

## **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 3: The substances listed below will be placed in category 3 because they were nominated with insufficient supporting information for FDA to evaluate them:

- DL-Phenylalanine
- L-Ornithine Hydrochloride
- Sodium Hydroxide 1N
- Verapamil

Revisions to category 3:

- “Racephpedrine Hydrochloride” will be corrected to “racedephedrine hydrochloride” to correct a spelling error.
- “Tartrate” will be corrected to “Tartrate (acid or salt)” to correct an error.
- “Bichloroacetic acid” will be corrected to “Bichloroacetic acid/Dichloroacetic acid” since they are the same substance but were initially listed separately.
- “Mercuric Sulfide” will be corrected to “Mercuric Sulfide, red/Mercury Sulfide” since they are the same substance but were initially listed separately.

Removals from category 3:

- “Psyllium” will be removed because it was originally added to category 3 in error.

Visit [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A<sup>1</sup>](#) and the [final rule](#) on bulk drug substances that can be used for compounding under section 503A, which became effective on March 21, 2019, for more information.

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<sup>1</sup> The draft guidance for industry “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act – Revision 2,” was published on December 7, 2023. The guidance, if finalized as written, would end the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of the final guidance. Visit <https://www.fda.gov/media/174456/download>.

**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
- GHK-Cu (except for injectable routes of administration)
- Glutaraldehyde
- Glutathione
- Glycolic Acid
- Glycyrrhizin
- Kojic Acid
- L-Citrulline
- L-Theanine
- 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

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

Visit [Safety Risks Associated with Certain Bulk Drug Substances Nominated for Use in Compounding](#) for a summary of the identified safety risks for bulk drug substances in category 2.

- AOD-9604
- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- CJC-1295
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Ipamorelin Acetate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Selank acetate (TP-7)
- Semax (heptapeptide)
- Thymosin-Alpha 1 (Ta1)
- Thymosin Beta-4, Fragment (LKKTETQ)

### 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
- Aluminum phosphate, Adjuvant
- Aminacrine Hydrochloride
- Ammonium bromide
- Ammonium hydroxide
- Anise seed
- Argentyn
- Aromatic powder
- Asafetida
- Asafetida tincture
- Asclepias tuberosa
- Asparagus
- Attapulgate
- Barosma
- Bean
- Beechwood creosote
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate
- Bichloroacetic acid/Dichloroacetic acid
- Calcium Folate
- Calcium Glycinate
- Capsaicin palmitate
- Carbazochrome
- Carbimazole
- Carbolic Acid
- Carbomer Gel - Aqueous
- Carbomer Gel - Hydroalcoholic
- Cedarwood Essential Oil
- Chlorhexidine Diacetate Hydrate
- Choline bitartrate
- Choline magnesium trisalicylate
- Chromium glycinate
- Cibinetide (ARA-290)
- Coenzyme Q50
- Copper
- Copper Bisglycinate
- Copper Hydrosol
- DL-Phenylalanine
- Decylmethylsulfoxide
- Diaminopyridine (3,4-)
- Dimethyl Ketone
- Dimethylaminoethanol Bitartrate
- Dimethylglycine Hydrochloride
- Dinitrochlorobenzene
- Edetate tetrasodium tetrahydrate
- Ethanolamine
- Folinic Acid Calcium Salt
- Fructose and Pregelatinized Starch
- Gamma Aminobutyric Acid
- GHRP-2
- GHRP-6
- Ginger root powder
- Ginkgo Biloba Standardized Extract
- Gluconic acid calcium salt
- Glycerol Formal
- Glydiazinamide
- Grape seed oil
- Gum Arabic
- Heart-leaf nettle leaf  
(Urtica chamaedryoides leaf)
- Hyaluronic Acid Sodium Salt
- Hydrazine sulfate
- Iodochlorhydroxyquin
- Indigo Carmine
- Indole-3-carbinol
- Inositol Hexanicotinate
- Iron Glycinate Chelate
- Karaya Gum
- L-Carnosine
- L-Ornithine Hydrochloride
- Levulose
- L-Histidine Monohydrochloride, Monohydrate
- Lactose, Monohydrate and Corn Starch
- Lactose, Monohydrate and Microcrystalline Cellulose
- Lactose, Monohydrate and Powdered Cellulose
- Lactose, spray dried
- L-Aspartic Acid Sodium Salt
- Levomenthol
- Liquid Paraffin
- Lysine aspirin

**Updated May 20, 2024**

- Magnesium ascorbate
- Magnesium bisglycinate
- Magnesium bisglycinate dehydrate
- Magnesium glycinate
- Magnesium glycinate 15%
- Malt
- Malt soup extract
- Maltodextrin
- Manganese Bisglycinate
- Manganese citrate
- m-cresol
- Mechano growth factor (MGF)
- Menfegol
- Menthol/peppermint oil
- Meralein sodium
- Merbromin
- Mercufenol chloride
- Mercuric chloride
- Mercuric oxide
- Mercuric salicylate
- Mercuric sulfide, red/Mercury sulfide
- Mercury
- Mercury-containing ingredient
- Mercury oleate
- Methapyrilene fumarate
- Methapyrilene Hydrochloride
- Methoxyphenamine Hydrochloride
- Methoxypolyoxyethyleneglycol 350 laurate
- Methyl nicotinate
- Milk and molasses
- Milk of sulfur
- milk solids, dried
- Mineral Oil and Lanolin Alcohols
- Molasses
- Myrrh gum tincture
- Monosodium L-Aspartate
- Mullein
- Molybdenum Glycinate
- Mycozyme
- Myrrh tincture
- Mustard oil (alltlishthiocyanate)
- 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
- Para-chloromercuriphenol
- Parethoxycaine Hydrochloride
- Parsley
- Passion flower extract
- Pennyroyal Oil
- Pentylenetetrazole
- Peppermint Oil and Sage Oil
- Peruvian balsam (Myroxylon balsamum var. pereirae balsam)
- Peruvian balsam oil
- Petrolatum and Lanolin Alcohols
- 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
- Polyoxeyethylene laurate

## Updated May 20, 2024

- Potash Lye
- Potassium chlorate
- Potassium ferrocyanide
- Potassium salicylate
- Povidone-vinylacetate copolymers
- Prolase
- Protease
- Prune concentrate dehydrate
- Prune powder
- Psyllium hydrophillic mucilloid
- Pyruvic aldehyde
- Pyruvic Aldehyde 40% Aqueous Solution
- Racephedrine 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
- Secretin, human 99%
- Selenium
- Shark liver oil
- Shark liver oil (combination only)
- Skin protectant
- Senecio aureus
- Senna syrup
- Serotonin Hydrochloride
- Sesame Seed
- Short Chain Fatty Acid
- Silver (see also argentyn)
- Silver, colloidal
- Sodium
- 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 Hydroxide 1N
- Sodium nitrate
- Sodium octanoate
- Sodium oleate
- Sodium para-amino benzoate
- Sodium perborate
- Sodium perborate monohydrate
- Sodium phosphate
- Sodium salicylic acid phenolate
- Sodium potassium tartrate
- Soft Paraffin
- Sols, secondary
- Soy meal
- Soybean protein
- Stannous pyrophosphate and zinc citrate
- Stevia Powder Extract
- Strychnine
- Sucros
- Sugars
- Sulferated oils of turpentine
- Squill preparations
- Sulfobutylether B-Cyclodextrin
- Tannic acid glycerite
- Taraxacum officinale
- Tartrate (acid or salt)
- Tetrahydrochloride
- Thenyldiamine Hydrochloride
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Thiocynoacetate
- Thonzylamine Hydrochloride
- Thylene blue
- Thymulin acetate
- Tolindate
- Toltrazuril
- Tolu preparations
- Tricalcium phosphate
- Triethanolamine
- Trillium
- Triple dye
- Triticum
- Turpentine Oil
- Turpentine Oil (oral)
- Turpentine Oil (rectified)
- Turpentine Oil (spirits of turpentine)
- Turpentine Oil (spirits of turpentine, oral)
- Turpentine Oil (spirits of turpentine, topical)

**Updated May 20, 2024**

- Turpentine, Venice
- Uinolinium bromide
- Ulose
- Uva ursi, extract of
- Uva ursi, potassium extract
- Valic acid
- Vegetable (green)
- Verapamil
- Vitamin A acetate
- Vitromersol
- Wax, Anionic Emulsifying
- Wheat germ
- Wheat germ (triticum aestivum/vulgare extract)
- White ointment
- Woodruff
- Yeast
- Yellow mercuric oxide
- Zinc
- Zinc caprylate
- Zinc citrate
- Zinc phenol sulfonate
- Zinc picolinate
- Zinc propionate
- Zinc sulfide
- Zirconium oxide
- Zyloxin