Updated July 1, 2017

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

- 17-alpha-Hydroxyprogesterone
- Acetylcysteine
- Adenosine
- Alpha Lipoic Acid
- Alprostadil
- Aluminum Chloride Hexahydrate
- Aluminum potassium sulfate
- Amitriptyline HCl
- Ascorbic acid
- Aspartic Acid
- Atenolol
- Atropine sulfate/ Atropine sulfate monohydrate
- Baclofen
- Betamethasone Acetate
- Betamethasone Sodium Phosphate
- Biotin
- Bismuth Nitrate Oxide
- Brilliant Blue
- Bromfenac sodim (for ophthalmic use)
- Brompheniramine maleate, USP
- Budesonide
- Bumetanide
- Bupivacaine Hydrochloride/ Bupivacaine Hydrochloride Monohydrate
- Caffeine
- Calcium Chloride
- Calcium EDTA
- Calcium Gluconate
- Cantharidin
- Caustic Soda (sodium hydroxide)
- Chloroquine Phosphate
- Chlorpheniramine Maleate
- Choline Bitartrate
- Choline Chloride
- Chromium chloride/ Chromium Chloride Hexahydrate
- Citric Acid Anhydrous
- Clindamycin Phosphate
- Clomipramine Hydrochloride
- Clonidine Hydrochloride
- Cyanocobalamin
- Cyclobenzaprine Hydrochloride
- Cyclopentolate
- Dapiprazole HCl
- Dexamethasone Acetate
- Dexamethasone Sodium Phosphate
- Dexpanthenol
- D-glucose
- Diazepam
- Diclofenac Sodium
- Diltiazem Hydrochloride
- Dimercapto-1-propanesulfonic acid (DMPS)
- Diphenylcyclopropenone
- Disulfiram
- Dopamine HCl
- Droperidol
- Edetate Disodium (EDTA)
- Ephedrine Hydrochloride
- Ephedrine sulfate, USP
- Epinephrine
- Epinephrine Bitartrate
- Estradiol Cypionate
- Estradiol
- Estriol
- Ethanol
- Ethyl Aminobenzoate
- Etomidate
- Famotidine
- Fentanyl Citrate
- Flurbiprofen
- Fluticasone Propionate
- Folic Acid
- Formaldehyde
- Furosemide
- Gabapentin
- Gentamicin Sulfate
- Glutamic acid
- Glutamine
- Glutathione
- Glycerin
- Glycopyrrolate/ Glycopyrrolate Bromide
- Heparin sodium

Updated July 1, 2017

- Hyaluronic acid sodium salt
- Hyaluronidase
- Hydralazine HCl
- Hydromorphone Hydrochloride
- Hydroxocobalamin Hydrochloride
- Hydroxyzine HCl
- Imipramine Hydrochloride
- Inositol
- Iodoform
- Itraconazole
- Ketamine Hydrochloride
- Ketoprofen
- Ketorolac Tromethamine
- Labetalol Hydrochloride
- Lansoprazole
- Lidocaine Hydrochloride
- Lincomycin HCl
- Lorazepam
- Magnesium Chloride
- Magnesium Sulfate Heptahydrate
- Malic Acid
- Medroxyprogesterone Acetate
- Meperidine Hydrochloride (a.k.a. Pethidine Hydrochloride)
- Methacholine Chloride
- Methionine/ Methionine (L)
- Methylcobalamin/ Methyl B12
- Methylprednisolone Acetate
- Methylsulfonylmethane (MSM)
- Midazolam Hydrochloride
- Mineral Oil
- Mitomycin
- Monosodium Glutamate
- Morphine Sulfate/ Morphine Sulfate Pentahydrate
- Moxifloxacin hydrochloride
- Nalbuphine HCl
- Naloxone Hydrochloride Dihydrate
- Neomycin sulfate
- Neostigmine Methylsulfate
- Niacin
- Niacinamide
- Nicardipine hydrochloride
- Nifedipine
- Norepinephrine Bitartrate
- Ondansetron HCl
- Ornithine Hydrochloride
- Oxymetazoline HCl
- Oxytocin
- Papaverine
- Phenol
- Phenoxybenzamine Hydrochloride
- Phentolamine Mesylate
- Phenylephrine HCl
- Phytonadione
- Pitcher Plant
- Podophyllum
- Polidocanol
- Polymyxin B Sulfate
- Potassium chloride
- Potassium phosphate/ Potassium Phosphate Dibasic Anhydrous
- Prednisolone
- Prednisolone Acetate
- Procainamide HCl
- Procaine Hydrochloride
- Progesterone
- Promethazine Hydrochloride
- Proparacaine HCl
- Propranolol hydrochloride
- Prostaglandin E1
- Pyridoxal 5-Phosphate Monohydrate
- Remifentanil Hydrochloride
- Riboflavin 5 PO4
- Rocuronium Bromide
- Ropivacaine Hydrochloride
- Salicylic Acid
- Scopolamine hydrobromide
- 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 Selenite
- Sodium Tetradecyl Sulfate
- Squaric acid dibutyl ester
- Succinylcholine Chloride Dihydrate
- Sufentanil Citrate
- Sulfan Blue

Updated July 1, 2017

- Taurine
- Testosterone
- Testosterone Propionate
- Tetracaine Hydrochloride
- Tetracycline Hydrochloride
- Thiamine HCl (vitamin B1)
- Thymol iodide
- Tramadol Hydrochloride
- Triamcinolone Acetonide
- Triamcinolone diacetate
- Tromethamine
- Tropicamide
- Trypan Blue
- Vanadium
- Vancomycin Hydrochloride
- Vasopressin
- Verapamil HCl
- Vecuronium Bromide
- Vitamin A acetate
- Vitamin D3
- Ziconotide
- Zinc Sulfate

Updated July 1, 2017

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

- Germanium sesquioxide

Updated July 1, 2017

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
- Allantoin
- 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
- Ascrobyl Palmitate
- Asefetida Tincture
- Asparagus
- Aspartame
- Aspergillus oryza enzymes
- Attapulgite
- Azelaic Acid
- Barosma
- Basic Fuchsin
- Beachwood creosote
- Bean
- Benzalkonium Chloride
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate
- Bethanechol
- Bichloroacetic Acid
- Bipeptide Biocosmetic
- Boric Acid
- Bromelain
- Bronopol
- Buffer Solution, pH Buffer Acid
- Butylated Hydroxytoluene
- Butylene Glycol
- Calcium Alginate
- Calcium Folinate
- Calcium glycinate
- Capsules, Empty Gelatin Vegetable
- Carbamide
- Carbazochrome
- Carbimazole
- Carbolic Acid
- Carbomer 940
- Caustic Potash
- Cedarwood Essential Oil
- Ceratonia
- Ceresin
- Cetrimide
- Chlorhexidine Diacetate Hydrate
- Choline magnesium trisalicylate
- Chondroitin Sulfate
- Chromic chloride

Updated July 1, 2017

- Chromium glycinate
- Chrysin
- Cidofovir
- Cocoa butter
- Coconut Oil Edible
- Coenzyme Q10
- Coenzyme Q50
- Collagenase
- Colophony
- Copper
- Copper Bisglycinate
- Copper Hydrosol
- Corn Oil
- Corn Starch
- Corn Starch and Pregelatinized Starch
- Cottonseed Oil
- Creatine, Monohydrate
- Cucumber Melon Fragrancce
- Cupric Sulfate
- 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
- Glycolic acid
- 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

Updated July 1, 2017

- Lactose Monohydrate
- Lactose, Monohydrate and Corn Starch
- Lactose, Monohydrate and Microcrystalline Ce ll
- 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
- 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 sulfate
- Magnesium trisilicate
- Malt
- Malt soup extract
- Maltodextrin
- Manganese Bisglycinate
- Manganese Chloride
- Manganese citrate
- Mannitol
- 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
- Methylbenzethoniuim chloride
- Methylcellulose
- Methylparaben
- Methypyrilene HCl
- Metoclopramide 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

Updated July 1, 2017

- Mustard oil (alltlishthiocyanate)
- 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 iodin
- Nonylphenxypoly nonoxynol 9
- Noscapine
- Noscapine HCl
- Nutmeg oil
- Nux vomica extract
- Nystatin
- Obtundia
- Octinoxate
- Octisalate
- Octocrylene
- Octoxynol 9
- Octyl Gallate
- 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
- 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 bitratrate
- 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

Updated July 1, 2017

- 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 Acetate
- Potassium bicarbonate
- Potassium bitartrate
- Potassium bromide
- Potassium carbonate
- Potassium chlorate
- Potassium citrate
- Potassium ferrocyanide
- Potassium guaiacolsulfonate
- Potassium hydroxide
- Potassium iodide
- Potassium nitrate
- Potassium salicylate
- Povidone
- Povidone-iodine
- Povidone-vinylacetate copolymers
- Powdered Cellulose
- Pracasil Plus
- Pramoxine HCl
- Precipitated sulfur
- 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
- Pyridoxine HCl
- Pyrilamine 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

Updated July 1, 2017

- Saccharin
- Sage Oil
- Salicyl alcohol
- Salicylamide
- Salsalate
- Sanguinaria extract
- Saponite
- Saw palmetto
- Scopolamine aminoxide HBr
- Scopolamine HBr
- 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
- Sincalide
- 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
- Sodium bromide
- Sodium caprylate
- Sodium carbonate
- Sodium carboxymethylcellulose
- Sodium caseinate
- Sodium diacetate
- Sodium dichromate
- Sodium dihydrogen phosphate
- Sodium dihydrogen phosphate monohydrate
- Sodium fluoride
- Sodium hyaluronate
- 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 priopionate
- Sodium salicylate
- 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
- Succinylcholine chloride, USP
- Sucrose
- Sugars
- Sulfacetamide sodium

Updated July 1, 2017

- 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
- Testosterone cypionate, USP
- Tetrafluoroethane
- Tetrahydrochloride
- Thaumatin
- Thenyldiamine HCl
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Theophylline sodium glycinate
- Theophylline, anhydrous
- Theophylline, USP
- Theophyllline compound with ethylenediamine
- Thiamine mononitrate (vitamin B1)
- Thimerosal
- Thioctic
- Thiocyanoacetate
- Thonzylamine HCl
- Threonine
- Thylene blue
- Thymol
- Titanium dioxide
- Tolindate
- Tolnaftate
- Toltrazuril
- Tolu balsam
- Tommy gel
- Topical starch
- Tranilast
- Triacetin
- Tricalcium phosphate
- Tricaprylin
- Trichloroacetic Acid
- Triclocarban
- Triclosan
- Triethanolamine
- Triglycerides
- Trillium
- Trilostane
- Triolein
- Tripelennamine HCl
- Triple dye
- Triprolidine HCl
- Triticum
- Trolamine salicylate (triethanolamine salicylate)
- Tryptophan
- Turpantine Oil
- Turpantine, Venice
- Tyrosine
- Uinolinium bromide
- Ulose
- Undecoylium chlorideiodine complex
- Undecylenic acid
- Urea
- 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

Updated July 1, 2017

- Zinc acetate
- Zinc caprylate
- Zinc carbonate
- Zinc chloride
- Zinc citrate
- Zinc oxide
- Zinc phenol sulfonate
- Zinc picolinate
- Zinc propionate
- Zinc pyrithione
- Zinc stearate
- Zinc sulfide
- Zinc undecylenate
- Zirconium oxide
- Zyloxin