Updates on USP Standards for Probiotics

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2016 - 2017
- Established the Probiotics Expert Panel
- Proposed a general chapter, <64> PROBIOTIC TESTS
- Proposed monographs (B. coagulans and its capsules) in PF 43(1)
- Published 5 official monographs (4 Lactobacillus + 3 Bifidobacterium strains) in USP40-NF35

2015
- Probiotic Roundtable

Before 2015
- 8 monographs in FCC
- 2012 USP-IFT Workshop: A co-sponsored workshop on identity and characterization of a probiotic microorganism used in food ingredients: Importance to Safety and Efficacy
- *Lactobacillus acidophilus* LA-14 → Approved
- *Lactobacillus acidophilus* NCFM → Approved
- *Lactobacillus paracasei* Lpc-37 → Approved
- *Lactobacillus rhamnosus* HN001 → Approved
- *Bifidobacterium animalis* ssp. *lactis* → Approved

- *Bacillus coagulans** → Proposed
- *Bacillus coagulans* Capsules → Proposed
- General Chapter <64> Probiotics Tests → Proposed

* The title is at the species level to include multiple strains in one monograph. Strain-level titled monographs will be revised to the species level in near future.
Industry needs science-based quality testing
- Most manufacturers use ID test with limited specificity.
- Very few ingredient manufacturers promote DNA-based ID test.

Best Practices Guidelines for Probiotics (CRN+IPA)
- Address strength, stability, and label claims
- Does not address ID tests and contaminants
- Does not address public standards of probiotics (USP monographs)

Limited awareness of USP probiotic standards
- Not familiar with USP standards
- Most DS manufacturers (ingredients/dosage forms) are not familiar with DNA-based ID tests as a QC release test.
- Need to address limits for micro-contaminants for probiotics
- Need to promote public standards for probiotics
Probiotic EP
- Formed in April 2017
- Review monographs and provide recommendation to NBDS-EC

Dr. Mary Ellen Sanders - Chair

Dr. Chris Elkins – FDA Government Liaison

Expert Panel Members (14)
- Subject-matter experts from major manufacturers (ingredients, dosage forms and testing laboratories)
- Experts in FDA, NIH, and NIST
## Probiotics Expert Panel – Members

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<td>Burguiere, Pierre</td>
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<td>Brooks, James</td>
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Probiotics Expert Panel – Major Tasks

- Monograph review and recommendation to NBDS-EC
  - *Bacillus coagulans*
  - *Bacillus coagulans* Capsules
  - General chapter: <64> Probiotic Tests

- Informational General Chapter of Probiotics – *proposed*
  - Planned in 2018-2019
  - Testing methods, principles, requirements etc. focusing on ID, purity, strength, and limits for contaminants etc.

- Some EP members will speak at the IPA-Probiotic Workshop co-sponsored by USP (Rockville, MD on 10/26/2017)
  - Tentative topics: regulatory compliance, standards, industry practices, advanced sciences etc.

- USP Probiotic Expert Panel meeting scheduled on 10/25/2017 (Rockville, MD)
Avoid duplicated procedures in monographs for Lactobacillus or Bifidobacterium (e.g. PCR, MRS enumeration, contaminants)

Subject to EP review and recommendation

Addresses probiotics used as dietary ingredients as well as dietary supplements such as dosage forms (tablets, capsules, etc.).

The scope of the chapter includes definition, identification, enumeration, specific tests, contaminants and other requirements for dietary supplement probiotics.

This chapter also provides tests for probiotic microorganisms as well as contaminant microorganisms which may be present in dietary supplement probiotics from raw materials to the finished forms.
Upcoming USP Monographs for Probiotics

Under development
- *Lactobacillus fermentum* strains
- *Bacillus coagulans* with additional strains
Stakeholder Perspectives on USP Probiotic Standards

USP Stakeholder Forum
Buffy Stahl – DuPont Nutrition and Health
7 June 2016
Discussions