

**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

- Removals from category 1 – Consistent with the [interim policy guidance](#), FDA is providing notice before removing the following bulk drug substance from category 1:
 - “GHK-Cu (except for injectable routes of administration)” will be removed from category 1 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has [announced](#) it intends to consult the Pharmacy Compounding Advisory Committee (PCAC) before the end of February 2027 regarding the potential inclusion of GHK-Cu on the 503A bulks list.
- Removals from category 2 – Consistent with the interim policy guidance, FDA is providing notice before removing the following bulk drug substances from category 2:
 - “BPC-157” will be removed from category 2 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has [announced](#) it intends to consult the PCAC on July 23, 2026, regarding the potential inclusion of BPC-157-related bulk drug substances (BPC-157 acetate and BPC-157 (free base)) on the 503A bulks list.
 - “Cathelicidin LL-37” will be removed from category 2 after seven calendar days because the nomination was withdrawn by the nominator. However, FDA has announced it intends to consult the PCAC before the end of February 2027 regarding the potential inclusion of Cathelicidin LL-37 on the 503A bulks list.
 - “Dihexa Acetate” will be removed from category 2 after seven calendar days because the nomination was withdrawn by the nominator. However, FDA has announced it intends to consult the PCAC before the end of February 2027 regarding the potential inclusion of Dihexa acetate on the 503A bulks list.
 - “Emideltide (DSIP)” will be removed from category 2 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has announced it intends to consult the PCAC on July 24, 2026, regarding the potential inclusion of Emideltide (DSIP)-related bulk drug substances (Emideltide (DSIP) acetate and Emideltide (DSIP) (free base)) on the 503A bulks list.
 - “Epitalon” will be removed from category 2 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has announced it intends to consult the PCAC on July 24, 2026, regarding the potential inclusion of Epitalon-related bulk drug substances (Epitalon acetate and Epitalon (free base)) on the 503A bulks list.
 - “GHK-Cu (for injectable routes of administration)” will be removed from category 2 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has

announced it intends to consult the PCAC before the end of February 2027 regarding the potential inclusion of GHK-Cu on the 503A bulks list.

- “KPV” will be removed from Category 2 after seven calendar days because the nomination was withdrawn by the nominator. However, FDA has announced it intends to consult the PCAC on July 23, 2026, regarding the potential inclusion of KPV-related bulk drug substances (KPV acetate and KPV (free base)) on the 503A bulks list.
 - “Mechano Growth Factor, Pegylated (PEG-MGF)” will be removed from category 2 after seven calendar days because the nomination was withdrawn by the nominator. However, FDA has announced it intends to consult the PCAC before the end of February 2027 regarding the potential inclusion of Mechano Growth Factor, Pegylated (PEG-MGF) on the 503A bulks list.
 - “Melanotan II” will be removed from category 2 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has announced it intends to consult the PCAC before the end of February 2027 regarding the potential inclusion of Melanotan II on the 503A bulks list.
 - “MOTs-C” - will be removed from category 2 after seven calendar days because the nomination was withdrawn by the nominator. However, FDA has announced it intends to consult the PCAC on July 23, 2026, regarding the potential inclusion of MOTs-C-related bulk drug substances (MOTs-C acetate and MOTs-C (free base)) on the 503A bulks list.
 - “Semax (heptapeptide)” will be removed from category 2 after seven calendar days because the nominations were withdrawn by the nominators. However, FDA has announced it intends to consult the PCAC on July 24, 2026, regarding the potential inclusion of Semax-related bulk drug substances (Semax acetate and Semax (free base)) on the 503A bulks list.
- “Thymosin Beta-4, Fragment (LKKTETQ),” also known as TB-500, will be removed from category 2 after seven calendar days because the nomination was withdrawn by the nominator. However, FDA has announced it intends to consult the PCAC on July 23, 2026, regarding the potential inclusion of TB-500-related bulk drug substances (TB-500 acetate and TB-500 (free base)) on the 503A bulks list.

Visit [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 of the FD&C Act.

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 for Use in Compounding](#) for a summary of the identified safety risks for bulk drug substances in Category 2, as well as other bulk drug substances that may present significant safety risks.

- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Semax (heptapeptide)
- TB-500 (Thymosin Beta-4), Fragment (LKKTTETQ)

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
- Betamechlothesone
- 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

- 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)
- Phenyltoloxamine dihydrogen citrate
- Phenyltoloxamine Hydrochloride
- Phosphate fluoride
- Phosphorated carbohydrate
- Phosphorus
- Phytolacca
- Picrotoxin
- Pimobendan
- Pine tar
- 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
- 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

- Piperocaine Hydrochloride
- Pipsissewa
- Piracetam dihydrogen citrate
- Piscidia erythrina
- Plantago ovata husks
- Poloxamer-iodine complex
- Polydimethylsiloxane and poloxamer
- Polyols, liquid
- Polyoxeethylene laurate
- 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
- Theophylline calcium salicylate
- Thiocynoacetate
- Thonzylamine Hydrochloride
- Thylene blue
- Thymulin acetate
- Tolindate
- Toltrazuril
- Tolu preparations
- Tricalcium phosphate
- Triethanolamine
- Trillium
- Triple dye
- Triticum
- 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

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- 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)
- 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