OmniActive Health Technologies and AstaReal obtain USP Verification for Dietary Ingredients

OmniActive Health Technologies and AstaReal recently obtained USP Verification for dietary ingredients. OmniActive’s dietary ingredient, CurcuWIN curcumin DNS powder 20%, and AstaReal’s dietary ingredient, AstaREAL® L10, met USP’s detailed and strict verification requirements and were awarded a Certificate of Standards Compliance. They were also granted use of the USP Verified Mark. The Mark can be used on the bulk label of each container of the verified dietary ingredient and on the accompanying certificate of analysis to demonstrate that the dietary ingredient meets the USP Verified requirements for quality and purity.

USP’s Ingredient Verification Program consists of three initial steps including (1) a manufacturing facility audit to assess compliance with applicable Good Manufacturing Practices (GMP), (2) product quality control and manufacturing documentation evaluation to help ensure ingredient consistency from batch to batch, and (3) laboratory testing of ingredient samples to verify conformance to pharmacopeial and/or manufacturer quality specifications for identity, strength, purity, quality and acceptable limits for impurities and contaminlants.

USP in India

Food ingredients-Health ingredients (Fi-Hi) trade show — India, November 9-11, 2017
Fi-Hi has been one of United Business Media’s flagship engagement platforms for last three decades and one of the world’s leading networking events for food and dietary supplements stakeholders. Annually, over 250,000 food and beverage senior professionals attend these events globally. The 12th edition of Fi-Hi India featured more than 200 exhibitors showcasing over 800 food, health, natural ingredients and related technological innovations from across the globe. Over 7,500 buyers and sellers from 46 countries attended the event exploring opportunities to build strategic business alliances in the ever-growing food and health industry in India.

USP-India had a booth at the event, where about 150 companies and 250 stakeholders stopped for information about USP services, particularly USP ‘s verification services and GMP audit program.

One of the seminars, "How pharmacopeias help nutraceutical/dietary supplement industry," was held in collaboration with the Health Foods and Dietary Supplements Association (HADSA).

**USP-AYUSH workshop - India, November 6, 2017**

USP and the Indian Ministry of AYUSH organized a workshop titled “Pharmacopeial monographs of ayurvedic/herbal medicines” in New Delhi, India. The workshop was organized as part of the USP Memorandum of Understanding (MoU) with Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) of the Ministry of the AYUSH (which stands for Ayurveda, Yoga, Unani, Siddha and Homeopathy).

The workshop was graced by the participation of the Honorable Minister for AYUSH, Shri Shripad Yesso Naik, the Secretary of the Ministry, Shri Vaidya Rajesh Kotecha, other dignitaries and participants from the AYUSH, members of academia and industry. Members of the USP South Asia Expert Panel chaired by Prof. Handa also participated in the workshop.

The workshop focused on providing scientists engaged in pharmacopeial work related to traditional/herbal medicines and botanical dietary supplements with information about the latest global trends and concerns in the development of standards with a special reference to analytical aspects, regulations pertaining to use of botanicals as Ayurvedic medicines, dietary supplements or nutraceuticals, and phytochemical markers.

USP botanical monographs and reference standards from the Herbal Medicines Compendium (HMC) and the Dietary Supplements Compendium (DSC) and the AYUSH Ayurvedic Pharmacopeia of India (API) standards were discussed during the workshop. Other topics included:

- Design and structure of the Ayurvedic Pharmacopoeia of India
- Introduction to Principles & Practice of Ayurvedic Drug Formulations

**Botanicals**

- *Angelica sinensis* Root Powder
- Baicalein
- Baicalein 7-O-Glucuronide
- Broccoli seed dry extract
- Chrysanthemum indicum Flower Dry Extract
- Chrysanthemum x morifolium Flower Dry Extract
- Cranberry fruit dry juice
- Cranberry fruit juice dry extract
- Ginger rhizome carbon dioxide soft extract
- Isochlorogenic Acid A
- Ligusticum chuanxiong Rhizome Powder
- Linarin
- Maca root
- Maca root extract
- Scutellaria baicalensis Root Dry Extract
- Senkyunolide A
- Z-Ligustilide

**Non-Botanicals**

- beta-Glycerolphosphorylcholine
- Choline Citrate
- Docosahexaenoic acid
- Eicosapentaenoic acid
- L-alpha-glycerophosphorylethanolamine
- L-alpha-glycerolphosphorylcholine
- L-alpha-glycerolphosphorylcholine solution
- Omega-3 free fatty acids
- Pyrroloquinoline quinone

Find a Reference Standard
Suggest a Reference Standard

**Purchase 2015 Dietary Supplements Compendium**
• Ayurvedic principles of identification and authentication of herbal drugs
• Traditional medicines in the U.S. dietary supplement framework – USP resources to address quality
• Identity standards – HPTLC, DNA and HPLC finger printing in pharmacopeial standards
• Regulatory Aspects of Nutraceutical & Phytopharmaceutical Quality Standards - Industry Needs and Challenges Regarding Botanical Quality Standards

Following the workshop, USP and AYUSH committed to forming a working group to implement the goals from the MoU to enhance global public health by increasing awareness, understanding and access to quality traditional/herbal medicines and botanical dietary supplements.

A related recent development is the recognition of USP quality standards in the Indian regulations for nutraceuticals. [See Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, available on their website. The agency responsible for the enforcement of these regulations, the Food Safety and Standards Authority of India (FSSAI), noted that the regulations will start being enforced on January 1, 2018.

IPA Probiotics Workshop co-sponsored by USP, October 26, 2017

The International Probiotics Association (IPA) and USP co-sponsored a workshop where the need for global probiotics standards was discussed. Probiotic standards have been developed in collaboration with industry and published in both the USP-NF and the Food Chemicals Codex (FCC). Collaboration from industry is being sought to develop standards for additional species/strains including bifido infantis. For further details, please contact Kit Goldman at kit.goldman@usp.org.

You can read more about this workshop on the NutraIngedients website, in an article entitled "The 18 things we learned from the IPA’s DC Workshop 2017".

Upcoming Events and Meetings

Dietary Supplements and Food Ingredients Adulteration Workshop
February 27 – 28, 2018, USP Rockville, MD

Adulteration and fraud in food ingredients and dietary supplements are major concerns for industry, consumers, and regulatory authorities. This fifth USP workshop brings together internationally recognized experts to discuss the current state of technologies for detecting economically motivated adulteration and ways to minimize supply chain risk. Speakers from Walmart, Pepsico, the European Commission, as well as technical experts from University of Guelph, FOCOS and Fonterra will be included. An optional olive oil tasting session will be held at the conclusion of the workshop. Attendees can also register for a Food Fraud Mitigation (Level 1 Training), to be held on March 1, to learn how to create a documented vulnerability assessment and mitigation plan. For more details and to register, please visit: http://www.usp.org/events-training/workshops/dietary-supplements-food-ingredients-adulteration-workshop.

Standards Open for Public Comment
Published for public comment Nov 1, 2017. Please click here to comment. Comments due January 31, 2018

New Monographs
• Vitamins with Minerals Oral Powder

Revised Monographs
• Beta carotenes Capsules
• Eleuthero Root and Rhizome Dry Extract Capsules and Tablets
• Rhodiola rosea Capsules and Tablets

Published for public comment Jan 1, 2018. Please click here to comment. Comments due March 31, 2018

New Monographs
• Bitter orange fruit flavonoids dry extract

Revised Monographs
• Lycopene
• Lycopene preparation
• Tomato lycopene extract

Slated for publication for public comment March 1, 2018. Please click here to comment. Comments due May 31, 2018

New Monographs
• Conjugated linoleic acids–triglycerides
• Guarana seed
• Guarana see powder and extract
• Chinese skullcap root
• Chinese skullcap root powder and dry extract
• Chrysanthemum flower
• Chrysanthemum flower powder
Food fraud mitigation level 1 training: Mitigating the risk of food fraud using the USP food fraud guidance (Classroom and Online) USP Rockville, MD, March 1, 2018
Register for Classroom Course or the Online Course here.

Dietary Supplements Stakeholder Forum
USP Rockville, MD, May 15, 2018

Stakeholder input is essential to the development of USP dietary supplement standards. This forum provides an open discussion of issues and to share perspectives related to USP dietary supplement standards. It also collects stakeholder feedback for current and future USP standards-setting efforts. The United States Pharmacopeial Convention (USP) will hold a Dietary Supplement Stakeholder Forum on May 15, 2018 at USP in Rockville, Maryland, from 9:00 a.m. - 4:30 p.m. To expand the opportunity for stakeholder participation, USP offers a web-based component for those who wish to attend the meeting remotely.

To this end, USP encourages manufacturers, organizations, service providers, and other interested parties who work with dietary supplements to attend and share perspectives and provide direct feedback on priority standards issues.

The agenda and briefing information from the last Dietary Supplement Stakeholder Forum is at here. For additional information, contact Stakeholder Operations, Jacqueline Starkes at jws@usp.org.

Register today for the upcoming DS Stakeholder Forum!

Public Health Impact

Earlier this year, FDA announced a public meeting and called for comments on their intent to develop pre-DSHEA list of dietary ingredients. Under the Dietary Supplement Health and Education Act (DSHEA), dietary ingredients marketed in the United States before October 15, 1994, are not New Dietary Ingredients and therefore are not subject to the premarket notification requirements in section 413 of the FD&C Act.

An authoritative list of such ingredients, often referred to as Old Dietary Ingredients (ODI) has never been established. USP representatives attended FDA’s public hearing on October 3, 2017, and submitted comments to the public comment docket.

Comments addressed both the evidence necessary to determine that an ingredient was marketed before October 15, 1994 and issues related to the process that should be used to develop the list. USP expressed support, noting that an FDA list of pre-DSHEA ingredients could improve transparency and clarity in the marketplace. Our comments highlighted the potential utility of public standards and stressed the importance of clear and consistent nonproprietary names, along with identity specifications, for ingredients included on the list.

USP supports a transparent, open process and welcomes the chance to work with stakeholders to advance dietary supplement quality and consumer safety. More information and a link to our submitted comments can be found here:

Quality Leadership
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 inclusion in other pharmacopeias. The committee also considers whether the article poses any serious risk to health when used as a dietary supplement.

If the article does not pose a serious risk to health, 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, meaning that it is admitted for monograph development. If the article poses a serious risk to health, it is placed in class B and is not admitted for monograph development.

The DSAE JS3 held a face-to-face meeting on November 14, 2017, where members of the sub-committee considered and admitted sichuan logave rhizome and dong quai root for monograph development. Members also deliberated on the preparation of new admission evaluation summaries, as well as updates to summaries in the Dietary Supplements Compendium (DSC version 2015) and their publication in the third edition of DSC, which will be published in 2018.

The DSAE JS3 also amended the label caution statement for the powdered decaffeinated green tea extract for clarity and brevity so that it now reads as follows:

"Do not take on an empty stomach. Take with food. Do not use if you have a liver problem. Discontinue use and consult a healthcare practitioner if you develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice (yellowing of the skin or eyes)."

For more information, please contact Hellen Oketch-Rabah, Ph.D., at Hao@usp.org or Kristi Jacobs, Ph.D., at KLJ@usp.org.

Nomenclature of Dietary Supplements

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

From August to December 2017, the Dietary Supplements and Herbal Medicines Nomenclature Joint Subcommittee (DSHM Nom JS) held one working meeting where the following listed monograph titles were recommended to the USP Nomenclature and Labeling Expert Committee for approval:

- Cranberry liquid preparation change to cranberry fruit juice concentrate;
- Lysine;
- Broccoli seed dry extract;
- Cranberry fruit dry juice;
- Cranberry fruit juice dry extract;
- Ginger rhizome carbon dioxide soft extract.

For more information on dietary supplements nomenclature, please contact: Hellen Oketch-Rabah, Ph.D., at Hao@usp.org.
Q. The majority of our products consist of dried/powdered herbs that are processed into tablets. We do have some products that are herbal powders, which we would classify as "chopped or powdered botanicals," but we were wondering if tablets should also be classified as such, or whether USP has another set of microbial limits for this type of dosage form. In addition, some of our herbal tablets contain a mixture of dried/powdered herbs and powdered extracts. USP specifies different microbial limits for dried/powdered botanicals and botanical extracts. What limit should we use for a product that contains a combination of the two types of ingredients?

A. The applicable limits for botanicals in tablet dosage forms are those for "Nutritional supplements with botanicals" as listed in USP General Chapter <2023>, Microbial attributes of nonsterile nutritional and dietary supplements; that is, total aerobic microbial count not more than (NMT) $10^4$ cfu/g; total, combined yeast and mold count NMT $10^3$ cfu/g; absence of Salmonella species and E. coli in 10 g. For combination products, the most stringent USP microbial limit applies.

Q. Can I use an alternative method to the USP’s to test my products?

A. An alternative method or procedure is defined as any method or procedure other than the compendial method or procedure for the article in question. The alternative method or procedure must be fully validated (see Validation of compendial procedures <1225>) and must produce comparable results to the compendial method or procedure within allowable limits established on a case-by-case basis.

Alternative methods or procedures can be developed for any reason, not limited to simplification of sample preparation, enhanced precision and accuracy, improved (shortened) run time, or being better suited to automation than the compendial method or procedure. Only those results obtained by the methods and procedures given in the compendia are conclusive.

For evaluation as a potential replacement or addition to the standard, alternative methods and procedures should be submitted to USP. For more information please see USP General Notices, section 6.30. Alternative and harmonized methods and procedures.