

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

503A Category 1 – Bulk Drug Substances Under Evaluation

- 7 Keto Dehydroepiandrosterone
- Acetyl L Carnitine/Acetyl-L- carnitine hydrochloride
- Acetyl-D-Glucosamine
- Alanyl-L-Glutamine
- Aloe Vera/ Aloe Vera 200:1 Freeze Dried
- Alpha Lipoic Acid
- Ammonium Tetrathiomolybdate
- Artemisia/Artemisinin
- Astragalus Extract 10:1
- Beta Glucan (1,3/1,4-D)
- Boswellia
- Brilliant Blue
- Bromelain
- Cantharidin
- Capsaicin palmitate
- Cetyl Myristoleate
- Choline Chloride
- Chondroitin Sulfate
- Chrysin
- Coenzyme Q10
- Creatine Monohydrate
- Curcumin
- Deoxy-D-Glucose
- Dichloroacetate
- Diindolylmethane
- Dimercapto-1- propanesulfonic acid (DMPS)
- Diphenylcyclopropenone (DPCP)
- EGCg
- Ferric Subulfate
- Glutaraldehyde
- Glutathione
- Glycoaminoglycans
- Glycolic Acid
- Glycyrrhizin
- Kojic Acid
- L-Citrulline
- Melatonin
- Methylcobalamin
- Methylsulfonylmethane (MSM)
- Nettle leaf (Urtica dioica subsp. dioica leaf)
- Nicotinamide Adenine Dinucleotide (NAD)
- Nicotinamide Adenine Dinucleotide Disodium Reduced (NADH)
- Ornithine Hydrochloride
- Oxitriptan
- Phosphatidylserine
- Piracetam
- Pregnenolone
- Pyridoxal 5-Phosphate Monohydrate
- Pyruvic Acid
- Quercetin/Quercetin Dihydrate
- Quinacrine Hydrochloride (except for intrauterine administration)
- Resveratrol
- Ribose (D)
- Rubidium Chloride
- Silver Protein Mild
- Squaric Acid Dibutyl Ester (aka dibutyl squarate)
- Tea tree oil (Melaleuca alternifolia leaf oil)
- Thymol Iodide
- Tranilast
- Trichloroacetic Acid
- Ubiquinol 30% Powder
- Vanadium
- Vasoactive Intestinal Peptide

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503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

- Cesium Chloride
- Domperidone
- Quinacrine Hydrochloride for
intrauterine administration
- Germanium Sesquioxide

Updated July 30, 2018

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

- Acetanilide
- Adenosine-5-triphosphate disodium salt
- Alcloxa
- Aldioxa
- Aldosterone
- Alfalfa
- Alfalfa leaves
- Almadrate sulfate
- Aloin
- Alpha Ketoglutaric acid
- Alumina Powder, hydrated
- Aluminum phosphate
- Aminacrine Hydrochloride
- Ammonium bromide
- Ammonium hydroxide
- Anise seed
- Argentyn
- Aromatic powder
- Asafetida
- Asclepias tuberosa
- Asefetida Tincture
- Asparagus
- Aspergillus oryza enzymes
- Barosma
- Beechwood creosote
- Bean
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate
- Bichloroacetic Acid
- Calcium Folate
- Calcium Glycinate
- Carbazochrome
- Carbimazole
- Cedarwood Essential Oil
- Chlorhexidine Diacetate Hydrate
- Choline bitartrate
- Choline magnesium trisalicylate
- Chromium glycinate
- Coenzyme Q50
- Copper
- Copper Bisglycinate
- Copper Hydrosol
- Decylmethylsulfoxide
- Diaminopyridine (3,4-)
- Dichloroacetic acid
- Dimethyl Ketone
- Dimethylaminoethanol Bitartrate
- Dimethylglycine Hydrochloride
- Dinitrochlorobenzene
- Disodium Phosphate
- Edetate tetrasodium tetrahydrate
- Gamma Aminobutyric Acid
- GHRP-2
- GHRP-6
- Ginger root powder
- Ginkgo Biloba Standardized Extract
- Gluconic acid calcium salt
- Glycerol Formal
- Glydiazinamide
- Grape seed oil
- Heart-leaf nettle leaf (Urtica chamaedryoides leaf)
- Hyaluronic Acid Sodium Salt
- Hydrazine sulfate
- Indigo Carmine
- Indole-3-carbinol
- Inositol Hexanicotinate
- Iron Glycinate Chelate
- Karaya Gum
- L-Carnosine
- Levulose
- L-Histidine Monohydrochloride, Monohydrate
- Magnesium ascorbate
- Magnesium bisglycinate
- Magnesium bisglycinate dehydrate
- Magnesium glycinate
- Malt
- Malt soup extract
- Maltodextrin
- Manganese Bisglycinate
- Manganese citrate
- m-cresol
- Menfegol
- Meralein sodium
- Merbromin

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- Mercufenol chloride
- Mercuric chloride
- Mercuric oxide
- Mercuric salicylate
- Mercuric sulfide
- Mercury
- Mercury oleate
- Mercury sulfide
- Methapyrilene fumarate
- Methoxyphenamine Hydrochloride
- Methoxypolyoxyethyleneglycol 350 laurate
- Methyl nicotinate
- Methypyrilene Hydrochloride
- Milk and molasses
- milk solids, dried
- Molasses
- Molybdenum Glycinate
- Monosodium L-Aspartate
- Mullein
- Mustard oil (alltlishthiocyanate)
- Mycozyme
- Myrrh gum tincture
- Myrrh tincture
- Natural estrogenic hormone
- Nickel-pectin
- Non-Fat Dry Milk
- Nonylphenoxypoly (ethyleneoxy) ethanol iodine
- Nonylphenoxypoly nonoxynol 9
- Noscapine Hydrochloride
- Nutmeg oil
- Nux vomica extract
- Obtundia
- 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
- Pennyroyal Oil
- Pentylenetetrazole
- 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
- Phenyltoloxamine dihydrogen citrate
- Phenyltoloxamine Hydrochloride
- Phosphate fluoride
- Phosphorated carbohydrate
- Phosphorus
- Phytolacca
- Picrotoxin
- Pimobendan
- Pine tar
- Piperocaine Hydrochloride
- Pipsissewa
- Piracetam dihydrogen citrate
- Piscidia erythrina
- Plantago ovata husks
- Poloxamer-iodine complex
- Polydimethylsiloxane and poloxamer
- Polyols, liquid
- Polyoxeythylene laurate
- Potash Lye
- Potassium chlorate
- Potassium ferrocyanide
- Potassium salicylate
- Povidone-vinylacetate copolymers
- Prolase
- Prune concentrate dehydrate
- Prune powder
- Psyllium
- Psyllium hydrophillic mucilloid
- P-T-butyl-m-cresol

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- Pyruvic aldehyde
- Pyruvic Aldehyde 40% Aqueous Solution
- Racephpedrine Hydrochloride
- Red petrolatum
- Reosote
- Rhubarb fluid extract
- Rhubarb, Chinese
- Rice pollishings
- Romohydrate
- Sabadilla, alkaloids
- Sage oil
- Salicyl alcohol
- Sanguinaria extract
- Saw palmetto
- Scopolamine aminoxide Hydrobromide
- Sea mineral
- Senecio aureus
- Senna syrup
- Serotonin Hydrochloride
- Sesame Seed
- Shark liver oil
- Short Chain Fatty Acid
- Silver (see also argentyn)
- Silver, colloidal
- Sodium 3, 4-dimethylphenyl- glyoxylate
- Sodium acetylsalicylate
- Sodium aluminum chlorohydroxy lactate
- Sodium aspartate
- Sodium biphosphate
- Sodium bisulfate
- Sodium borate monohydrate
- Sodium caseinate
- Sodium diacetate
- Sodium dichromate
- Sodium dihydrogen phosphate monohydrate
- Sodium nitrate
- Sodium octanoate
- Sodium oleate
- Sodium para-amino benzoate
- Sodium perborate
- Sodium perborate monohydrate
- Sodium phosphate
- Sodium potassium tartrate
- Sols, secondary
- Soy meal
- Soybean protein
- Squill preparations
- Stannous pyrophosphate and zinc citrate
- Stevia Powder Extract
- Strychnine
- Sucros
- Sugars
- Sulferated oils of turpentine
- Sulfobutylether B-Cyclodextrin
- Tannic acid glycerite
- Taraxacum officinale
- Tartrate
- Tetrahydrochloride
- Thenyldiamine Hydrochloride
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Thioctic
- Thiocyanacetate
- Thonzylamine Hydrochloride
- Thylene blue
- Tolindate
- Toltrazuril
- Tolu preparations
- Tricalcium phosphate
- Triethanolamine
- Trillium
- Triple dye
- Triticum
- Turpentine Oil
- Turpentine, Venice
- Uinolinium bromide
- Ulose
- Uva ursi, extract of
- Valic acid
- Vitamin A acetate
- Vitromersol
- Wheat germ
- Wheat germ (triticum aestivum/vulgare extract)
- White ointment
- Woodruff
- Yeast
- Yeast cell derivative
- Yellow mercuric oxide
- Zinc caprylate
- Zinc citrate
- Zinc phenol sulfonate

Updated July 30, 2018

- Zinc picolinate
- Zinc propionate
- Zinc sulfide
- Zirconium oxide
- Zyloxin

Updated July 30, 2018

Notice of Updates to Section 503A Categories

The information below describes the updates FDA announced in July 2018 to the categories of bulk drug substances under its interim policy on compounding bulk drug substances under section [503A](#) of the Federal Food, Drug, and Cosmetic Act.

- Notice for July 30, 2018
 - Recategorization from category 1 to category 2 after 7 calendar days from July 23, 2018 notice
 - Cesium chloride – FDA has identified significant safety risk
- Notice for July 23, 2018
 - Recategorization from category 3 to category 1
 - Melatonin- renominated with adequate support
 - Creatine monohydrate- renominated with adequate support
 - Removal from category 3
 - L-ornithin hydrochloride – withdrawn by nominator
 - Lactobacillus acidophilus – biologic; ineligible for compounding under section 503A
 - Removal from category 1 after 30 calendar days
 - Ammonium tetrathiomolybdate – withdrawn by nominator
 - Bromelain – biologic; ineligible for compounding under section 503A
 - Glycoaminoglycans – withdrawn by nominator
 - Beta glucan (1,3/1,4-D) – withdrawn by nominator
 - Phosphatidylserine – withdrawn by nominator
 - Ornithine hydrochloride – withdrawn by nominator
 - Cetyl myristoleate – withdrawn by nominator