

Updated November 2, 2021

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

Includes three categories of bulk drug substances:

- [Category 1: Bulk Drug Substances Under Evaluation](#)
- [Category 2: Bulk Drug Substances that Raise Significant Safety Concerns](#)
- [Category 3: Bulk Drug Substances Nominated Without Adequate Support](#)

Notice of Updates to Section 503A Categories

Additions to category 1

- Ammonium Tetrathiomolybdate – This bulk drug substance was nominated with sufficient supporting information to permit FDA to evaluate it and may be eligible for inclusion on the 503A Bulks List
- Enclomiphene Citrate- This bulk drug substance was nominated with sufficient supporting information to permit FDA to evaluate it and may be eligible for inclusion on the 503A Bulks List

For more information, please see the [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A](#) and the [final rule](#) on bulk drug substances that can be used for compounding under section 503A, which became effective on March 21, 2019.

503A Category 1 – Bulk Drug Substances Under Evaluation

- 7 Keto Dehydroepiandrosterone
- Acetyl L Carnitine/Acetyl-L- carnitine Hydrochloride
- Alanyl-L-Glutamine
- Aloe Vera/ Aloe Vera 200:1 Freeze Dried
- Alpha Lipoic Acid
- Ammonium Tetrathiomolybdate
- Artemisia/Artemisinin
- Astragalus Extract 10:1
- Boswellia
- Choline Chloride
- Chondroitin Sulfate
- Chrysin
- Coenzyme Q10
- Creatine Monohydrate
- Curcumin
- Deoxy-D-Glucose
- Dichloroacetate
- Diindolylmethane
- Dimercapto-1- propanesulfonic acid (DMPS)
- EGCg
- Enclomiphene Citrate
- Ferric Subsulfate
- Glutaraldehyde
- Glutathione
- 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)
- Pregnenolone
- Pyridoxal 5-Phosphate Monohydrate
- Pyruvic Acid
- Quercetin/Quercetin Dihydrate
- Quinacrine Hydrochloride (except for intrauterine administration)
- Resveratrol
- Ribose (D)
- Rubidium Chloride
- Tea tree oil (*Melaleuca alternifolia* leaf oil)
- 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

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
- Bean
- Beechwood creosote
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate
- Bichloroacetic Acid
- Calcium Folate
- Calcium Glycinate
- Capsaicin palmitate
- 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
- 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
- Mercufenol chloride

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- 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 (allitishthiocyanate)
- 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
- P-T-butyl-m-cresol
- Pyruvic aldehyde
- 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 hydrophilic mucilloid
- Soy meal

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- Pyruvic Aldehyde 40% Aqueous Solution
- Racedephedrine Hydrochloride
- Red petrolatum
- Reosote
- Rhubarb fluid extract
- Rhubarb, Chinese
- Rice polishings
- 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
- Zinc picolinate
- Zinc propionate
- Zinc sulfide
- 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
- 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
- Yellow mercuric oxide
- Zinc caprylate
- Zinc citrate
- Zinc phenol sulfonate

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- Zirconium oxide
- Zyloxin