols changed from Annatto Seed Oil Tocotrienols Extract

DSHM Nom JSC revised the Guideline for Assigning Titles to USP Dietary Supplement Monographs available at hao@usp.org.

Empowering a healthy tomorrow

http://www.usp.org/sites/default/files/usp/document/get-involved/submission-guidelines/guideline-for-assigning-titles-to-usp-dietarysupplement-monograph.pdf. For more information on dietary supplements nomenclature, please contact: Hellen Oketch-Rabah, Ph.D., at If you received this newsletter as a forward and wish to receive it directly in your inbox, please sign up here.

Forward to a Colleague or Friend Copyright © 2019, All rights reserved. Our mailing address is: © The United States Pharmacopeial Convention 12601 Twinbrook Parkway | Rockville, MD 20852-1790

> Manage Your USP email Subscription Preferences Unsubscribe from all USP emails

Phone: +1-301-881-0666 or 00-800-4875-5555 (select Europe)

USP.org | Contact Us | Privacy Statement

usp.org