New Standards and 2019-2020 Plans

Kit Goldman, Ph.D.
Director Dietary Supplements and Herbal Medicines
Agenda

- Monographs and General Chapters 2018-2019
- Ongoing Monographs 2018-2019
- Prioritization Process
- 2019-2020 Plans
2018-2019 New Botanical Standards

Submitted to PF

- Japanese Sophora Flower
- Japanese Sophora Flower Dry Extract
- Japanese Sophora Flower Powder
- Pummelo Peel
- Pummelo Peel Powder
- Pummelo Peel Dry Extract

- Picrorhiza sp. Root and Rhizome
- Picrorhiza sp. Root and Rhizome Powder
- Picrorhiza sp. Root and Rhizome Dry Extract
- Coptis sp. Rhizome
- Coptis sp. Rhizome powder
- Coptis sp. Rhizome dry extract
2018- 2019 Modernized Botanical Standards

Submitted to PF

- Asian Ginseng Root and Rhizome
- Asian Ginseng Root and Rhizome Powder
- Asian Ginseng Root and Rhizome Dry Extract
- American Ginseng Root and Rhizome
- American Ginseng Root and Rhizome Powder
- American Ginseng Root and Rhizome Dry Extract
2018-2019 Revised Botanical Standards

Submitted to PF

- Chrysanthemum Flower
- Chrysanthemum Flower Powder
- Chrysanthemum Flower Dry Extract
- Wild Chrysanthemum Flower
- Wild Chrysanthemum Flower Powder
- Wild Chrysanthemum Flower Dry Extract
## 2018-2019 New and Revised Non-Botanical Standards

### New - Submitted to PF
- Cobamamide
- Citicoline
- Calcium Magnesium Citrate
- D-*chiro*-Inositol
- Fish Oil Omega-3 Ethyl Esters Concentrate
- Multivitamin Chewable Gels (Gummies)
- Creatine
- PQQ

### Revisions – Submitted to PF
- L-α-glycerylphosphorylcholine
- Cod Liver Oil
- Cod Liver Oil Capsules
- Lactase
- Cholecalciferol
- Ergocalciferol
- Lactase
- Taurine (Revision bulletin)
2018-2019 Non-Botanical Modernizations

- Calcium with Vitamin D Tablets
- Calcium and Vitamin D with Minerals Tablets
- Oil-Soluble Vitamins Tablets
- Oil-Soluble Vitamins with Minerals Tablets
- Water-Soluble Vitamins Tablets
- Water-Soluble Vitamins with Minerals Tablets
- Oil- and Water-Soluble Vitamins Tablets
- Oil- and Water-Soluble Vitamins with Minerals Tablets
- Vitamin A Tablets
Prioritization for 2020

- DSHM strategic direction
  - Support International markets
    - Botanicals
    - Mineral salts
  - Support DSVP & DIVP
2020 Plan

- Botanicals will be prioritized and added to the ongoing work plan
- Many non-botanicals already in work plan
- Potential new non-botanical monographs will be prioritized
- Input from DSVP program
- Work plan for 2020 will be informed by prioritization activities
International Markets - Botanicals

- Botanicals identified as of interest in Brazil, South Asia and East Asia were analyzed for the number of commercial products (on store shelves with DS labeling)

- Sales of products in US were added

- # of products using these botanicals was identified

- Information will be used for prioritization using model

- Further information from India, China, Korea added to prioritization
New Botanicals - Ongoing Development 2019-2020

- Aloe vera Leaf Juice Concentrate
- Aloe vera Leaf Dry Juice Preparation
- Cranberry Fruit Juice Concentrate
- Cranberry Fruit Juice Dry Extract
- Cranberry Fruit Dry Juice
- Pomegranate Fruit Dry Extract
- Broccoli Seed Extract
- Black Cumin Cold Pressed Seed Oil
- Lutein esters
- Sour Jujube Seed
- Sour Jujube Seed Powder
- Sour Jujube Seed Dry Extract
- White Peony Root
- White Peony Root Powder
- White Peony Root Dry Extract
- Moringa Leaf Extract
- Santalum album oil
- Mangifera indica bark
FY 2020 – Botanicals - planned

- *Cinnamomum verum* bark family
- *Cinnamomum cassia* bark family
- *Saposhnikova divaricate* root family
- *Gastrodia elata* root family
- Cranberry whole fruit powder
- Cranberry pomace extract
- Green tea extract
- Feverfew Extract
- Tocotrienols
- *Angelica gigas* root
- Ajowan Fruit family
Non-Botanicals

High Priority

- Vitamins
- Proteins
- Probiotics
- Amino acid modernizations
- Mineral Salts
New Non-Botanicals - Ongoing Development 2019-2020

- Oil soluble Vitamin Premixes
- Water Soluble Vitamin Premixes
- Ascorbate mineral salts (Ca modernization, Mg)
- Choline Citrate
- SAMe butanedisulfonate
- Astaxanthin esters capsules
- Lysine
- General chapter <582> LC/MS methods for water soluble vitamin assay

- Water soluble vitamins preparation
- *Lactobacillus reuterii* 1E1
- *Bifidobacterium longum* BI-05
- *Bifidobacterium bifidum* BB-06
- Hydrolyzed collagen
- Native collagen
- Hydroxymethylbutyrate and CaHMB
- General Chapter <2750> revision GMP for dietary supplements
FY2020 Non- Botanicals Planned

- General Chapter <2740> GMP for dietary ingredients
- Rice protein
- Keratin (sponsor needed)
- *Lactobacillus* spp.
- *Bacillus coagulans* – 2 strains
- Ascorbate salts (Mn, Zn)
- Phytosterol esters
- Citrulline
- Salmon Oil
- Glycinate, Bisglycinate mineral salts (Ca, Cu, K, Fe, Mg, Mn, Zn)
- Modernization of amino acid methods
- Levocarnitine tartrate
New Initiative?

- General Notice or General Chapter on multi-ingredient dosage forms
  - Methods for assay
  - Matrix effects
  - Rational combinations
  - Potential Roundtable to discuss at SSW
For More Information

- **https://www.usp.org/dietary-supplements/resources** - link to the quarterly dietary supplement e-newsletter

- **https://www.usp.org/dietary-supplements-herbal-medicines/development-process** - link to monograph development process for information about the standards development process and list of prioritized monographs

For suggestions for monograph revisions or development of new monographs e-mail to kit.goldman@usp.org
Thank You

Empowering a healthy tomorrow