

New Standards and Prioritization for Development, Non-Botanical and Botanical Standards

Gabriel Giancaspro, Ph.D.

Vice President, Foods Dietary Supplements and Herbal
Medicines

María Monagas, Ph.D.

Scientific Liaison, Dietary Supplements and Herbal
Medicines

1. FISCAL YEARS 2016 AND 2017 PRODUCTION

- New Monographs
- Revisions /Modernizations
- General Chapters

2. EC PORTFOLIO

- New Consolidated List of Monographs
 - Top 50-Botanicals
 - Non-Botanicals Ingredient and Dosage Forms

3. PRIORITY TOOL

- Updates: EC feedback on Scientific Feasibility and Public Health Impact
- Changes proposed in variables, scores and weights
- Analysis of the Consolidated List

1. FISCAL YEARS 2016 AND 2017 PRODUCTION

- **Non-Botanicals**

- **New Monographs**

Vitamins

- COBAMAMIDE
- CHOLECALCIFEROL TABLETS
- MENAQUINONE-4
- ASCORBIC ACID CHEWABLE GELS
- CHOLECALCIFEROL CHEWABLE GELS

Minerals

- CALCIUM CITRATE MALATE

Amino Acids

- CITRULLINE

Specialties

- CREATINE
- CHIA SEED OIL
- PLANT STANOL ESTERS
- ANNATTO SEED TOCOTRIENOLS EXTRACT
- CONJUGATED LINOLEIC ACIDS-FREE FATTY ACIDS
- CONJUGATED LINOLEIC ACIDS-TRIGLYCERIDES
- CITICOLINE SODIUM
- CAROTENES

Probiotics

- LACTOBACILLUS ACIDOPHILUS LA-14
- LACTOBACILLUS ACIDOPHILUS NCFM
- LACTOBACILLUS RHAMNOSUS HN001
- LACTOBACILLUS PARACASEI LPC-37
- BIFIDOBACTERIUM ANIMALIS SSP. LACTIS
- BACILLUS COAGULANS GBI-30, 6086
- BACILLUS COAGULANS GBI-30, 6086 CAPSULES

- **Stimuli Articles**

FACTORS TO CONSIDER FOR ESTABLISHING OVERAGES OF DIETARY INGREDIENTS IN DIETARY SUPPLEMENTS

- **Non-Botanicals**

- **Revision/Modernization**

Vitamins

- CYANOCOBALAMIN
- METHYLCOBALAMIN
- METHYLCOBALAMIN TABLETS
- NIACIN EXTENDED-RELEASE TABLETS
- THIAMINE HYDROCHLORIDE TABLETS
- RIBOFLAVIN TABLETS
- ASCORBIC ACID INJECTION
- CALCIUM L-5-METHYLTETRAHYDROFOLATE TABLETS
- CALCIUM L-5-METHYLTETRAHYDROFOLATE CAPSULES

Minerals

- TRIBASIC CALCIUM PHOSPHATE
- POTASSIUM GLUCONATE
- POTASSIUM CITRATE EXTENDED-RELEASE TABLETS

Amino Acids

- CYSTEINE HYDROCHLORIDE
- ASPARTIC ACID
- LEUCINE
- ISOLEUCINE
- VALINE
- METHIONINE
- GLYCINE
- TAURINE

Specialties

- OMEGA-3 ACIDS ETHYL ESTERS
- OMEGA-3-ACID ETHYL ESTERS CAPSULES
- RUTIN
- CRYPTHECODINIUM COHNII OIL
- BETA CAROTENE PREPARATION
- FLAX SEED OIL
- CHONDROITIN SULFATE SODIUM, SHARK

- **Revision of General Chapters**

- <91> CALCIUM PANTOTHENATE ASSAY
- <115> DEXPANTHENOL ASSAY

- **Botanicals**

- **New Monographs**

- TIENCHI GINSENG ROOT AND RHIZOME POWDER TABLETS
- SALIX SPECIES BARK
- SALIX SPECIES BARK POWDER
- SALIX SPECIES BARK DRY EXTRACT
- CINNAMOMUM CASSIA TWIG
- CINNAMOMUM CASSIA TWIG POWDER
- ST. JOHN'S WORT FLOWERING TOP DRY EXTRACT CAPSULES
- ST. JOHN'S WORT FLOWERING TOP DRY EXTRACT TABLETS
- COFFEE FRUIT DRY EXTRACT
- ELEUTHERO ROOT AND RHIZOME POWDER CAPSULES
- ECHINACEA SPECIES DRY EXTRACT CAPSULES
- ECHINACEA SPECIES DRY EXTRACT TABLETS
- RHODIOLA CRENULATA ROOT AND RHIZOME
- RHODIOLA CRENULATA ROOT AND RHIZOME POWDER
- RHODIOLA CRENULATA ROOT AND RHIZOME DRY EXTRACT
- TANGERINE PEEL
- TANGERINE PEEL POWDER
- TANGERINE PEEL DRY EXTRACT
- COIX SEED
- COIX SEED POWDER
- ECHINACEA SPECIES POWDER CAPSULES
- EUROPEAN ELDER BERRY DRY EXTRACT
- VALERIAN ROOT DRY EXTRACT CAPSULES
- VALERIAN ROOT POWDER CAPSULES
- VITEX NEGUNDO LEAF
- VITEX NEGUNDO LEAF POWDER
- VITEX NEGUNDO LEAF DRY EXTRACT
- SICHUAN LOVAGE RHIZOME
- SICHUAN LOVAGE RHIZOME POWDER

- **Stimuli Articles**

THE ADVISABILITY AND FEASIBILITY OF DEVELOPING USP STANDARDS FOR MEDICAL CANNABIS

- **Botanicals**

- **Revision/Modernization**

- POWDERED ELEUTHERO (Future: ELEUTHERO ROOT AND RHIZOME POWDER)
- POWDERED ELEUTHERO EXTRACT (Future: ELEUTHERO ROOT AND RHIZOME DRY EXTRACT)
- ELEUTHERO (Future: ELEUTHERO ROOT AND RHIZOME)
- ST. JOHN'S WORT
- POWDERED ST. JOHN'S WORT
- POWDERED ST. JOHN'S WORT EXTRACT
- POWDERED ASHWAGANDHA ROOT EXTRACT
- ASHWAGANDHA ROOT
- POWDERED ASHWAGANDHA ROOT
- MENTHOL
- COLCHICINE
- POWDERED DECAFFEINATED GREEN TEA EXTRACT

- DIGOXIN
- CARAWAY
- CARDAMOM SEED
- CASCARA SAGRADA
- ALOE
- CHOCOLATE
- DIGITALIS
- IPECAC
- MYRRH
- PLANTAGO SEED
- PODOPHYLLUM
- RAUWOLFIA SERPENTINA
- BELLADONNA LEAF
- SENNA LEAF
- SENNA PODS
- STORAX
- VANILLA
- WITCH HAZEL
- POWDERED DIGITALIS

- **Revision of General Chapters**

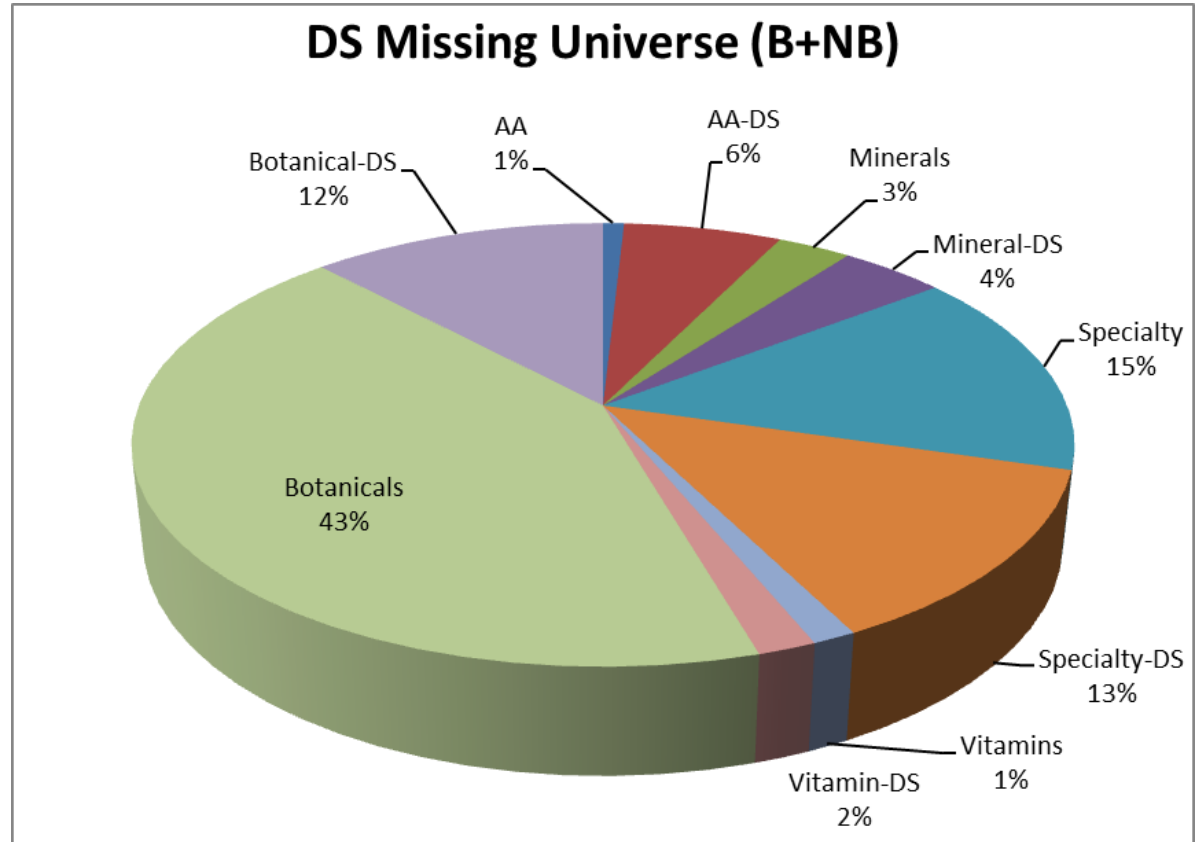
<2251> SCREENING FOR UNDECLARED DRUGS AND DRUG ANALOGUES

2. EC PORTFOLIO

- USP Missing Universe of DS

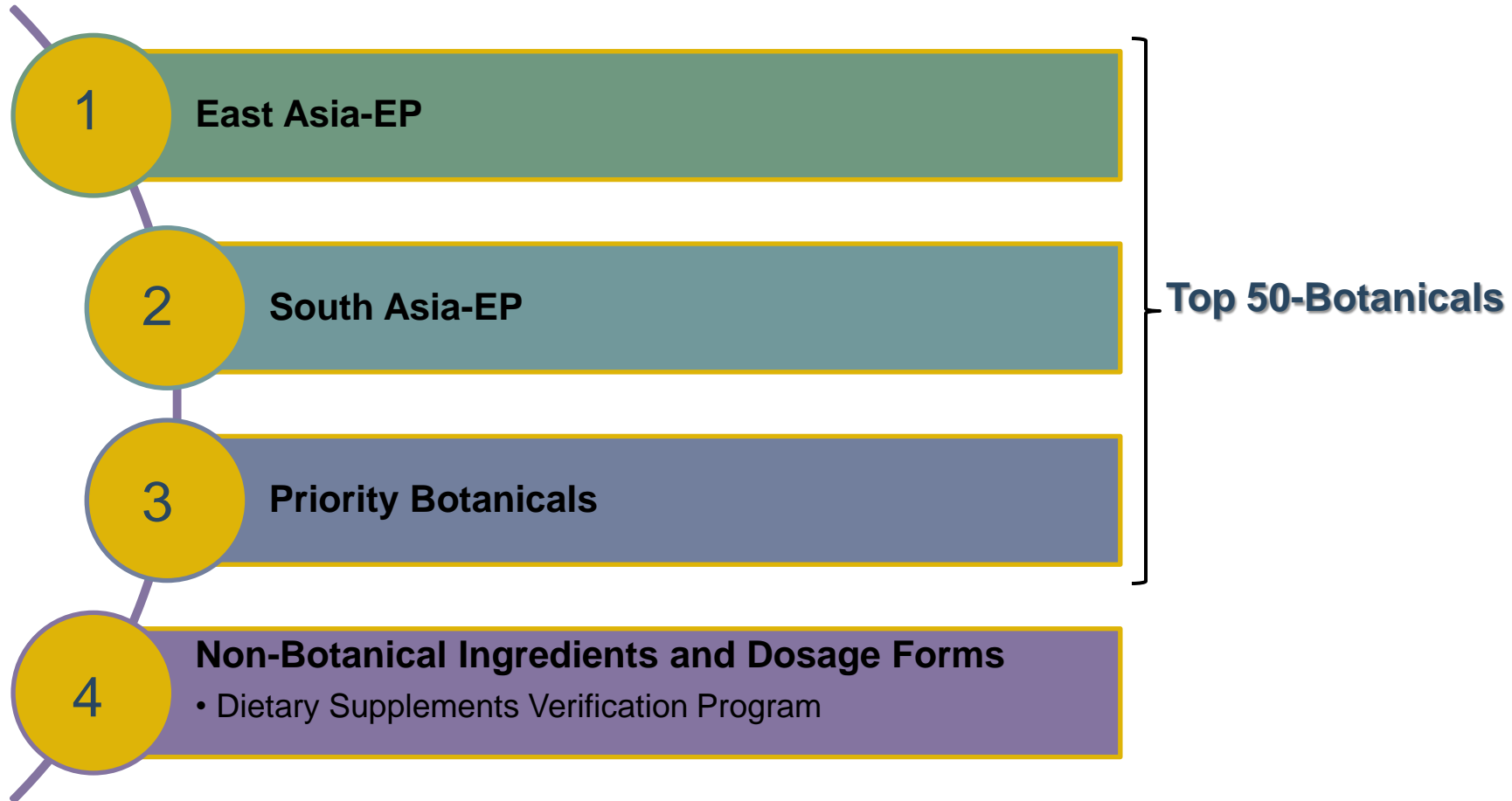
- Identification of Candidate Monographs

- Nutritional Business Journal-100 top List
- Herbal Gram Report
- Trade Journals/Newsletters
- DS Products Catalogs
- Mintel
- USP Marketing Department and DS Verification Program

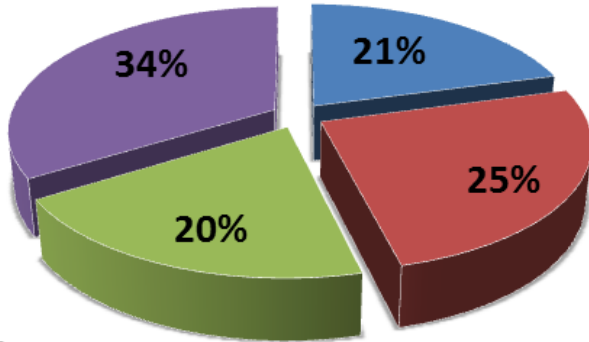


Ingredients	146
Dosage forms	87
TOTAL	233

New Consolidated List of Monograph topics

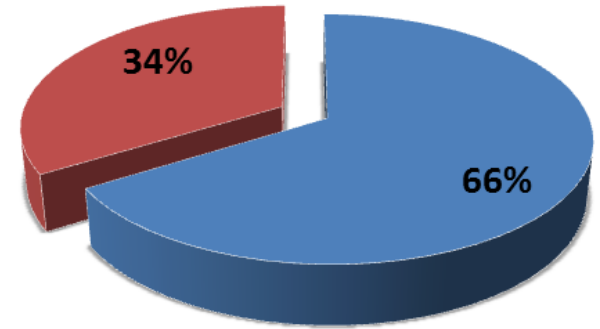


New Consolidated List of Monograph topics



- South Asia-EP
- East Asia-EP
- Other Priority Botanicals
- Non Botanical Ingredients and Dosage Forms

South Asia-EP	27
East Asia-EP	33
Other Priority Botanicals	26
Non Botanical Ingredients and Dosage Forms	44
TOTAL	130



- Top-Botanicals
- Non Botanical Ingredients and Dosage Forms

Monograph list per category is located in Annex I

3. PRIORITY TOOL

- Original version

Can we do it?

Probability

Regulatory Information

- NDI
- FDA-GRAS
- Self-GRAS
- Grandfathered List
- EU Novel Food Approval
- DMF

Monograph type

- Botanical
- Non-botanical
- Overlapping with foods/excipients
- Overlapping with chemical medicines (drugs)

Scientific feasibility

- Existence of specific ID tests
- Existence of Assay tests
- Lab Resources Needed

Should we do it ?

Impact

Public Health

- Adulteration/ Safety

Regulatory Relief

- Existence of EP, BP or JP Monograph

Demand/Sales

- Existence/position on the NBJ Top 100 DS list
- Existence/position on the HerbalGram list
- USP Marketing and DS Verification awareness

Number of products in market

- DS Label Database (NIH)-USA data
- Mintel Database-Global data

- **Probability**

Probability

Regulatory
Information

- NDI
- FDA-GRAS
- Self-GRAS
- Grandfathered List
- Other (EU Novel Food Approval/DMF)**

Monograph
type

- Overlapping with foods/excipients/**drugs**
- Overlapping with HM-SA and EA Panels**

Scientific
feasibility

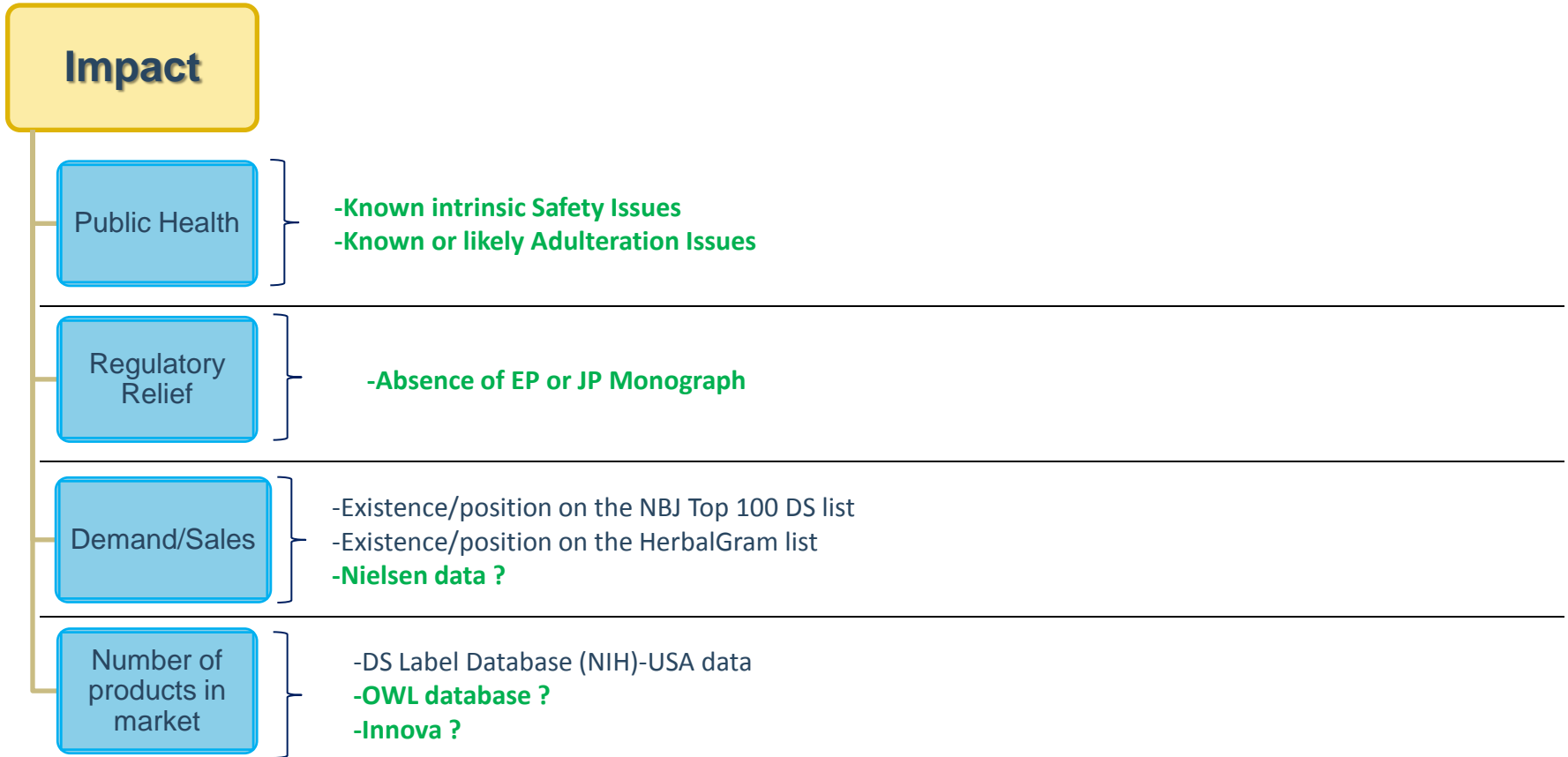
- Existence of specific ID tests
- Existence of Assay tests
- Lab Resources Needed
- Reference Standard Availability**
- Sponsor Availability**

PRIORITIZATION TOOL: UPDATES

- Probability

Criteria	Sub-Criteria	Score	Weight
Regulatory Information	-NDI	10	30%
	-FDA-GRAS	7	
	-Grandfathered List	1	
	-Other (EU Novel /DMF)	1	
	-Self-GRAS	4	
Monograph type	-Foods/excipients/drugs	7	20%
	-HM SA and ES Panel	4	
Scientific feasibility	-Lab Resources Needed	-7	25%
	-Existence of specific ID tests	7	
	-Existence of Assay tests	10	
	-RS Availability	4	
Sponsor/ Donor	-Sponsor Availability	10	25%

Total Probability Score = $\sum (\text{Score} \times \text{Weight})$



PRIORITIZATION TOOL: UPDATES

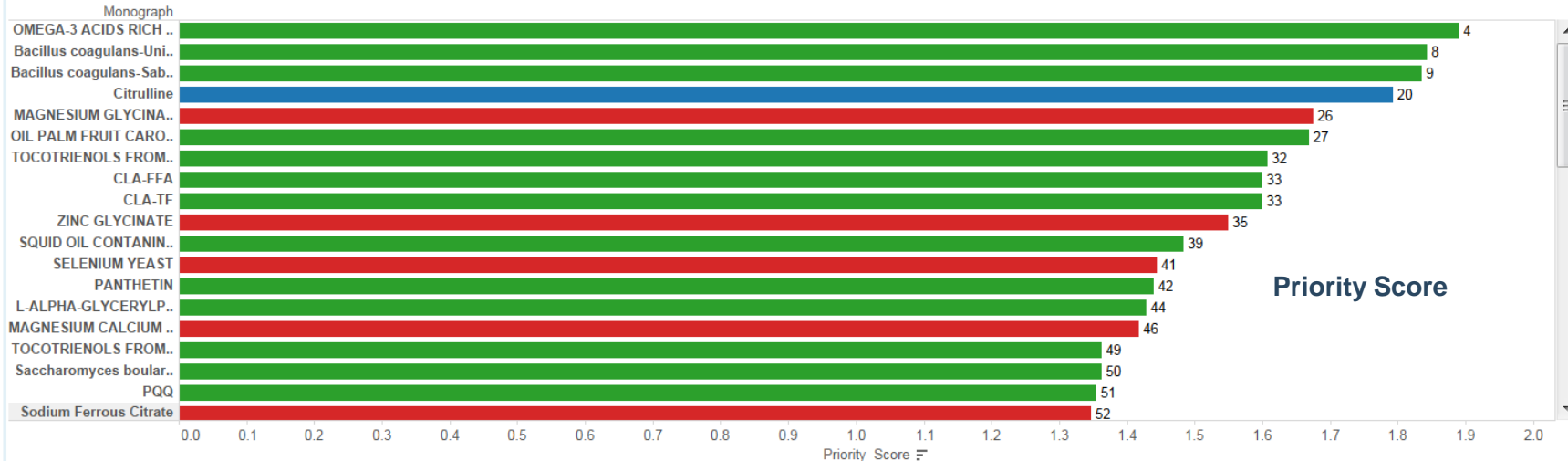
- **IMPACT**

Criteria	Sub-Criteria	Score	Weight
Public Health	-Known Intrinsic Public Health -Known or Likely Adulteration	10 7	20%
Regulatory Relief	-Absence of EP or JP Monograph	10	5%
Demand/Sales	-Existence/position on the NBJ Top 100 DS list -Existence/position on the HerbalGram list	1-4-7-10 (Brackets set in quarters from 1-100 position)	20%
Number of products in market	-DS Label Database (NIH)-USA data	1-4-7-10 (Brackets set from 10-1000 products)	25%

Total Impact Score = $\sum (\text{Score} \times \text{Weight})$

Calibrators: Vitamins, Minerals and Specialties

Updated DS Priority

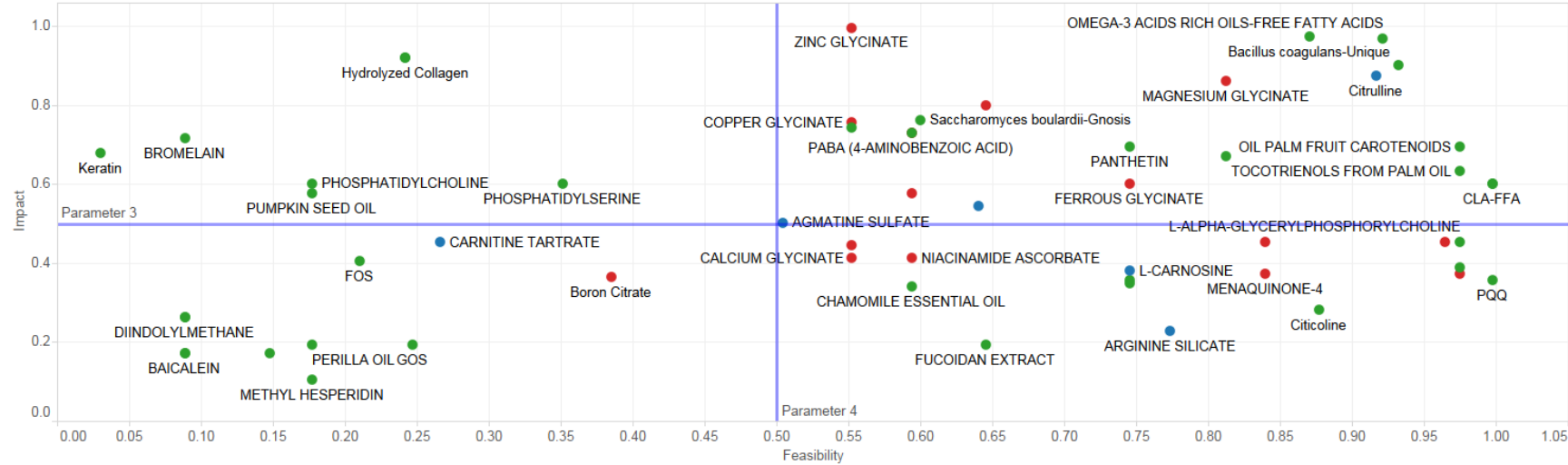


Category1
(Multiple values)

Category1

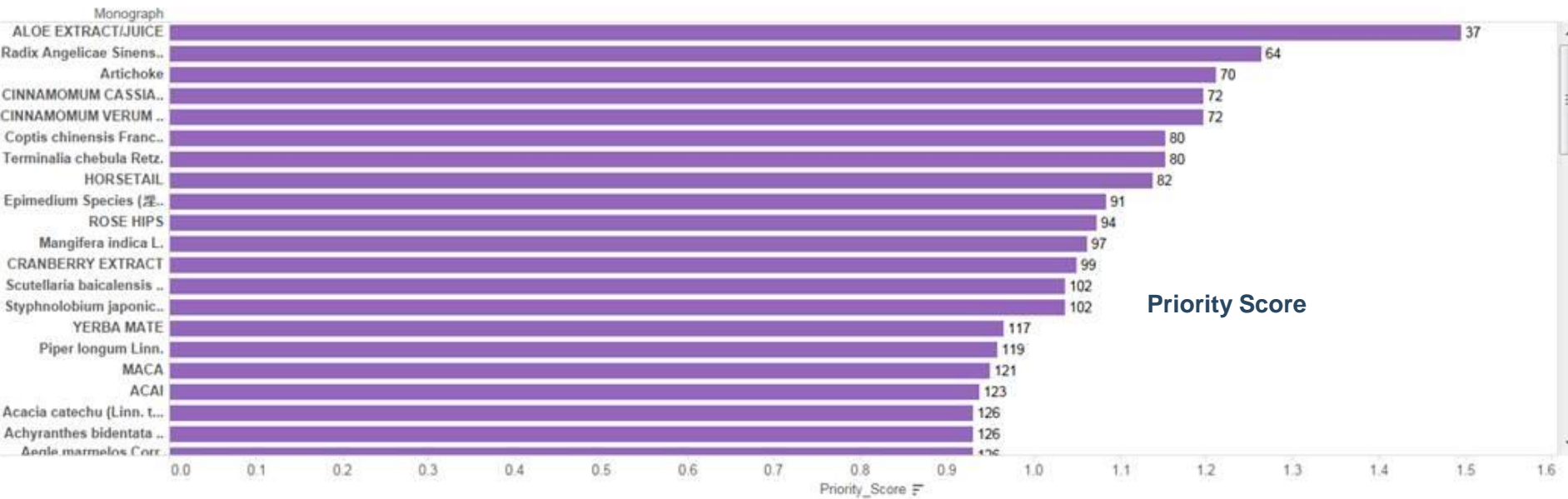
- Aminoacids
- Specialty-Evidence..
- Vitamins and Miner..

Original DS Priority



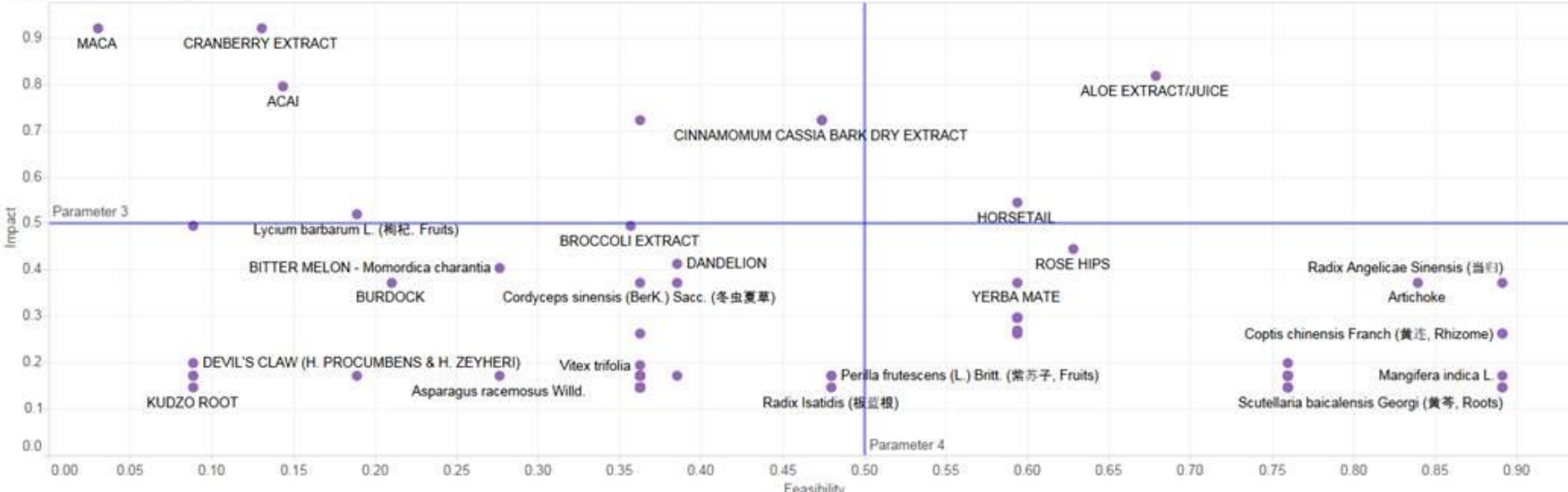
Top 50-Botanicals

Updated DS Priority

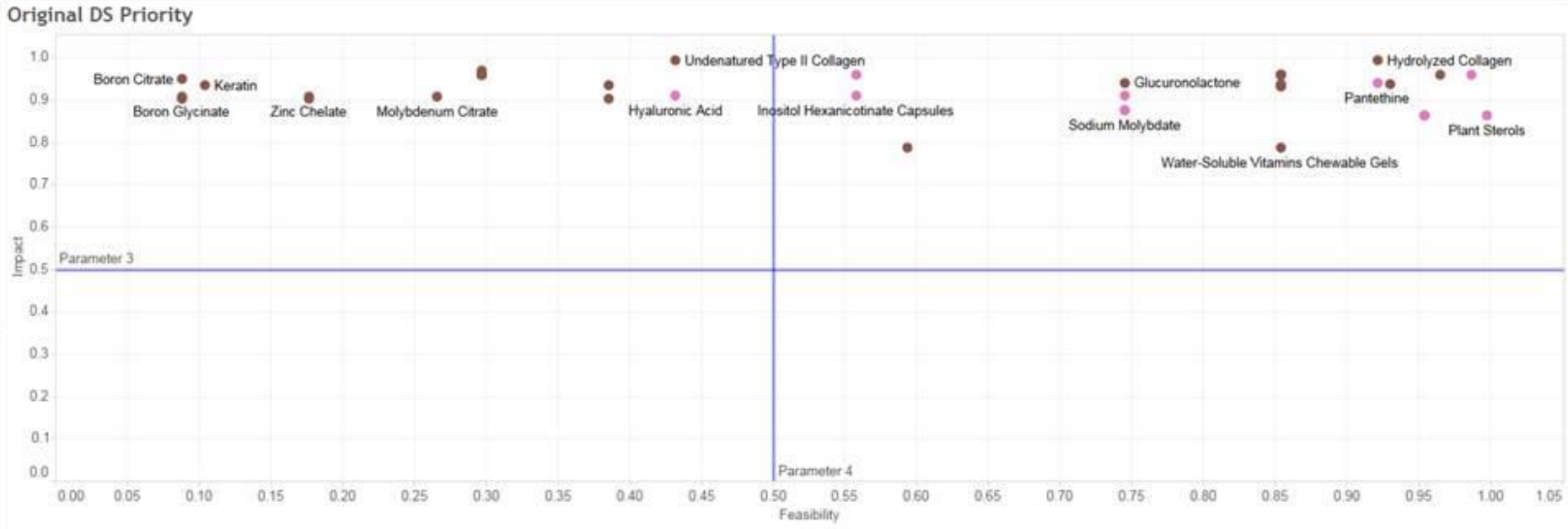
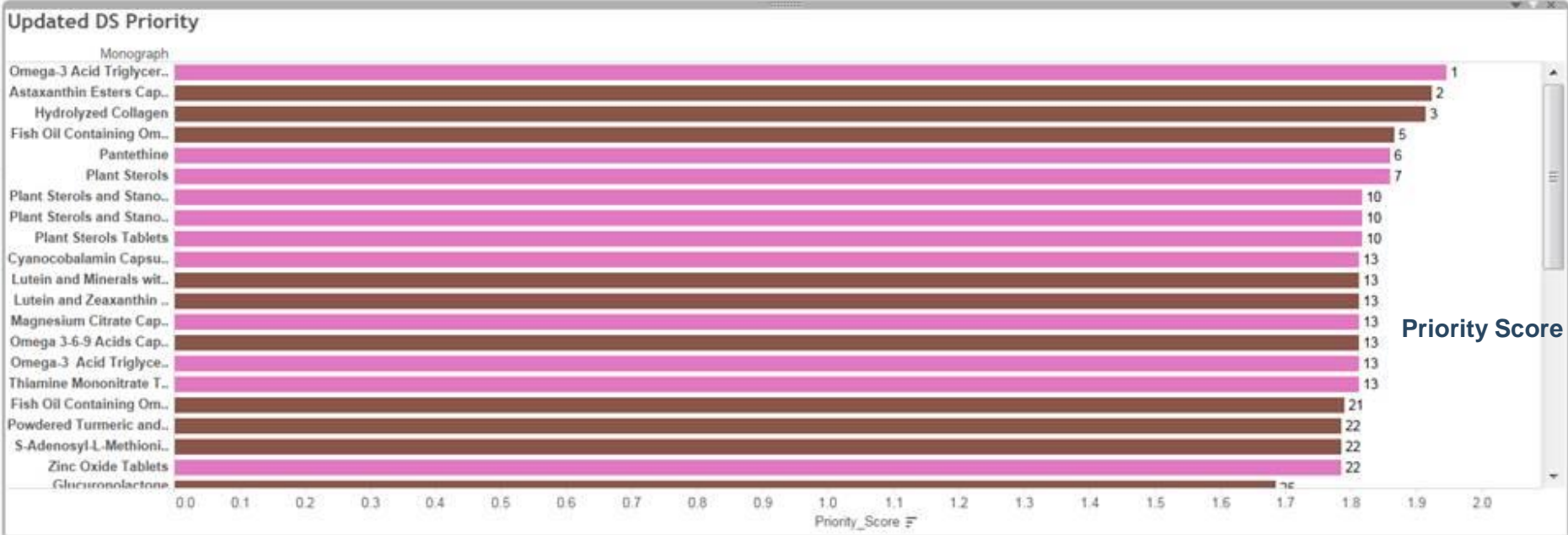


Priority Score

Original DS Priority



Non-Botanical Ingredients and Dosage Forms (DSVP)



FY17 Q4 New Monographs, Modernizations and Revisions

- Bitter Orange Flavonoids Extract
- Guarana Seed
- Guarana Seed Powder
- Guarana Seed Extract
- Calcium Magnesium Citrate
- Menaquinone 7 Revision
- Menaquinone Preparation Revision
- Histidine Revision
- D-Chiro-Inositol
- Omega-3 Free Fatty Acids
- Tocotrienols
- Leucine modernization
- Isoleucine modernization
- Krill Oil revision
- Cod Liver Oil Revision
- Vitamins and Mineral Powders (Unicef)
- Krill Oil Capsules Revision
- Krill Oil Delayed Release Capsule Revision
- Rhodiola rosea Capsules/Tablets Revision
- Eleuthero Finished Products Revision
- Cyanocobalamin Chewable Gels
- B. coagulans
- L. fermentum

- GC<2040> Revision
- GC<64> Probiotics

Q1

- Magnesium Glycinate
- Plant Sterols
- Plant Sterols and Stanols Esters
- Omega-3 Acids EE60/Concentrate
- Cobamamide
- Collagen Type II
- Hydrolyzed Collagen
- HVP Chelate
- Whey Protein
- Vitamin premixes (DSM)
- Ginkgo Capsules/Tablets Revision
- Red Clover Tablets Revision
- SAMe 1,4-butanedisulfonate
- Sodium Selenate
- Sodium Molybdate
- Sodium Selenite
- PQQ Sodium
- Choline Citrate
- Pomegranate Extract
- Cola

Q2

- Inositol Hexanicotinate
- Inositol Hexanicotinate Capsules
- Thiamine Mononitrate Tablets
- Cyanocobalamin Capsules
- Zinc Oxide Tablets
- Pantethine
- Levocarnitine Tartrate
- Agmatine Sulfate (?)
- Salmon Oil
- Lutein and Zeaxanthin
- Astaxanthin ester capsules
- Maca

Q3

- Magnesium Citrate Capsules
- Omega-3 Acid Triglyceride Preparation
- Omega-3 Acid Triglyceride Preparation Chewable Gels
- Omega-3 Acid Triglycerides with Vitamin D Capsules
- Plant Sterols Tablets
- Plant Sterols and Stanols Esters Capsules
- Fe Glycinate
- Zn Glycinate
- Phytosterols
- Omega-3 Acids Ethyl Ester- *DS Specification*
- GABA

Q4

- Cranberry extract
- Squid oil with omega 3
- Molybdenum citrate

FY18 Modernizations, New GCs and Major GC Revisions

Modernizations

- Oil and Water Soluble Vitamins Capsules
- Oil and Water Soluble Vitamins Tablets
- Oil Soluble Vitamins Capsules
- Water Soluble Vitamins Capsules
- Oil Soluble Vitamins Tablets
- Water Soluble Vitamins Tablets
- Arginine
- Lysine
- Cholecalciferol
- Ergocalciferol

GC

- <171> Vitamin B12
- <582> Multivitamin Determinations
- <561> Articles of Botanical Origin
- <2750> Update to meet CFR 117
- Water Activity

Points for Discussion

- Approach to identify the “top-50” based on our knowledge
- Parameters for impact and probability and their relative weights for the decision making
- Sources of information for the parameters
- Information gaps for several parameters, such as analytical methods data, regulatory status, etc.
- Challenges when we do not have sponsor data on high priority ingredients
- How to reduce the complexity of the analysis without losing the information from important variables
- Next steps ??



Questions



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Thank You