

USP Dietary Supplements Stakeholder Forum
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New Standards and Prioritization for Development and 2018-2019 Plans

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Agenda

- ▶ New Monographs 2017- 2018
- ▶ Revisions 2017-2018
- ▶ Ongoing Monographs 2018-2019
- ▶ Prioritization Process
- ▶ 2018-2019 Plans



2017- 2018 New and Revised Standards - DSHM



New Botanicals – Submitted to PF

- ▶ Bitter Orange Flavonoid Dry Extract
- ▶ Chrysanthemum Flower
- ▶ Chrysanthemum Flower Dry Extract
- ▶ Chrysanthemum Flower Powder
- ▶ Chinese Skullcap Root
- ▶ Chinese Skullcap Root Dry Extract
- ▶ Chinese Skullcap Root Powder
- ▶ Guarana Seed
- ▶ Guarana Seed Dry Extract
- ▶ Guarana Seed Powder
- ▶ *Terminalia chebula* fruit
- ▶ *Terminalia chebula* fruit powder
- ▶ *Terminalia chebula* fruit dry extract
- ▶ Indian barberry stem
- ▶ Indian barberry stem powder
- ▶ Indian barberry stem dry extract
- ▶ Bael Tree fruit
- ▶ Bael Tree fruit powder
- ▶ Bael Tree fruit dry extract

2017- 2018 New and Revised Standards - DSHM



New Non-Botanicals Submitted to PF

- ▶ Vitamins with Minerals Oral Powder
- ▶ Creatine (resubmission)
- ▶ Conjugated Linoleic Acids – Triglycerides
- ▶ Cyanocobalamin Chewable Gels
- ▶ Pyrroloquinoline quinone disodium
- ▶ Omega-3 Free Fatty Acids

Botanicals submitted for HMC

- ▶ *Cullen corylifolium* fruit
- ▶ *Cullen corylifolium* fruit dry extract
- ▶ *Cullen corylifolium* fruit powder
- ▶ *Vitex negundo* leaf
- ▶ *Vitex negundo* leaf powder
- ▶ *Vitex negundo* leaf dry extract



Botanicals submitted for Omission

- ▶ Belladonna Leaf
- ▶ Belladonna Extract
- ▶ Belladonna Extract Tablets
- ▶ Belladonna Tincture
- ▶ Digitalis
- ▶ Powdered Digitalis
- ▶ Digitalis capsules
- ▶ Digitalis Tablets



Revisions - Botanicals

- ▶ Tienchi Ginseng Root and Rhizome
- ▶ Tienchi Ginseng Root and Rhizome Dry Extract
- ▶ Tienchi Ginseng Root and Rhizome Powder
- ▶ Witch Hazel (Botanical drug)
- ▶ Ashwaganda Root
- ▶ Ashwaganda Root Powder
- ▶ Ashwaganda Root Powder Extract
- ▶ Ginkgo capsules
- ▶ Ginkgo Tablets
- ▶ Salix Species Bark
- ▶ Salix Species Bark Powder
- ▶ Salix Species Bark Dry Extract
- ▶ Tienchi Ginseng Root and Rhizome Dry Extract capsules
- ▶ Tienchi Ginseng Root and Rhizome Dry Extract Tablets
- ▶ Tienchi Ginseng Root and Rhizome Powder capsules
- ▶ Tienchi Ginseng Root and Rhizome Powder tablets



Revisions: Non-Botanicals

- ▶ Beta carotene capsules
- ▶ Lycopene
- ▶ Lycopene preparation
- ▶ Tomato extract containing Lycopene
- ▶ Vitamin A
- ▶ Vitamin A capsules
- ▶ Vitamin A Oral Liquid preparation
- ▶ Vitamin A Tablets
- ▶ Vitamin E
- ▶ Vitamin E capsules
- ▶ Vitamin E preparation
- ▶ Astaxanthin esters
- ▶ Ascorbic acid chewable gels
- ▶ Cholecalciferol chewable gels
- ▶ Menaquinone-7 ingredient
- ▶ Menaquinone-7 Preparation

Ongoing Development 2018- 2019



New Non-Botanicals

- ▶ Oil soluble Vitamin Premixes
- ▶ Water Soluble Vitamin Premixes
- ▶ Multivitamin Chewable Gels
- ▶ Citicoline
- ▶ Magnesium bisglycinate
- ▶ Tocotrienols
- ▶ Calcium Magnesium Citrate
- ▶ Choline Citrate
- ▶ SAMe Butanedisulfonate
- ▶ D-Chiro-Inositol
- ▶ Lysine
- ▶ Fish Oil Omega-3-Acid Concentrate Ethyl esters
- ▶ Cobamamide
- ▶ Probiotics
- ▶ Proteins

Ongoing Development 2018- 2019



Botanicals

- ▶ Cranberry Family
- ▶ Pomegranate Family
- ▶ Coptis Species Rhizome Family
- ▶ Japanese Sophora Flower Family
- ▶ Pummelo Peel Family
- ▶ Ginger (CO₂ extract)
- ▶ Broccoli Seed Extract
- ▶ Psyllium Husk capsule

Prioritization for 2019



- ▶ Model
 - Presented SF 2017
 - Feasibility of monograph development
 - Factors: availability of scientific information, monographs in other pharmacopeias, NDI notifications, GRAS, ODI status, availability of RS candidates
 - Impact
 - Factors: Interest from regulatory agencies, interest from public (sales, marketing analysis), adulteration, safety issues.
- ▶ Model updated with new streams from Herbal Medicines with potential as DS

DSHM strategic direction



- ▶ USP up-to-date
- ▶ Support International markets
- ▶ Botanicals being considered as Herbal Medicines in other regulatory systems
- ▶ Non-botanicals: Focus on probiotics, proteins and new dosage forms (Ch. Gels)

International Markets and Traditional Medicines - 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 to prioritize in model

Non-Botanicals



High Priority

- ▶ Dietary Proteins
 - Collagen
 - Vegetable proteins
 - Whey
- ▶ Probiotics
- ▶ Amino acid modernizations
- ▶ Non-botanicals identified as high priority by international markets

- ▶ Work plan for 2019 will be informed by prioritization activities
- ▶ Carry over ongoing activities
- ▶ Continue Focus on USP up-to-date
- ▶ Many high priority ingredients already in work plan
- ▶ Response to Stakeholder requests

Questions



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