

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

503A List 1 – Bulk Drug Substances Under Evaluation¹

7 Keto Dehydroepiandrosterone (DHEA)	Inositol
Acetyl L Carnitine/Acetyl-L-carnitine hydrochloride	Kojic Acid
Acetyl-D-Glucosamine	L-Citrulline
Alanyl-L-Glutamine	Methylcobalamin
Aloe Vera/ Aloe Vera 200-1 Freeze Dried	MSM (methylsulfonylmethane)/MSM-1
Alpha Lipoic Acid/Alpha Lipoic Acid-1	Nettle leaf (Urtica dioica subsp. dioica leaf)
Ammonium Tetrahydroxymolybdate	Nicotinamide Adenine Dinucleotide (NAD)
Artemisia Artemisinin	Nicotinamide Adenine Dinucleotide Disodium Reduced (NADH)
Astragalus Extract 10-1	Ornithine Hydrochloride
Beta Glucan (1,31,4-D)	Oxitriptan
Boswellia	Phosphatidylserine
Brilliant Blue	Piracetam
Bromelain	Pregnenolone
Cantharidin	Pyridoxal 5-Phosphate Monohydrate
Cesium Chloride	Pyruvic Acid
Cetyl Myristoleate Oil	Quercetin/ Quercetin Dihydrate
Choline Chloride	Quinacrine Hydrochloride
Chondroitin Sulfate	Resveratrol
Chrysin	Ribose (D)
Curcumin	Rubidium Chloride
Deoxy-D-Glucose	Silver Protein Mild
Dichloroacetic acid	Squaric Acid Dibutyl Ester (aka dibutyl squarate)
Diindolylmethane	Tea tree oil (Melaleuca alternifolia leaf oil)
Dimercapto-1-propanesulfonic acid (DMPS)	Thymol Iodide
Diphenylcyclopropenone (DPCP)	Tranilast
EGCg	Trichloroacetic Acid
Germanium Sesquioxide	Ubiquinol 30% Powder
Glutaraldehyde	Vanadium
Glutathione	Vasoactive Intestinal Peptide
Glycoaminoglycans	
Glycolic Acid	
Glycyrrhizin	

¹These are substances that do not appear on any other lists.

503A List 2: Bulk Drug Substances that Raise Safety Concerns

Domperidone

503A List 3: Bulk Drug Substances Nominated Without Adequate Support

Acacia Gum, Spray-Dried Powder	Bichloroacetic Acid
Acetanilide	Bipeptide Biocosmetic
Acetone Sodium Bisulfite	Boswellia Serrata Extract
Acetyl Hexapeptide-3	Bronopol
Acidophilus Lactobacillus	Buffer Solution, pH Buffer Acid
Adenosine-5-triphosphate disodium salt	Ca EDTA
Alcloxa	Calcium Alginate
Aldioxa	Calcium Folate
Aldosterone	Calcium glycinate
Alfalfa	Capsules, Empty Gelatin Vegetable
Alfalfa leaves	Carbamide
Aliphatic Polyesters	Carbazochrome
Almadrate sulfate	Carbimazole
Aloin	Carbolic Acid
Alpha Ketoglutaric acid	Caustic Potash
Alumina Powder, hydrated	Caustic Soda
Aluminum acetate	Cedarwood Essential Oil
Aluminum chloride hexahydrate	Ceratonia
Aluminum phosphate	Ceresin
Aminacrine Hydrochloride	Cetrimide
Ammonium Alginate	Cetyl Myristoleate Powder
Ammonium bromide	Chlorhexidine Diacetate Hydrate
Ammonium hydroxide	Choline bitartrate
Ammonium tetrathiomolybdate	Choline magnesium trisalicylate
Anise seed	Chromium glycinate
Argentyn	Coenzyme Q10
Aromatic powder	Coenzyme Q50
Asafetida	Colophony
Asclepias tuberosa	Copper
Ascorbic acid corn	Copper Bisglycinate
Ascorbic acid non-corn	Copper Hydrosol
Asefetida Tincture	Creatine, Mmonohydrate
Asparagus	Cucumber Melon Fragrance
Aspergillus oryza enzymes	Decyl Oleate
Barosma	Decylmethylsulfoxide
Beachwood creosote	Diaminopyridine (3,4-)
Bean	Difluoroethane
Betamechlomathasone	Diindolymethane
Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate	Dimercaptosuccinic acid (DMSA)
	Dimethyl Ether (aka Methoxymethane)

Dimethyl Ketone
Dimethyl Phthalate
Dimethyl Sulfone
Dimethylacetamide
Dimethylaminoethanol
Bitartrate
Dimethylaminoethanol Complex
Dimethylglycine Hydrochloride
Dinitrochlorobenzene
Dipropylene Glycol
Disodium Hydrogen Phosphate
Disodium Phosphate
DL-Phenylalanine
Dodecyl Gallate
Edetate tetrasodium
tetrahydrate
EDTA
Ethyl Lactate
Ethylene Vinyl Acetate
Ethylenediaminetetraacetic Acid
Disodium Salt
Ferric Subsulfate
Ferric sulfate hydrate
Folinic acid calcium salt
Gamma Aminobutyric Acid
Ginger root powder
Ginko Biloba Standardized
Extract
Gluconic acid calcium salt
Glycerol Formal
Glyceryl Palmitostearate
Glycofurol
Glydiazinamide
Grape seed oil
Gum Arabic
Heart-leaf nettle leaf (Urtica
chamaedryoides leaf)
Hectorite
Heptafluoropropane
Hexetidine
Hyaluronic Acid Sodium Salt
Hydrazine sulfate
Hydrochloric Acid
Hydroxyethylpiperazine Ethane
Sulfonic Acid

Hydroxymethylmethyl Cellulose
Indigo Carmine
Indole-3-carbinol
Inositol Hexanicotinate
Iodochlorhydroxyquin
Iron Glycinate Chelate
Isopropyl Isostearate
Karaya Gum
Ketoifen Fumarate
Lactose, Spray-Dried
Lavender Oil
L-Carnosine
Lecithin Soya Granular
Lecithin Organogel
Levomenthol
Levulose
L-Histidine Monohydrochloride,
Monohydrate
Linoleic Acid
L-Ornithin Hydrochloride
Loxasperse
L-Triiodothyronine Sodium
Magnesium ascorbate
Magnesium bisglycinate
Magnesium bisglycinate
dihydrate
Magnesium glycinate
Malt
Malt soup extract
Maltodextrin
Manganese Bisglycinate
Manganese citrate
MBK
m-cresol
Medium Cream
Melatonin
Menfegol
Meralein sodium
Merbromin
Mercufenol chloride
Mercuric chloride
Mercuric oxide
Mercuric salicylate
Mercuric sulfide
Mercury

Mercury oleate
Mercury sulfide
Methapyrilene fumarate
Methoxyphenamine
Hydrochloride
Methoxypolyoxyethyleneglycol
350 laurate
Methyl nicotinate
Methyl sulfone
Methpyrilene Hydrochloride
Milk and molasses
Milk of sulfur
milk solids, dried
Minerals
Molasses
Molybdenum Glycinate
Monosodium L-Aspartate
Monosodium Phosphate
Mullein
Mustard oil (alltlishthiocyanate)
Mycozyme
Myrrh gum tincture
Myrrh tincture
Natural estrogenic hormone
Neohesperidine
Dihydrochalcone
Nickel-pectin
Nicotinic Acid
Non-Fat Dry Milk
Nonylphenoxypoly
(ethyleneoxy) ethanol iodine
Nonylphenoxypoly nonoxynol 9
Noscapine Hydrochloride
Nutmeg oil
Nux vomica extract
Obtundia
Octyl Gallate
Octyl triazone
Oil of erigeron
Organic vegetables
Orthophosphoric acid
Ox bile
Ox bile extract
Oxyquinoline
Padimate a

Pambron
Pantothenic acid
Papaya enzymes
Papaya, natural
Para-chloromercuriphenol
Parethoxycaine Hydrochloride
Parsley
Passion flower extract
Patchouli Essential Oil
Pennyroyal Oil
Pentylene-tetrazole
Peppermint Oil and Sage Oil
Pepsin
Peruvian balsam (Myroxylon
balsamum var. pereirae balsam)
Phenacaine Hydrochloride
Phenindamine Tartrate
Phenolate sodium
Phenolphthalein
Phenoxyacetic acid
Phenyl salicylate (Salol)
Phenyl salicylate
Phenylalanine
Phenylmercuric Borate
Phenyltoloxamine dihydrogen
citrate
Phenyltoloxamine Hydrochloride
Phosphate fluoride
Phosphorated carbohydrate
Phosphorus
Phytolacca
Picrotoxin
Pimobendan
Pine tar
Pineapple enzymes
Piperocaine Hydrochloride
Pipsissewa
Piracetam dihydrogen citrate
Piscidia erythrina
Plantago ovata husks
Podoophyllum resin
Poloxamer-iodine complex
Poly (DL-Lactic Acid)
Poly(methyl vinyl ether/maleic
anhydride)

Polydimethylsiloxane and poloxamer
Polyethylene Glycol 1450
Polyethylene Glycol 300
Polyethylene Glycol 400
Polyethylene Glycol 6000
Polyols, liquid
Polyoxyethylene laurate
Potash Lye
Potassium chlorate
Potassium ferrocyanide
Potassium salicylate
Povidone-vinylacetate copolymers
Pracasil Plus
Prolase
Prune concentrate dehydrate
Prune powder
Psyllium
Psyllium hydrophillic mucilloid
P-T-butyl-m-cresol
Pyridoxal-5-Phosphate
Pyrrolidone
Pyruvic aldehyde
Pyruvic Aldehyde 40% Aqueous Solution
Quinine
Racephpedrine Hydrochloride
Raffinose
Red petrolatum
Reosote
Retinoic Acid-All Trans
Rhubarb fluid extract
Rhubarb, Chinese
Rice pollishings
Romohydrate
Sabadilla, alkaloids
Sage oil
Salicyl alcohol
Sanguinaria extract
Saponite
Saw palmetto
Scopolamine aminoxide Hydrobromide
Sea mineral

Senecio aureus
Senna syrup
Serotonin Hydrochloride
Sesame Seed
Shark liver oil
Shea Butter, Organic
Short Chain Fatty Acid
Silver (see also argentyn)
Silver, colloidal
Simplgel 30
Sodium 3, 4-dimethylphenyl-glyoxylate
Sodium acetylsalicylate
Sodium aluminum chlorohydroxy lactate
Sodium aspartate
Sodium biphosphate
Sodium bisulfate
Sodium borate monohydrate
Sodium carboxymethylcellulose
Sodium caseinate
Sodium diacetate
Sodium dichromate
Sodium dihydrogen phosphate
Sodium dihydrogen phosphate monohydrate
Sodium hyaluronate
Sodium nitrate
Sodium octanoate
Sodium oleate
Sodium para-amino benzoate
Sodium perborate
Sodium perborate monohydrate
Sodium phosphate
Sodium potassium tartrate
Soft Paraffin
Sols, secondary
Soy meal
Soybean protein
Splenda
Squill preparations
Stannous pyrophosphate and zinc citrate
Stevia Powder Extract
Strawberry

Strychnine	Trillium
Sucros	Triolein
Sugars	Triple dye
Sulferated oils of turpentine	Triticum
Sulfobutylether B-Cyclodextrin	Turpantine Oil
Supposibase-F	Turpantine, Venice
T3 Sodium Dilution	Uinolinium bromide
Tannic acid glycerite	Ulose
Taraxacum officinale	Undecylenic acid
Tartrate	Uva ursi, extract of
Teaberry Oil	Valic acid
Tetrafluoroethane	Vitamin A acetate
Tetrahydrochloride	Vitromersol
Thaumatococin	Water and additives
Thenyldiamine Hydrochloride	Wheat germ
Theobromine Sodium Salicylate	Wheat germ (triticum aestivum/vulgare extract)
Theophylline calcium salicylate	White ointment
Theophylline, anhydrous	Woodruff
Thioctic	Yeast
Thiocyanoacetate	Yeast cell derivative
Thonzylamine Hydrochloride	Yellow mercuric oxide
Threonine	Zinc caprylate
Thylene blue	Zinc citrate
Tolindate	Zinc phenol sulfonate
Toltrazuril	Zinc picolinate
Tolu preparations	Zinc propionate
Tommygel	Zinc sulfide
Tricalcium phosphate	Zirconium oxide
Tricaprylin	Zyloxin
Triethanolamine	
Triglycerides	

**503A List 4 – Bulk Drug Substances That May Not Be Used to Compound Drug Products Under Section
503A**

To be developed