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Dietary Supplements Stakeholder Forum

Michael McGuffin, Chair
Summary Discussions
Wednesday, June 1, 2016

What We Heard

USP Updates and Discussions—Adulterants Database

- ▶ Stakeholders—consumers, marketers, regulators—will work together to solve the problem caused by adulterated products that masquerade as dietary supplements (DSs).
- ▶ USP should make more clear that tools to detect adulteration by drug spiking are not meant as standards for manufacturers, but rather as tests for regulators in enforcement/forensic actions.
- ▶ There is sensitivity in the industry about screening methods being required as regular tests for GMP compliance.
- ▶ The adulterants database was well received, but stakeholders emphasized that adulteration by ingredient substitution, dilution, and spiking with botanical chemical markers are areas more relevant for the manufacturers than adulteration by drug spiking.

What We Heard

USP Updates and Discussions—Adulterants Database

- ▶ USP must make the planned database comprehensible, segregating the drug/drug analog tainted products of interest to regulators from the economically motivated adulteration of interest to dietary supplement ingredient purchasers.
 - Confusion can arise because the adulterants database is perceived as a tool for industry, but in reality it is a tool for regulators, enforcement agencies and forensic laboratories.
 - Separate section on authentication would highlight the function of the database as a product and ingredient integrity tool manufacturers can use to protect themselves against Economically Motivated Adulteration.

Action Item: Attendees interested in participating in beta-testing the USP database will contact Mr. Anton Bzhelyansky (anb@usp.org).

What We Heard

USP Updates and Discussions—DNA-based Methods for Botanical Identification

- ▶ DNA testing is an emerging tool of indisputable value. However, it can not be used to identify different parts of the plant. RNA may be used for that purpose but it is too fragile. At the current stage of development, nucleic acids techniques are not suitable for regular quality control to determine parts of the plants.
- ▶ No single DNA method can fully define a pharmacopeial article; identity must be determined on a case-by-case basis involving orthogonal tests including physical and chemical methods.

What We Heard

USP Updates and Discussions—DNA-based Methods for Botanical Identification

- ▶ USP could take the lead in consolidating information from the various DNA libraries into a single repository targeted for dietary supplements as a reliable resource for researchers and ingredient purchasers. USP could leverage its experience in other similar library resources supplemental to public standards and explore how to apply that experience to DNA libraries.
- ▶ Industry is looking to USP to take a lead role in exploring development of a repository of authenticated plant material that could serve validation purposes in DNA procedures.
- ▶ Plants within a single species can be highly variable. Industry is looking for partnerships to ensure that if a DNA method is developed as a standard, it identifies material representative of articles in commerce.

What We Heard

USP Updates and Discussions—Residual Solvents

- ▶ Some attendees recommended that DS ingredients be excluded from General Chapter <467> Residual Solvents because of inconsistency with the scope and limitations of similar guidelines from ICH¹.
 - USP staff responded that revised language in <467> clarified previous application of residual solvents by *USP General Notices* to finished dietary supplements (not ingredients). Industry is invited to provide comments to USP on this topic and about potential exceptions to residual solvents for dietary supplements.

1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

What We Heard

USP Updates and Discussions—Modernization of Monographs

- ▶ There was general support for USP up-to-date efforts. However, some attendees noted that it is important to protect existing methods that work well and to be mindful of capital expenditures that might be associated with adoption of high-tech methods.
- ▶ USP staff noted the benefit of building in flexibility in general chapters and monographs when results are equivalent so industry has options.

What We Heard

Stimuli Articles—Overages

- ▶ What can USP do to get FDA to allow shortages in dietary supplements (less than 100% label claim) that are in line with what USP allows as an industry standard?
 - USP staff responded that USP had discussed this topic with FDA officials in the past. USP could revisit the topic in future meetings with FDA officials
- ▶ CRN encouraged USP to raise the issue with FDA. In other countries, the minimum acceptance limit for dietary supplements is consistent with pharmacopeial monographs, but in US is consistent with regulations for fortified foods (NLT 100%).

What We Heard

Stimuli Articles—Pesticides

- ▶ In context of USP Pesticide stimuli article: EPA Crop Group #19 includes herbs and spices—and additional limits for Crop Groups have recently been issued. FDA action limit is 10 ppb.

What We Heard

Stimuli Articles—Nomenclature of Dietary Supplements

- ▶ AHPA intends to produce a third edition of *Herbs of Commerce* this year.
- ▶ USP Nomenclature and Labeling Expert Committee is discussing a name for “gummies”.
- ▶ The established name in dietary supplement industry is “gummies.” A concern is the dosage form is also a potential vehicle for drugs, therefore a compatible pharmacopeial name for the dosage form may be established by the Nomenclature EC.

What We Heard Standards for High-Impact Supplements— Probiotics

Standards for High-Impact Supplements

- ▶ USP invited industry comments on recent proposals for probiotics in Pharmacopeial Forum, which include USP species-level monographs listing available strains with strain-specific tests linked to the label claim.

What We Heard

Open Forum: Stakeholder Topics

USP Standards as a Resource for Industry

- ▶ It has been suggested in a USP article by USP staff that public health could be enhanced by strengthening Good Manufacturing Practices (GMPs) by requiring greater adoption and compliance with USP or other public compendial standards.
- ▶ Industry does not support such changes to the existing FDA GMPs.
- ▶ There was agreement that transparency is important for consumers, and that a minimum standard for quality should be established.
- ▶ USP staff suggested that adoption of public standards provides an opportunity to establish minimum common standards and increase transparency in communication of internal specifications that now remain private and unknown.

What We Heard

Open Forum: Stakeholder Topics

- ▶ What topics would industry stakeholders like USP to propose for future Roundtables?
 - USP is considering cranberry, modernization, contaminants, GMP quality standards Roundtables.
 - USP should consider a 2017 Roundtable on the topic of protein methodologies for authentication
 - USP should consider a 2017 Roundtable on the topic of mineral and mineral salt monograph development

What We Heard

Open Forum: Stakeholder Topics

- ▶ Work with mineral suppliers to develop new monographs for ingredients suitable for food
 - USP has numerous monographs for mineral ingredients with specific tests and defined limits. Industry sponsorship providing analytical data for the development of new monographs is needed.
 - Mineral suppliers typically do not have analytical and safety data.
 - New monographs for minerals should be developed in parallel for *FCC* and *USP*.
 - USP should consider a 2017 Roundtable on the topic of mineral and mineral salt monograph development

What We Heard

Open Forum: Stakeholder Topics

- ▶ Aggressive enforcement by regulators is needed.
- ▶ Industry is looking to USP to ensure excellent quality standards for herbal dietary supplements.
- ▶ Develop ID and testing standards for protein
 - FDA's New Nutrition Labeling Guidelines are relevant to protein discussion
- ▶ USP could explore developing allergen testing standards.

What We Heard

Open Forum: Stakeholder Topics

- ▶ What is the role of Third Party Certification?
 - Stakeholders did not support the idea that third party certification be mandated by legislation.
 - Some reports have asserted that consumers assume that marketed products are vetted by FDA
 - Educate consumers with a “Got Milk”-like campaign for DSs
 - Quality seals should indicate verification and URL for more information on the basis for the verification.
 - Separate quality assurance and excellence from drug spiking discussions.
 - Ensure all companies are using the same measuring stick for GMP compliance

How to Stay Engaged

- ▶ Participate in Stakeholder Forums
- ▶ Sign up for the Dietary Supplements e-Newsletter.
- ▶ Visit the Call for Candidates page on USP.org and apply for a USP Expert Committee, Chair position, or Expert Panel.
- ▶ Offer public comments on proposed methods through USP's *Pharmacopeial Forum*.



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Thank You