

## 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
  - **GHK-Cu (except for injectable routes of administration)** - 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. FDA will add GHK-Cu for injectable routes of administration to Category 2 due to significant safety risks associated with its use in compounding.
  - **L-Theanine** - 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.

- Additions to Category 2

The following substances will be added to Category 2 because FDA has identified significant safety risks with these substances:

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

## Updated September 29, 2023

- 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:

- Aluminum Phosphate Adjuvant
- Attapulgit
- Carbolic Acid
- Carbomer Gel - Aqueous
- Carbomer Gel – Hydroalcoholic
- Cibinetide (ARA-290)
- Ethanolamine
- Folinic Acid Calcium Salt
- Fructose and Pregelatinized Starch
- Gum Arabic
- Iodochlorhydroxyquin
- 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
- Magnesium Glycinate 15%
- Mechano Growth Factor (MGF)
- Menthol/peppermint oil
- Mercury-containing ingredient
- Milk of Sulfur
- Mineral Oil and Lanolin Alcohols
- Peruvian balsam oil
- Petrolatum and Lanolin Alcohols
- Protease
- Secretin, human 99%
- Selenium
- Shark liver oil (combination only)
- Skin protectant
- Sodium
- Sodium salicylic acid phenolate
- Soft Paraffin
- Thymulin acetate
- Turpentine oil (oral)
- Turpentine oil (rectified)
- Turpentine oil (spirits of turpentine)
- Turpentine oil (spirits of turpentine) (oral)
- Turpentine oil (spirits of turpentine) (topical)
- Uva ursi, potassium extract
- Vegetable (green)
- Wax, Anionic Emulsifying
- Zinc

- Revisions to Category 3

- “Asefetida Tincture” will be corrected to “Asafetida tincture” to correct a spelling error.
- “Methypyrene Hydrochloride” will be corrected to “Methapyrene Hydrochloride” to correct a spelling error.

FDA will not consider biological products subject to licensure under section 351 of the PHS Act for inclusion on the 503A Bulks List because such products are not eligible for the exemptions in section 503A of the FD&C Act.<sup>1</sup> FDA will remove the following substances from Category 3 because they are biological products:

- Aspergillus oryza enzymes
- Pepsin

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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<sup>1</sup> See 503A Bulks Interim Policy Guidance at 6.

### 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**

- 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
- Attapulgit
- Barosma
- Bean
- Beechwood creosote
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide  
Disodium Salt Trihydrate
- Bichloroacetic Acid
- Calcium Folate
- Calcium Glycinate
- Capsaicin palmitate
- Carbazochrome
- Carbimazole
- Carboic 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
- Decylmethylsulfoxide
- Diaminopyridine (3,4-)
- Dichloroacetic acid
- 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
- 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

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- 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
- Mercury
- Mercury-containing ingredient
- Mercury oleate
- Mercury sulfide
- 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

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- Potash Lye
- Potassium chlorate
- Potassium ferrocyanide
- Potassium salicylate
- Povidone-vinylacetate copolymers
- Prolase
- Protease
- Prune concentrate dehydrate
- Prune powder
- Psyllium
- Psyllium hydrophillic mucilloid
- 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
- 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 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
- Tetrahydrochloride
- Thenyldiamine Hydrochloride
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Thiocyanacetate
- 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)

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- Turpentine, Venice
- Uinolinium bromide
- Ulose
- Uva ursi, extract of
- Uva ursi, potassium extract
- Valic acid
- Vegetable (green)
- 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