

Updated July 1, 2020

## **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](#)

### **Updates to Section 503A Categories**

- Removal from category 3
  - Artesunate – This bulk drug substance is a component of an FDA-approved drug product (NDA 213036) and compounded drug products containing this substance may be eligible for the exemptions under section 503A of the FD&C Act pursuant to section 503A(b)(1)(A)(i)(II). This change will be effective immediately and will not have a waiting period.

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.

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### 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
- 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
- Ferric Sub sulfate
- 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

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### 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
- Mercufenol chloride
- 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

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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 (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
- 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
- Racephedrine 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