

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

503B Category 1 – Bulk Drug Substances Under Evaluation

- 5-Methyltetrahydrofolate Calcium
- 17-alpha-Hydroxyprogesterone
- Acetylcysteine
- Acyclovir
- Adapalene
- Adenosine
- Allantoin
- Alpha Lipoic Acid
- Alprostadil
- Aluminum Chloride Hexahydrate
- Aluminum potassium sulfate
- Amantadine HCl
- Amitriptyline HCl
- Ascorbic acid
- Ascorbyl Palmitate
- Aspartic Acid
- Atenolol
- Atropine sulfate/ Atropine sulfate monohydrate
- Azelaic Acid
- Baclofen
- Benzocaine
- Betamethasone Acetate
- Betamethasone Dipropionate
- Betamethasone Sodium Phosphate
- Biotin
- Bismuth Nitrate Oxide
- Brilliant Blue
- Brimonidine Tartrate
- Bromfenac sodium (for ophthalmic use)
- Brompheniramine maleate, USP
- Budesonide
- Bupivacaine Hydrochloride/ Bupivacaine Hydrochloride Monohydrate
- Caffeine
- Calcipotriene
- Calcium Chloride
- Calcium EDTA
- Calcium Gluconate
- Cantharidin
- Chloroquine Phosphate
- Chlorpheniramine Maleate
- Choline Chloride
- Chromic Chloride
- Chromium chloride/ Chromium Chloride Hexahydrate
- Ciclopirox Oleate
- Cimetadine
- Citric Acid Anhydrous
- Clindamycin Phosphate
- Clioquinol
- Clobetasol Propionate
- Clomipramine Hydrochloride
- Clonidine Hydrochloride
- Coal Tar Solution
- Cupric Sulfate
- Cyanocobalamin
- Cyclobenzaprine Hydrochloride
- Dapiprazole HCl
- Dapsone
- Desoximetasone
- Dexamethasone Acetate
- Dexamethasone Sodium Phosphate
- Dexpanthenol
- D-glucose
- Diazepam
- Dibucaine HCl
- Diclofenac Sodium
- Diltiazem Hydrochloride
- Dimercapto-1-propanesulfonic acid (DMPS)
- Diphenylcyclopropenone
- Dipyridamole
- Disulfiram
- Dobutamine Hydrochloride
- Dopamine HCl
- Droperidol
- Econazole Nitrate
- Edetate Disodium (EDTA)
- Ephedrine Hydrochloride
- Ephedrine sulfate, USP
- Epinephrine
- Epinephrine Bitartrate
- Estradiol Cypionate

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- Estradiol
- Estriol
- Ethanol
- Ethyl Aminobenzoate
- Etomidate
- Famotidine
- Fentanyl Citrate
- Finasteride
- Fluconazole
- Fluocinolone Acetonide
- Fluocinonide
- Flurbiprofen
- Fluticasone Propionate
- Folic Acid
- Formaldehyde
- Furosemide
- Gabapentin
- Gentamicin Sulfate
- Glutamic acid
- Glutamine
- Glutathione
- Glycerin
- Glycolic Acid
- Glycopyrrolate/ Glycopyrrolate Bromide
- Heparin sodium
- Hyaluronic acid sodium salt
- Hyaluronidase
- Hydralazine HCl
- Hydrocortisone
- Hydromorphone Hydrochloride
- Hydroquinone
- Hydroxocobalamin Hydrochloride
- Hydroxyzine HCl
- Ibuprofen
- Imipramine Hydrochloride
- Imiquimod
- Inositol
- Iodoform
- Itraconazole
- Ivermectin
- Ketamine Hydrochloride
- Ketoconazole
- Ketoprofen
- Ketorolac Tromethamine
- Labetalol Hydrochloride
- Lactic Acid
- Lansoprazole
- Levocetirizine Dihydrochloride
- Lidocaine Hydrochloride
- Lincomycin HCl
- Lorazepam
- Magnesium Chloride
- Magnesium Sulfate/Magnesium Sulfate Heptahydrate
- Malic Acid
- Manganese Chloride
- Mannitol
- Medroxyprogesterone Acetate
- Meperidine Hydrochloride (a.k.a. Pethidine Hydrochloride)
- Methacholine Chloride
- Methionine/ Methionine (L)
- Methylcobalamin/ Methyl B12
- Methylprednisolone Acetate
- Methylsulfonylmethane (MSM)
- Metoclopramide HCl
- Metronidazole
- Midazolam Hydrochloride
- Mineral Oil
- Minoxidil
- Mitomycin
- Mometasone Furoate
- Monosodium Glutamate
- Morphine Sulfate/ Morphine Sulfate Pentahydrate
- Moxifloxacin hydrochloride
- Mupirocin
- Nalbuphine HCl
- Naloxone Hydrochloride Dihydrate
- Neomycin sulfate
- Neostigmine Methylsulfate
- Nepafenac
- Niacin
- Niacinamide
- Nicardipine hydrochloride
- Nifedipine
- Norepinephrine Bitartrate
- Ondansetron HCl
- Ornithine Hydrochloride
- Oxymetazoline HCl
- Oxytocin
- Pentoxifylline
- Phenol
- Phenoxybenzamine Hydrochloride
- Phentolamine Mesylate
- Phenylephrine HCl
- Phytonadione
- Pitcher Plant
- Podophyllum
- Polidocanol

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- Polymyxin B Sulfate
- Potassium Acetate
- Potassium chloride
- Potassium Phosphate Monobasic [KH₂PO₄]
- Potassium Phosphate Dibasic [K₂HPO₄]/ Potassium Phosphate Dibasic Anhydrous
- Precipitated Sulfur
- Prednisolone
- Prednisolone Acetate
- Prilocaine
- Procainamide HCl
- Procaine Hydrochloride
- Progesterone
- Promethazine Hydrochloride
- Proparacaine HCl
- Propranolol hydrochloride
- Prostaglandin E1
- Pyridoxal 5-Phosphate Monohydrate
- Pyridoxine HCl
- Remifentanyl Hydrochloride
- Riboflavin 5 PO₄
- Rocuronium Bromide
- Ropivacaine Hydrochloride
- Salicylic Acid
- Scopolamine hydrobromide
- Sincalide
- Sodium Acetate Anhydrous
- Sodium Ascorbate
- Sodium Benzoate
- Sodium Bicarbonate
- Sodium Chloride
- Sodium Citrate
- Sodium Citrate Dihydrate
- Sodium L-Aspartate Monohydrate
- Sodium phosphate/ Sodium Phosphate Monobasic Anhydrous
- Sodium Tetradecyl Sulfate
- Spironolactone
- Squaric acid dibutyl ester
- Succinylcholine Chloride
- Succinylcholine Chloride Dihydrate
- Sufentanil Citrate
- Sulfacetamide Sodium Monohydrate
- Sulfan Blue
- Tacrolimus
- Taurine
- Tazarotene
- Terbinafine HCl
- Testosterone
- Testosterone Cypionate
- Testosterone Propionate
- Tetracaine Hydrochloride
- Tetracycline Hydrochloride
- Theophylline
- Thiamine HCl (vitamin B1)
- Thymol iodide
- Tolnaftate
- Tramadol Hydrochloride
- Tretinoin
- Triamcinolone Acetonide
- Triamcinolone diacetate
- Tromethamine
- Tropicamide
- Trypan Blue
- Urea
- Vancomycin Hydrochloride
- Vasopressin
- Verapamil HCl
- Vecuronium Bromide
- Vitamin A acetate
- Vitamin D3
- Ziconotide
- Zinc Oxide
- Zinc Sulfate

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

- Germanium sesquioxide

503B Category 3: Bulk Drug Substances Nominated Without Adequate Support

- 4-Aminopyridine
- 7-Keto Dehydroepiandrosterone, Micronized
- Acacia Gum, Spray-Dried Powder
- Acacia Syrup
- Acesulfame Potassium
- Acetanilide
- Acetic acid
- Acetone
- Acetone Sodium Bisulfite
- Acetyl Hexapeptide-3
- Acidophilus Lactobacillus
- Adenosine-5-triphosphate disodium salt
- Agar
- Alcloxa
- Aldioxa
- Aldosterone
- Alfalfa
- Alfalfa leaves
- Alginic acid
- Aliphatic Polyesters
- Almadrate sulfate
- Aloin
- Alpha Ketoglutaric acid
- Alumina Powder, hydrated
- Aluminum acetate
- Aluminum chloride
- Aluminum phosphate
- Aluminum sulfate
- Aminacrine HCl
- Aminoacetic acid
- Ammonia solution, strong
- Ammonium Alginate
- Ammonium bromide
- Ammonium chloride
- Ammonium hydroxide
- Amylase
- Anise oil
- Anise seed
- Argentyn
- Arginine
- Aromatic powder
- Asafetida
- Asclepias tuberosa
- Asefetida Tincture
- Asparagus
- Aspartame
- Aspergillus oryza enzymes
- Attapulgate
- Barosma
- Basic Fuchsin
- Beachwood creosote
- Bean
- Benzalkonium Chloride
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate
- Bethanechol
- Bichloroacetic Acid
- Bipeptide Biocosmetic
- Bronopol
- Buffer Solution, pH Buffer Acid
- Butylated Hydroxytoluene
- Butylene Glycol
- Calcium Alginate
- Calcium Folate
- Calcium glycinate
- Capsules, Empty Gelatin Vegetable
- Carbamide
- Carbazochrome
- Carbimazole
- Carboic Acid
- Carbomer 940
- Caustic Potash
- Caustic Soda (sodium hydroxide)
- Cedarwood Essential Oil
- Ceratonia
- Ceresin
- Cetrimide
- Chlorhexidine Diacetate Hydrate
- Choline Bitartrate
- Choline magnesium trisalicylate
- Chondroitin Sulfate
- Chromium glycinate
- Chrysin
- Cidofovir
- Cocoa butter
- Coconut Oil Edible
- Coenzyme Q10
- Coenzyme Q50
- Collagenase
- Colophony

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- Copper
- Copper Bisglycinate
- Copper Hydrosol
- Corn Oil
- Corn Starch
- Corn Starch and Pregelatinized Starch
- Cottonseed Oil
- Creatine, Monohydrate
- Cucumber Melon Fragrance
- Cyclopentolate
- Decyl Oleate
- Decylmethylsulfoxide
- Deoxy-D-Glucose
- Desonide
- Diaminopyridine (3,4-)
- Dichloroacetic Acid
- Difluoroethane
- Diindolymethane
- Dimercaptosuccinic acid
- Dimethyl Ether (aka Methoxymethane)
- Dimethyl Ketone
- Dimethyl Phthalate
- Dimethylacetamide
- Dimethylaminoethanol Bitartrate
- Dimethylaminoethanol Complex
- Dimethylglycine HCl
- Dinitrochlorobenzene
- Diphenhydramine
- Dipropylene Glycol
- Disodium Hydrogen Phosphate
- Disodium Phosphate
- DL-Phenylalanine
- Docosanol
- Dodecyl Gallate
- Domperidone
- Edetate tetrasodium tetrahydrate
- Ethanolamine
- Ethyl Lactate
- Ethylene Vinyl Acetate
- Ferric subsulfate
- Ferric sulfate hydrate
- Ferric sulfate solution
- Folinic acid calcium salt
- Formoterol Fumarate Dihydrate
- Fructose and Pregelatinized Starch
- Gamma Aminobutyric Acid
- GHRP-2
- GHRP-6
- Ginger root powder
- Ginko Biloba Standardized Extract
- Gloconic acid calcium salt
- Glutaraldehyde solution
- Glycerol Formal
- Glyceryl Monostearate
- Glyceryl Palmitostearate
- Glycofurol
- Glydiazinamide
- Grape seed oil
- Gum Arabic
- Hectorite
- Heptafluoropropane
- Hexetidine
- Hyaluronidase, salt free
- Hydrazine sulfate
- Hydrochloric Acid
- Hydroxyethylpiperazine Ethane Sulfonic Acid
- Hydroxymethylmethyl Cellulose
- Ichthammol
- ICU Bottom Paste (Maalox)
- Indigo Carmine
- Indole-3-carbinol
- Inositol Hexanicotinate
- Iodochlorhydroxyquin
- Iopanoic Acid
- Iron Glycinate Chelate
- Isopropyl Isostearate
- Kaolin, Colloidal Powder
- Karaya Gum
- Ketoifen Fumarate
- Kojic Acid
- Lactose Monohydrate
- Lactose, Monohydrate and Corn Starch
- Lactose, Monohydrate and Microcrystalline Cellulose
- Lactose, Monohydrate and Powdered Cellulose Lactose, Spray-Dried
- Lanolin, Hydrous
- L-Aspartic Acid Sodium Salt
- Lavender Oil
- L-Carnitine
- L-Carnosine
- L-Citrulline
- L-Cysteine
- Lecithin Soya Granular

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- Lecithin Organogel
- Levomenthol
- Levulose
- L-Histidine Monohydrochloride, Monohydrate
- Lidocaine, Epinephrine, and Tetracaine
- Linoleic Acid
- L-Ornithin HCl
- Loxasperse
- L-Triiodothyronine Sodium
- Lysine
- Magaldrate
- Magnesium
- Magnesium aluminum silicate
- Magnesium ascorbate
- Magnesium bisglycinate
- Magnesium bisglycinate dihydrate
- Magnesium carbonate
- Magnesium citrate
- Magnesium glycinate
- Magnesium hydroxide
- Magnesium oxide
- Magnesium salicylate
- Magnesium stearate
- Magnesium trisilicate
- Malt
- Malt soup extract
- Maltodextrin
- Manganese Bisglycinate
- Manganese citrate
- Mannitol and sorbitol
- MBK
- m-cresol
- Meclizine HCl
- Medium Cream
- Menfegol
- Menthol
- Menthol/peppermint oil
- Meradimate (menthyl anthranilate)
- Meralein sodium
- Merbromin
- Mercufenol chloride
- Mercuric chloride
- Mercuric oxide
- Mercuric salicylate
- Mercuric sulfide
- Mercury
- Mercury oleate
- Mercury sulfide
- Mercury, ammoniated
- Metaproterenol sulfate
- Methenamine
- Methoxyphenamine HCl
- Methoxypolyoxyethyleneglycol 350 laurate
- Methyl nicotinate
- Methyl salicylate
- Methylbenzethonium chloride
- Methylcellulose
- Methylparaben
- Methypyrilene HCl
- Miconazole nitrate
- Microcrystalline Cellulose
- Milk and molasses
- Milk of sulfur
- Milk solids, dried
- Mineral oil and Lanolin Alcohols
- Minerals
- Molasses
- Molybdenum Glycinate
- Mono- and di-glycerides
- Monosodium L-Aspartate
- Monosodium Phosphate
- Mullein
- Mustard oil (allitliothiocyanate)
- Mycozyme
- Myrrh
- Myrrh gum tincture
- Myrrh tincture
- N-Acetyl-D-Glucosamine
- Naphazoline HCl
- Natural estrogenic hormone
- Neohesperidine Dihydrochalcone
- Nettle
- Nickel-pectin
- Nicotinamide
- Nicotinic Acid
- Nitromersol
- Non-Fat Dry Milk
- Nonylphenoxypoly (ethyleneoxy) ethanol iodine
- Nonylphenoxypoly nonoxynol 9
- Noscapine
- Noscapine HCl
- Nutmeg oil
- Nux vomica extract
- Nystatin
- Obtundia
- Octinoxate
- Octisalate
- Octocrylene
- Octoxynol 9
- Octyl Gallate

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- Octyl triazone
- Oil of erigeron
- Opium powder
- Opium tincture
- Organic vegetables
- Orthophosphoric acid
- Ox bile
- Ox bile extract
- Oxitriptan
- Oxybenzone
- Oxyquinoline
- Oxytetracycline HCl
- Padimate a
- Padimate o
- Pambron
- Pancreatin
- Pancrelipase
- Panthenol
- Pantothenic acid
- Papain
- Papaverine
- Papaverine HCl
- Papaya enzymes
- Papaya, natural
- Para-chloromercuriphenol
- Paraffin
- Paregoric
- Parethoxycaine HCl
- Parsley
- Passion flower extract
- Patchouli Essential Oil
- Pectin
- Pennyroyal Oil
- Pentylenetetrazole
- Peppermint
- Peppermint Oil
- Peppermint Spirit
- Pepsin
- Peruvian Balsam
- Petrolatum
- Phenacaine HCl
- Phenindamine Tartrate
- Pheniramine Maleate
- Phenobarbital
- Phenolate sodium
- Phenolphthalein
- Phenoxyacetic acid
- Phenyl salicylate
- Phenylalanine
- Phenylephrine bitartrate
- Phenylmercuric Borate
- Phenylmercuric cetate
- Phenylmercuric nitrate
- Phenylpropanolamine bitartrate
- Phenylpropanolamine HCl
- Phenylpropanolamine maleate
- Phenyltoloxamine citrate
- Phenyltoloxamine dihydrogen citrate
- Phenyltoloxamine HCl
- Phosphate fluoride
- Phosphorated carbohydrate
- Phosphoric acid
- Phosphorus
- Phytolacca
- Picrotoxin
- Pilocarpine Nitrate
- Pimobendan
- Pine tar
- Pineapple enzymes
- Piperazine citrate
- Piperocaine HCl
- Piperonyl butoxide
- Pipsissewa
- Piracetam
- Piracetam dihydrogen citrate
- Piscidia erythrina
- Plantago ovata husks
- Plantago seed
- Poloxamer
- Poloxamer-iodine complex
- Poly (DL-Lactic Acid)
- Poly(methyl vinyl ether/maleic anhydride)
- Polycarbophil
- Polydimethylsiloxane and poloxamer
- Polyethylene Glycol 1450
- Polyethylene Glycol 300
- Polyethylene Glycol 400
- Polyethylene Glycol 6000
- Polyols, liquid
- Polyoxeythylene laurate
- Polysorbate 20
- Polysorbate 80
- Polyvinyl alcohol
- Potash Lye
- Potassium bicarbonate
- Potassium bitartrate
- Potassium bromide

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- Potassium carbonate
- Potassium chlorate
- Potassium citrate
- Potassium ferrocyanide
- Potassium guaiacolsulfonate
- Potassium hydroxide
- Potassium iodide
- Potassium nitrate
- Potassium Phosphate Tribasic [K₃PO₄]
- Potassium salicylate
- Povidone
- Povidone-iodine
- Povidone-vinylacetate copolymers
- Powdered Cellulose
- Pracasil Plus
- Pramoxine HCl
- Pregnenolone micronized
- Prolase
- Propionic acid
- Propylene glycol
- Propylhexedrine
- Propylparaben
- Protease
- Protein hydrolysate
- Protirelin
- Prune concentrate dehydrate
- Prune powder
- Pseudoephedrine HCl
- Pseudoephedrine Sulfate
- Psyllium
- Psyllium hydrophilic mucilloid
- Psyllium seed
- P-T-butyl-m-cresol
- Pyrantel pamoate
- Pyrethrum extract
- Pyridoxine
- Pylamine maleate
- Pyrithione zinc
- Pyrrolidone
- Pyruvic Aldehyde 40% Aqueous Solution
- Quinine
- Racemethionine
- Racephpedrine HCl
- Raffinose
- Red petrolatum
- Reosote (Creosote?)
- Resorcinol
- Resorcinol monoacetate
- Resveratrol
- Retinoic Acid-All Trans
- Rhubarb fluid extract
- Rhubarb, Chinese
- Rice polishings
- Romohydrate
- Sabadilla, alkaloids
- Saccharin
- Sage Oil
- Salicyl alcohol
- Salicylamide
- Salsalate
- Sanguinaria extract
- Saponite
- Saw palmetto
- Sea mineral
- Secretin, human 99%
- Selenium
- Selenium sulfide
- Senecio aureus
- Senna
- Senna fluid extract
- Senna pod concentrate
- Senna syrup
- Sennosides a and b
- Serotonin HCl
- Sesame Oil
- Sesame Seed
- Shark liver oil
- Shea Butter, Organic
- Short Chain Fatty Acid
- Silver Bulk Drug Substance
- Silver nitrate
- Silver protein mild
- Silver, colloidal
- Silver[1] (Canadian_License_Sovereign_)
- Simethicone
- Simplgel 30
- Skin protectant
- Sodium
- Sodium 3, 4-dimethylphenyl-glyoxylate
- Sodium acetylsalicylate
- Sodium aluminum chlorohydroxy lactate
- Sodium aspartate
- Sodium biphosphate
- Sodium bisulfate
- Sodium borate
- Sodium borate monohydrate

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- Sodium bromide
- Sodium caprylate
- Sodium carbonate
- Sodium carboxymethylcellulose
- Sodium caseinate
- Sodium diacetate
- Sodium dichromate
- Sodium dihydrogen phosphate
- Sodium dihydrogen phosphate monohydrate
- Sodium fluoride
- Sodium monofluoro phosphate
- Sodium nitrate
- Sodium octanoate
- Sodium oleate
- Sodium para-amino benzoate
- Sodium perborate
- Sodium perborate monohydrate
- Sodium phosphate dibasic
- Sodium phosphate monobasic
- Sodium potassium tartrate
- Sodium propionate
- Sodium salicylate
- Sodium Selenite
- Sodium sulfide
- Sodium thiosulfate
- Soft Paraffin
- Sols, secondary
- Sorbitol
- Soy meal
- Soybean oil
- Soybean protein
- Splenda
- Squill preparations
- Stannous fluoride
- Stannous pyrophosphate
- Stearyl alcohol
- Stem bromelain
- Stevia Powder Extract
- Strawberry
- Strontium chloride
- Strychnine
- Sublimed sulfur
- Sucrose
- Sugars
- Sulfacetamide sodium
- Sulferated oils of turpentine
- Sulfobutylether B-Cyclodextrin
- Sulfur
- Sulisobenzone
- Supposibase-F
- T3 Sodium Dilution
- Talc
- Tannic acid
- Tannic acid glycerite
- Taraxacum officinale
- Tartaric acid
- Tartrate
- Tea Tree Oil
- Teaberry Oil
- Terpin hydrate preparations
- Tetrafluoroethane
- Tetrahydrochloride
- Thaumatin
- Thenyldiamine HCl
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Theophylline sodium glycinate
- Theophylline, anhydrous
- Theophylline compound with ethylenediamine
- Thiamine mononitrate (vitamin B1)
- Thimerosal
- Thioctic
- Thiocynoacetate
- Thonzylamine HCl
- Threonine
- Thylene blue
- Thymol
- Titanium dioxide
- Tolindate
- Toltrazuril
- Tolu balsam
- Tommy gel
- Topical starch
- Tranilast
- Triacetin
- Tricalcium phosphate
- Tricaprylin
- Trichloroacetic Acid
- Triclocarban
- Triclosan
- Triethanolamine
- Triglycerides
- Trillium
- Trilostane
- Triolein
- Tripelennamine HCl

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- Triple dye
- Triprolidine HCl
- Triticum
- Trolamine salicylate (triethanolamine salicylate)
- Tryptophan
- Turpentine Oil
- Turpentine, Venice
- Tyrosine
- Uinolinium bromide
- Ulose
- Undecoylium chlorideiodine complex
- Undecylenic acid
- Uva ursi, extract of
- Valic acid
- Valine
- Vitamin A palmitate
- Vitamin E
- Vitromersol
- Water and additives
- Water, purified
- Wax, Anionic Emulsifying
- Wax, white
- Wax, yellow
- Wheat germ
- White ointment
- White petrolatum
- Witch hazel (hamamelis water)
- Witch hazel skin
- Woodruff
- Xanthan gum
- Xylometazoline HCl
- Yeast
- Yeast cell derivative
- Yellow mercuric oxide
- Zinc
- Zinc acetate
- Zinc caprylate
- Zinc carbonate
- Zinc chloride
- Zinc citrate
- Zinc phenol sulfonate
- Zinc picolinate
- Zinc propionate
- Zinc pyrithione
- Zinc stearate
- Zinc sulfide
- Zinc undecylenate
- Zirconium oxide
- Zyloxin

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Notice of Updates to Section 503B Categories

The information below describes the updates FDA announced in November 2018 to the categories of bulk drug substances under its interim policy on compounding bulk drug substances under section [503B](#) of the Federal Food, Drug, and Cosmetic Act.

- Removal from category 3
 - Sodium hyaluronate – already listed in category 1 as hyaluronic acid sodium salt