

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

Three categories of bulk drug substances:

- [Category 1: Bulk Drug Substances Under Evaluation](#)
- [Category 2: Bulk Drug Substances that Raise Significant Safety Risks](#)
- [Category 3: Bulk Drug Substances Nominated Without Adequate Support](#)

### **Updates to Categories of Substances<sup>1</sup> Nominated for the 503B Bulk Drug Substances List**

These bulk drug substances were nominated prior to the date of publication of the guidance for industry “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act” (January 2025).<sup>2</sup>

Additions to category 1:

- Albuterol sulfate
- Atorvastatin calcium
- Eflornithine hydrochloride
- Rosuvastatin calcium
- Topiramate
- Vardenafil hydrochloride

Additions to category 3:

- Phenylpropanolamine bitartrate
- Phenylpropanolamine maleate

FDA will add phenylpropanolamine bitartate and phenylpropanolamine maleate to category 3 because they were nominated with insufficient supporting information for FDA to evaluate them. However, FDA has identified significant safety risks related to these substances. Therefore, the category 3 entry will include a notation of the safety risks associated with phenylpropanolamine bitartate and phenylpropanolamine maleate, including hemorrhagic stroke.

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<sup>1</sup> For purposes of section 503B of the FD&C Act, bulk drug substance means an active pharmaceutical ingredient as defined in 21 CFR 207.1. “Bulk drug substance” (BDS) and “active pharmaceutical ingredient” (API) may be used interchangeably with “substance” throughout this document.

<sup>2</sup> This guidance replaced the 2017 503B Interim Policy Guidance and ended 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 (January 7, 2025). Visit <https://www.fda.gov/media/94402/download>.

FDA will move the following substances from category 3 to category 1 because FDA received new nominations for them with sufficient supporting information:

- Cidofovir
- Desonide

Revisions to category 3:

- FDA will remove “Disodium phosphate” because it is the same substance as Sodium phosphate dibasic, which is in category 3.
- FDA will remove “Disodium Salt, Trihydrate” because the agency determined that it is a typographical error. FDA did not receive a nomination for “Disodium Salt, Trihydrate.”
- FDA will remove “Iodochlorhydroxyquin” because it is the same substance as Clioquinol, which is in category 1.
- Remove Lactose monohydrate from category 3 because the agency determined that it was originally added to category 3 in error. FDA did not receive a nomination for “Lactose monohydrate.”
- Remove Mercuric oxide from category 3 because the agency determined that it was originally added to Category 3 in error. FDA did not receive a nomination for “Mercuric oxide.”
- Remove Mercuric sulfide from category 3 because the agency determined that it was originally added to category 3 in error. FDA did not receive a nomination for “Mercuric sulfide.”
- Remove Microcrystalline cellulose from category 3 because the agency determined that it was originally added to category 3 in error. FDA did not receive a nomination for “Microcrystalline cellulose.”
- Remove “Monosodium phosphate” from category 3 because it is the same substance as Sodium phosphate monobasic, which is in category 1.
- Remove Potassium hydroxide from category 3 because the agency determined that it was originally added to category 3 in error. FDA did not receive a nomination for “Potassium hydroxide.”
- Remove Powdered cellulose from category 3 because the agency determined that it was originally added to category 3 in error. FDA did not receive a nomination for “Powdered cellulose.”
- Remove Pyridoxine from category 3 because the agency determined that it was originally added to category 3 in error. FDA did not receive a nomination for “Pyridoxine.”
- FDA will remove “Theophylline, anhydrous” because it is included in the USP monograph for theophylline, which is in category 1.

## 503B Category 1: Bulk Drug Substances Under Evaluation

\*\*Designates bulk drug substances that are components of FDA approved drugs<sup>3</sup>

Bulk drug substances used in compounding under section 503B of the FD&C Act must meet certain other requirements, including, if an applicable monograph exists under the United States Pharmacopeia (USP), National Formulary (NF) or another compendium or pharmacopeia recognized by the Secretary, the bulk drug substance complies with the monograph.

For the purposes of the bulk drug substance names in the categories, hydrates of a bulk drug substance (i.e., compounds containing water of crystallization), when described in the applicable USPNF drug substance monograph, are included in the scope of the bulk drug substance name. However, the differences in physico-chemical properties (e.g., solubility, stability) of anhydrous versus hydrated forms of the nominated bulk drug substance could have potential impact on the performance of the compounded drug product.

As a result, outsourcing facilities should be mindful of any such potential differences, and when evaluating the appropriate form (anhydrous or hydrate) of the nominated BDS for compounding should assess whether such difference in physico-chemical characteristics (e.g., solubility, stability) could have any adverse impact on the performance of the compounded preparation.

- |                                    |                                     |
|------------------------------------|-------------------------------------|
| • 5-Methyltetrahydrofolate Calcium | • Arginine Hydrochloride/L-arginine |
| • Acetaminophen**                  | Hydrochloride**                     |
| • Acetylcysteine**                 | • Ascorbic acid**                   |
| • Acyclovir**                      | • Ascorbyl Palmitate                |
| • Adapalene**                      | • Aspartic Acid                     |
| • Adenosine**                      | • Atenolol**                        |
| • Albuterol sulfate**              | • Atorvastatin calcium**            |
| • Allantoin                        | • Atropine sulfate**                |
| • Alpha Lipoic Acid                | • Azelaic Acid**                    |
| • Alprostadil**                    | • Azithromycin**                    |
| • Aluminum Chloride                | • Baclofen**                        |
| • Aluminum potassium sulfate       | • Benzocaine                        |
| • Amantadine Hydrochloride**       | • Benzoyl Peroxide**                |
| • Aminophylline**                  | • Betahistine Hydrochloride         |
| • Amiodarone Hydrochloride**       | • Betamethasone Acetate**           |
| • Amitriptyline Hydrochloride**    | • Betamethasone Dipropionate**      |
| • Amphotericin B**                 | • Betamethasone Sodium Phosphate**  |
| • Anastrozole**                    | • Betamethasone Valerate**          |

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<sup>3</sup> A condition of section 503B of the FD&C Act is that the compounded drug product is not essentially a copy of one or more approved drug products. For more information about the “essentially a copy” provision in section 503B, visit FDA’s guidance for industry [“Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”](#) In addition, FDA does not intend to take action against an outsourcing facility for failing to compound in accordance with section 503B(a)(5) if it fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed. Bulk drug substances in category 1 that are components of FDA-approved drugs are designated with two asterisks (\*\*) below.

- Beta-Nicotinamide Adenine Dinucleotide
- Bethanechol Chloride\*\*
- Bimatoprost\*\*
- Biotin\*\*
- Bismuth Nitrate Oxide
- Boric Acid
- Brilliant Blue G\*\*
- Brimonidine Tartrate\*\*
- Bromfenac sodium (for ophthalmic solutions only) \*\*
- Brompheniramine maleate\*\*
- Budesonide\*\*
- Bumetanide\*\*
- Bupivacaine Hydrochloride\*\*
- Caffeine\*\*
- Calcipotriene\*\*
- Calcium Chloride\*\*
- Calcium Gluconate\*\*
- Cantharidin
- Capsaicin\*\*
- Carbamazepine\*\*
- Chloramphenicol (except for oral administration)
- Chloroquine Phosphate\*\*
- Chlorpheniramine Maleate\*\*
- Chlorpromazine Hydrochloride\*\*
- Cholestyramine Resin\*\*
- Choline Chloride
- Chromic Chloride\*\*
- Chromium Chloride\*\*
- Ciclopirox Olamine\*\*
- Cidofovir\*\*
- Cimetidine\*\*
- Ciprofloxacin Hydrochloride\*\*
- Citric Acid Anhydrous\*\*
- Citrulline/L-Citrulline
- Clindamycin Hydrochloride\*\*
- Clindamycin Phosphate\*\*
- Clioquinol\*\*
- Clobetasol Propionate\*\*
- Clomipramine Hydrochloride\*\*
- Clonidine Hydrochloride\*\*
- Clotrimazole\*\*
- Coal Tar Solution
- Cocaine Hydrochloride\*\*
- Copper Gluconate
- Cromolyn Sodium\*\*
- Cupric Sulfate\*\*
- Cyanocobalamin\*\*
- Cyclobenzaprine Hydrochloride\*\*
- Cyclopentolate Hydrochloride\*\*
- Cyclosporine/Cyclosporine A\*\*
- Dapiprazole Hydrochloride\*\*
- Dapsone\*\*
- Deoxy-D-Glucose
- Desonide\*\*
- Desoximetasone\*\*
- Dexamethasone Acetate
- Dexamethasone Sodium Phosphate\*\*
- Dexpanthenol\*\*
- Dextromethorphan hydrobromide\*\*
- DHEA (dehydroepiandrosterone) \*\*
- D-glucose\*\*
- Dibucaine Hydrochloride\*\*
- Diclofenac Sodium\*\*
- Diiodohydroxyquinoline
- Diltiazem Hydrochloride\*\*
- Dimercaprol\*\*
- Dimercapto-1-propanesulfonic acid (DMPS)\*\*
- Diphenhydramine Hydrochloride\*\*
- Disulfiram\*\*
- Dorzolamide Hydrochloride\*\*
- Doxycycline Hyclate\*\*
- Droperidol\*\*
- Dutasteride\*\*
- Dyclonine Hydrochloride\*\*
- Econazole Nitrate\*\*
- Edetate disodium (for ophthalmic use only)
- Eflornithine hydrochloride\*\*
- Enalapril Maleate\*\*
- Ephedrine Hydrochloride
- Epinephrine\*\*
- Epinephrine Bitartrate\*\*
- Erythromycin Ethylsuccinate\*\*
- Estradiol\*\*
- Estradiol Cypionate\*\*
- Estriol
- Estrone\*\*
- Ethanol\*\*
- Etomidate\*\*

- Famotidine\*\*
- Fentanyl Citrate\*\*
- Ferric subsulfate
- Finasteride\*\*
- Fluconazole\*\*
- Fluocinolone Acetonide\*\*
- Fluocinonide\*\*
- Fluorouracil\*\*
- Fluoxetine HCl\*\*
- Flurbiprofen\*\*
- Fluticasone Propionate\*\*
- Furosemide\*\*
- Gabapentin\*\*
- Gamma-Aminobutyric Acid
- Gatifloxacin (for ophthalmic solutions only)\*\*
- Gentamicin Sulfate\*\*
- GHRP-2 (except for injectable and nasal routes of administration)
- Glucosamine Sulfate Potassium Chloride
- Glucosamine Sulfate Sodium Chloride
- Glutamic acid\*\*
- Glutamine\*\*
- Glutathione
- Glycerin\*\*
- Gonadorelin Acetate\*\*
- Guaifenesin\*\*
- Haloperidol\*\*
- Heparin sodium\*\*
- Hyaluronic acid sodium salt
- Hydralazine Hydrochloride\*\*
- Hydrochloric Acid
- Hydrocortisone\*\*
- Hydromorphone Hydrochloride\*\*
- Hydroquinone\*\*
- Hydroxocobalamin\*\*
- Hydroxocobalamin Hydrochloride
- Hydroxyprogesterone caproate\*\*
- Hydroxyzine Pamoate\*\*
- Ibuprofen\*\*
- Imipramine Hydrochloride\*\*
- Imiquimod\*\*
- Indomethacin\*\*
- Inositol
- Iodoform
- Isoproterenol Hydrochloride\*\*
- Isotretinoin\*\*
- Itraconazole\*\*
- Ivermectin\*\*
- Ketamine Hydrochloride\*\*
- Ketoconazole\*\*
- Ketoprofen\*\*
- Ketorolac Tromethamine\*\*
- Labetalol Hydrochloride\*\*
- Lactic Acid\*\*
- Lansoprazole\*\*
- Latanoprost\*\*
- Levocarnitine\*\*
- Levocetirizine Dihydrochloride\*\*
- Lidocaine\*\*
- Lidocaine Hydrochloride\*\*
- Lincomycin Hydrochloride\*\*
- L-Lysine
- L-lysine Hydrochloride/Lysine Hydrochloride
- Lorazepam\*\*
- Loteprednol etabonate\*\*
- L-Ornithine Hydrochloride
- L-Proline
- Magnesium Chloride \*\*
- Magnesium Sulfate \*\*
- Malic Acid
- Manganese Chloride\*\*
- Manganese Sulfate \*\*
- Medroxyprogesterone Acetate\*\*
- Menthol\*\*
- Meperidine Hydrochloride (a.k.a. Pethidine Hydrochloride) \*\*
- Methadone Hydrochloride\*\*
- Methionine/ Methionine (L)
- Methylcobalamin/Methyl B12
- Methylprednisolone Acetate\*\*
- Methylsulfonylmethane (MSM)
- Metronidazole\*\*
- Miconazole nitrate\*\*
- Midazolam Hydrochloride\*\*
- Mineral Oil\*\*
- Minocycline Hydrochloride\*\*
- Minoxidil\*\*
- Mitomycin\*\*
- Mometasone Furoate\*\*
- Monosodium Glutamate

- Morphine Sulfate \*\*
- Moxifloxacin hydrochloride\*\*
- Mupirocin\*\*
- Naloxone Hydrochloride\*\*
- Naltrexone\*\*
- Naltrexone Hydrochloride\*\*
- Nandrolone Decanoate\*\*
- Neostigmine Methylsulfate\*\*
- Nepafenac\*\*
- Niacin\*\*
- Niacinamide\*\*
- Nicotinamide riboside chloride
- Nifedipine\*\*
- Norepinephrine Bitartrate\*\*
- Nystatin\*\*
- Ondansetron Hydrochloride\*\*
- Oxymetazoline Hydrochloride\*\*
- Oxytocin\*\*
- Papaverine Hydrochloride
- Pentoxifylline\*\*
- Phenol
- Phenoxybenzamine Hydrochloride\*\*
- Phentolamine Mesylate\*\*
- Phenylephrine Hydrochloride\*\*
- Phosphatidylcholine
- Phytonadione\*\*
- Podophyllum
- Podophyllum Resin
- Polidocanol\*\*
- Polymyxin B Sulfate\*\*
- Potassium chloride\*\*
- Potassium Phosphate Monobasic [KH<sub>2</sub>PO<sub>4</sub>]\*\*
- Potassium Phosphate Dibasic [K<sub>2</sub>HPO<sub>4</sub>]/ Potassium Phosphate Dibasic Anhydrous\*\*
- Pramoxine hydrochloride\*\*
- Precipitated Sulfur
- Prednisolone\*\*
- Prednisolone Acetate\*\*
- Prednisolone Sodium Phosphate\*\*
- Prilocaine\*\*
- Procaine Hydrochloride\*\*
- Progesterone\*\*
- Promethazine Hydrochloride\*\*
- Proparacaine Hydrochloride\*\*
- Propranolol hydrochloride\*\*
- Prostaglandin E1\*\*
- Pyridoxal 5-Phosphate Monohydrate
- Pyridoxine Hydrochloride\*\*
- Remifentanyl Hydrochloride\*\*
- Riboflavin Sodium Phosphate \*\*
- Rocuronium Bromide\*\*
- Ropivacaine Hydrochloride\*\*
- Rosuvastatin calcium\*\*
- Ruxolitinib phosphate\*\*
- Salicylic Acid
- Scopolamine hydrobromide
- Sermorelin Acetate\*\*
- Sildenafil Citrate\*\*
- Sincalide \*\*
- Sodium Acetate Anhydrous\*\*
- Sodium Ascorbate\*\*
- Sodium Benzoate\*\*
- Sodium Chloride\*\*
- Sodium Citrate\*\*
- Sodium Iodide I-131\*\*
- Sodium L-Aspartate Monohydrate
- Sodium Molybdate
- Sodium phosphate/Sodium Phosphate Monobasic\*\*
- Sodium Selenite Pentahydrate
- Sodium Tetradecyl Sulfate\*\*
- Sodium thiosulfate (for topical administration only)\*\*
- Spironolactone\*\*
- Succinylcholine Chloride\*\*
- Sufentanil Citrate\*\*
- Sulfacetamide Sodium\*\*
- Sulfamethoxazole\*\*
- Sulfan Blue
- Tacrolimus\*\*
- Tadalafil\*\*
- Taurine
- Tazarotene\*\*
- Terbinafine Hydrochloride\*\*
- Testosterone\*\*
- Testosterone Cypionate\*\*
- Testosterone Enanthate\*\*
- Testosterone Propionate\*\*
- Tetracaine\*\*
- Tetracaine Hydrochloride\*\*

- Tetracycline Hydrochloride\*\*
- Theophylline\*\*
- Thiamine Hydrochloride (vitamin B1) \*\*
- Thymol iodide
- Timolol Maleate\*\*
- Tofacitinib Citrate\*\*
- Tolnaftate\*\*
- Topiramate\*\*
- Tramadol Hydrochloride\*\*
- Tranexamic Acid\*\*
- Tretinoin\*\*
- Triamcinolone
- Triamcinolone Acetonide\*\*
- Triamcinolone diacetate\*\*
- Trimethoprim\*\*
- Tromethamine\*\*
- Tropicamide\*\*
- Trypan Blue\*\*
- Ubidecarenone (Coenzyme Q10)
- Urea\*\*
- Valacyclovir Hydrochloride\*\*
- Vancomycin Hydrochloride\*\*
- Vardenafil Hydrochloride\*\*
- Vecuronium Bromide\*\*
- Vitamin A acetate
- Vitamin D3\*\*
- Ziconotide\*\*
- Zinc chloride\*\*
- Zinc Oxide\*\*
- Zinc pyrithione\*\*
- Zinc Sulfate\*\*

### 503B 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.

- Chloral Hydrate
- Diethylstilbestrol<sup>4</sup>
- Edetate Disodium (except for ophthalmic use)
- GHRP-2 (for injectable and nasal routes of administration)
- GHRP-6
- Ibutamoren Mesylate
- Ipamorelin Acetate
- Neomycin sulfate (all parenteral drug products containing neomycin sulfate except when used for ophthalmic or otic use or in combination with polymyxin B sulfate for irrigation of the intact bladder)
- Quinacrine Hydrochloride for intrauterine administration
- Tranilast

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<sup>4</sup> All oral and parenteral drug products containing 25 mg or more of diethylstilbestrol per unit dose are on the list of drug products withdrawn or removed from the market for reasons of safety or effectiveness (Withdrawn or Removed List) (21 CFR 216.24). The agency is placing diethylstilbestrol products containing less than 25 mg of diethylstilbestrol per unit dose in category 2 given the established positive association between diethylstilbestrol exposure and cancer.

### 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
- Acetic Acid, 3% (w/v) Aqueous Solution
- Acetic Acid, 5% (w/v) Aqueous Solution
- Acetone
- Acetone Sodium Bisulfite
- Acetyl Hexapeptide-3
- Acetyl-L-Carnitine hydrochloride
- Adenosine-5-triphosphate disodium salt
- Agar
- Alcloxa
- Aldioxa
- Aldosterone
- Alfalfa
- Alfalfa leaves
- Alginic acid
- Aliphatic Polyesters
- Allantoin (with aminobenzoic acid)
- Almadrate sulfate
- Aloe ingredients (aloe, aloe extract, aloe flower extract, aloe vera, aloe vera gel extract)
- Aloin
- Alpha Ketoglutaric acid
- Alumina Powder, hydrated
- Aluminum acetate
- Aluminum phosphate adjuvant
- Aluminum phosphate
- Aluminum sulfate
- Aminacrine Hydrochloride
- Aminoacetic acid
- Ammonia solution, strong
- Ammonium Alginate
- Ammonium bromide
- Ammonium chloride
- Ammonium hydroxide
- Anise oil
- Anise seed
- Argentyn
- Arginine
- Aromatic powder
- Asafetida
- Asafetida Tincture
- Asclepias tuberosa
- Asparagus
- Aspartame
- Attapulgit
- Barosma
- Basic Fuchsin
- Beachwood creosote
- Bean
- Benzalkonium Chloride
- Betamechlothesone
- Beta-nicotinamide adenine dinucleotide disodium salt, trihydrate
- Bethanechol
- Bichloroacetic Acid/Dichloroacetic Acid
- Bipeptide Biocosmetic
- Bronopol
- Buffer Solution, pH Buffer Acid (pH 4.01)
- Buffer Solution, pH Buffer Alkaline (pH 10.00)
- Buffer Solution, pH Buffer Neutral (pH 7.00)
- Butylated Hydroxytoluene
- Butylene Glycol
- Calcium Alginate
- Calcium Folate
- Calcium glycinate
- Cannabidiol and cyclodextrin
- Capsules, Empty Gelatin Vegetable
- Carbamide
- Carbazochrome
- Carbimazole
- Carbolic Acid
- Carbomer 940 /Carbomer gel (aqueous)/Carbomer gel (hydroalcoholic)
- Caustic Potash
- Caustic Soda (sodium hydroxide)
- Cedarwood Essential Oil
- Ceratonia
- Ceresin
- Cetrimide
- Chloramphenicol Palmitate (for topical and otic administration)
- Chlorhexidine Diacetate Hydrate
- Choline Bitartrate

- Choline magnesium trisalicylate
- Chondroitin Sulfate
- Chromium glycinate
- Chrysin
- Cocoa butter
- Coconut Oil Edible
- Coenzyme Q50
- Colophony
- 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
- Diaminopyridine (3,4-)
- Difluoroethane
- Diindolymethane
- Dimercaptosuccinic acid
- Dimethyl Ether (aka Methoxymethane)
- Dimethyl Ketone
- Dimethyl Phthalate
- Dimethylacetamide
- Dimethylaminoethanol Bitartrate
- Dimethylaminoethanol Complex
- Dimethylglycine Hydrochloride
- Dinitrochlorobenzene
- Dipropylene Glycol
- Disodium Hydrogen Phosphate
- DL-Phenylalanine
- Docosanol
- Dodecyl Gallate
- Domperidone
- Edetate tetrasodium tetrahydrate
- Epinephrine hydrochloride
- Ergoloid Mesylates
- Ergotamine Tartrate
- Ethanolamine
- Ethyl Lactate
- Ethylene Vinyl Acetate
- Ferric sulfate hydrate
- Ferric sulfate solution
- Folinic acid calcium salt
- Formaldehyde
- Formoterol Fumarate Dihydrate
- Fructose and Pregelatinized Starch
- Germanium Sesquioxide<sup>5</sup>
- Ginger root powder
- Ginko Biloba Standardized Extract
- Gluconic acid calcium salt
- Glutaraldehyde solution
- Glycerol Formal
- Glyceryl Monostearate
- Glyceryl Palmitostearate
- Glycofurol
- Glydiazinamide
- Grape seed oil
- Gum Arabic
- Hectorite
- Heptafluoropropane
- Hexetidine
- Hydrazine sulfate
- Hydrogen Peroxide
- Hydroxyethylpiperazine Ethane Sulfonic Acid
- Hydroxymethylmethyl Cellulose
- Ichthammol
- ICU Bottom Paste (Maalox)

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<sup>5</sup> Germanium sesquioxide is likely to be contaminated with highly toxic inorganic forms of germanium salts which can be toxic to the kidneys. Germanium products, including products offered under the name germanium sesquioxide, have resulted in nephrotoxicity (kidney injury) and death, even at recommended use levels. Visit <https://wayback.archive-it.org/7993/20170723121621/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmaceuticalCompoundingAdvisoryCommittee/UCM465542.pdf>, [Import Alert 54-07 \(fda.gov\)](https://www.fda.gov/alerts/54-07).

- Indigo Carmine
- Indole-3-carbinol
- Inositol Hexanicotinate
- Iopanoic Acid
- Iron Glycinate Chelate
- Isopropyl Isostearate
- Kaolin, Colloidal Powder
- Karaya Gum
- Ketotifen Fumarate
- Kojic Acid
- 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-Carnosine
- L-Cysteine
- Lecithin Soya Granular
- Lecithin Organogel
- Levomenthol
- Levulose
- L-Histidine Monohydrochloride, Monohydrate
- Linoleic Acid
- Liquid paraffin
- Liquid petrolatum
- Loxasperse
- L-Triiodothyronine Sodium
- Lysine aspirin
- Magaldrate
- Magnesium
- Magnesium aluminum silicate
- Magnesium aluminosilicate
- Magnesium ascorbate
- Magnesium bisglycinate
- Magnesium Bisglycinate Dihydrate 11%
- Magnesium carbonate
- Magnesium citrate
- Magnesium citrate (oral)
- Magnesium glycinate
- Magnesium Glycinate 15%
- 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 Hydrochloride
- Medium Cream
- Menfegol
- Menthol/peppermint oil
- Meradimate (menthyl anthranilate)
- Meralein sodium
- Merbromin
- Mercufenol chloride
- Mercuric chloride
- Mercuric salicylate
- Mercuric sulfide, red/Mercury sulfide
- Mercury
- Mercury-containing ingredient
- Mercury oleate
- Mercury, ammoniated
- Metaproterenol sulfate
- Methapyrilene fumarate
- Methapyrilene hydrochloride
- Methenamine
- Methoxyphenamine Hydrochloride
- Methoxypolyoxyethyleneglycol 550 laurate
- Methyl nicotinate
- Methyl salicylate
- Methylbenzethonium chloride
- Methylcellulose
- Methylcellulose Gel 1%
- Methylcellulose Oral Solution
- Methylparaben
- Milk and molasses
- Milk of sulfur
- Milk solids, dried

- Mineral oil and Lanolin Alcohols
- Mineral oil, light
- Minerals
- Molasses
- Molybdenum Glycinate
- Mono- and di-glycerides
- Monosodium L-Aspartate
- Mullein
- Mustard oil (allitlishtiocyanate)
- Mycozyme
- Myrrh
- Myrrh (fluid extract)
- Myrrh gum tincture
- Myrrh tincture
- N-Acetyl-D-Glucosamine
- Naphazoline Hydrochloride
- Naphazoline Hydrochloride (jelly)
- Natural estrogenic hormone
- Neohesperidine Dihydrochalcone
- Neomycin ointment (combination only)
- Neomycin sulfate
- Neomycin sulfate cream
- Nettle
- Nickel-pectin
- Nicotinamide
- Nicotinic Acid
- Nitromersol
- Non-Fat Dry Milk
- Nonylphenoxypoly (ethyleneoxy) ethanol iodine
- Nonylphenoxypoly nonoxynol 9
- Noscapine
- Noscapine Hydrochloride
- Nutmeg oil
- Nux vomica extract
- 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 Hydrochloride
- Padimate a
- Padimate o
- Pambron
- Panthenol
- Pantothenic acid
- Papaverine
- Papaya enzymes
- Papaya, natural
- Para-chloromercuriphenol
- Paraffin
- Paregoric
- Parethoxycaine Hydrochloride
- Parsley
- Passion flower extract
- Patchouli Essential Oil
- Pectin
- Pennyroyal Oil
- Pentylene tetrazole
- Peppermint
- Peppermint Oil
- Peppermint Oil (mouthwash)
- Peppermint Oil and Sage Oil
- Peppermint Spirit
- Peruvian Balsam
- Peruvian balsam oil
- Petrolatum
- Petrolatum and lanolin alcohols
- Phenacaine Hydrochloride
- Phenindamine Tartrate
- Pheniramine Maleate
- Phenobarbital
- Phenolate sodium
- Phenolphthalein
- Phenoxyacetic acid
- Phenyl salicylate
- Phenylalanine

- Phenylephrine bitartrate (effervescent)
- Phenylmercuric Borate
- Phenylmercuric acetate
- Phenylmercuric nitrate
- Phenylpropanolamine bitartrate<sup>6</sup>
- Phenylpropanolamine maleate<sup>7</sup>
- Phenyltoloxamine citrate
- Phenyltoloxamine dihydrogen citrate
- Phenyltoloxamine Hydrochloride
- Phosphate fluoride
- Phosphorated carbohydrate
- Phosphoric acid
- Phosphorus
- Phytolacca
- Picrotoxin
- Pilocarpine Nitrate
- Pimobendan
- Pine tar
- Pine tar preparations (extract white pine compound, pine tar, syrup of)
- Piperazine citrate
- Piperocaine Hydrochloride
- Piperonyl butoxide
- Pipsissewa
- Piracetam
- Piracetam dihydrogen citrate
- Piscidia erythrina
- Pitcher Plant
- Plantago ovata husks
- Plantago seed
- Plantago seed/Psyllium seed, blond
- Plantago seed/Psyllium seed husks
- Poloxamer 188
- Poloxamer 407
- 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
- Polyoxethylene laurate
- Polysorbate 20
- Polysorbate 80
- Polyvinyl alcohol
- Potash Lye
- Potassium bicarbonate
- Potassium bitartrate
- Potassium bromide
- Potassium carbonate
- Potassium chlorate
- Potassium citrate
- Potassium ferrocyanide
- Potassium guaiacolsulfonate
- Potassium hydroxide, 10% (w/v) Solution
- Potassium iodide
- Potassium nitrate
- Potassium Phosphate Tribasic [K<sub>3</sub>PO<sub>4</sub>]
- Potassium salicylate
- Povidone
- Povidone-iodine
- Povidone-vinylacetate copolymers
- Pracasil Plus
- Pregnenolone micronized
- Prolase
- Propionic acid
- Propylene glycol
- Propylhexedrine
- Propylparaben
- Protease
- Protein hydrolysate
- Protirelin

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<sup>6</sup> Phenylpropanolamine products have been associated with an increased risk of hemorrhagic stroke among women using the drug for weight control and nasal decongestion. Men may also be at risk. Visit <https://www.fda.gov/drugs/information-drug-class/fda-issues-public-health-warning-phenylpropanolamine> and <https://www.fda.gov/drugs/information-drug-class/phenylpropanolamine-ppa-information-page>.

<sup>7</sup> Phenylpropanolamine products have been associated with an increased risk of hemorrhagic stroke among women using the drug for weight control and nasal decongestion. Men may also be at risk. Visit <https://www.fda.gov/drugs/information-drug-class/fda-issues-public-health-warning-phenylpropanolamine> and <https://www.fda.gov/drugs/information-drug-class/phenylpropanolamine-ppa-information-page>.

- Prune concentrate dehydrate
- Prune powder
- Pseudoephedrine Hydrochloride
- Pseudoephedrine Sulfate
- Pseudoephedrine Sulfate (oral)
- Psyllium (hemicellulose)
- Psyllium hydrophilic mucilloid
- Psyllium seed
- P-T-butyl-m-cresol
- Pyrantel pamoate
- Pyrethrum extract
- Pyridoxyl-5-Phosphate
- Pyriline maleate
- Pyrrolidone
- Pyruvic Aldehyde 40% Aqueous Solution
- Quinine
- Racemethionine
- Racephedrine hydrochloride
- Racephedrine hydrochloride (oral/topical)
- Racepinephrine hydrochloride
- Raffinose
- Red petrolatum
- Reosote
- Resorcinol
- Resorcinol (when combined with sulfur)
- Resorcinol monoacetate
- Resorcinol monoacetate (in combination with sulfur)
- Resveratrol
- Retinoic Acid-All Trans
- Rhubarb fluid extract
- Rhubarb, Chinese
- Riboflavin
- Rice polishings
- Romohydrate
- Sabadilla, alkaloids
- Saccharin
- Sage Oil
- Salicyl alcohol
- Salicylamide
- Salsalate
- Sanguinaria extract
- Saponite
- Saw palmetto
- Scopolamine aminoxide hydrobromide
- Sea mineral
- Secretin, human 99%
- Selenium
- Selenium sulfide
- Selenium sulfide, micronized
- Senecio aureus
- Senna
- Senna fluid extract
- Senna pod concentrate
- Senna syrup
- Sennosides a and b
- Serotonin Hydrochloride
- Sesame Oil
- Sesame Seed
- Shark liver oil
- Shark liver oil (combination only)
- 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
- Sodium bromide
- Sodium caprylate
- Sodium carbonate
- Sodium carboxymethylcellulose
- Sodium caseinate
- Sodium diacetate
- Sodium dichromate
- Sodium dihydrogen phosphate

- Sodium dihydrogen phosphate monohydrate
- Sodium fluoride
- Sodium fluoride (aqueous)
- Sodium fluoride (aqueous) (acidulated phosphate fluoride with 0.01% fl)
- Sodium fluoride (aqueous) (acidulated phosphate fluoride with 0.2% fl)
- Sodium fluoride gel or paste
- Sodium fluoride powder
- Sodium Hexachloroplatinate (IV) Hexahydrate
- Sodium hydroxide 1N
- Sodium monofluoro phosphate
- Sodium monofluoro phosphate (gel or paste)
- Sodium monofluoro phosphate (rinse)
- Sodium nitrate
- Sodium octanoate
- Sodium oleate
- Sodium para-amino benzoate
- Sodium perborate
- Sodium perborate monohydrate
- Sodium phosphate dibasic
- Sodium potassium tartrate
- Sodium propionate
- Sodium salicylate
- Sodium salicylic acid phenolate
- Sodium sulfide
- Soft Paraffin
- Sols, secondary
- Sorbitol
- Soy meal
- Soybean oil, hydrogenated (powder)
- Soybean protein
- Splenda
- Squill preparations
- Stannous fluoride
- Stannous fluoride (gel)
- Stannous fluoride (rinse)
- Stannous pyrophosphate and zinc citrate
- Stearyl alcohol
- Stevia Powder Extract
- Strawberry
- Strontium chloride
- Strychnine
- Sublimed sulfur
- Sucrose
- Sugars
- Sulferated oils of turpentine
- Sulfobutylether B-Cyclodextrin
- Sulfur
- Sulfur (when combined w/ resorcinol, resorcinol monoacetate)
- Sulisobenzone
- Supposibase-F
- T3 Sodium Dilution
- Talc
- Tannic acid
- Tannic acid glycerite
- Taraxacum officinale
- Tartaric acid
- Tartrate (acid or salt)
- Tea Tree Oil
- Teaberry Oil
- Terpin hydrate preparations
- Tetrafluoroethane
- Tetrahydrochloride
- Thaumatin
- Thenyldiamine Hydrochloride
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Theophylline sodium glycinate
- Theophylline compound with ethylenediamine
- Theophylline mens
- Thiamine mononitrate (vitamin B1)
- Thimerosal
- Thiocynoacetate
- Thonzylamine Hydrochloride
- Threonine
- Thylene blue
- Thymol
- Thymol (lozenge)
- Thymol (mouthwash)
- Thymosin alpha-1
- Titanium dioxide
- Tolindate
- Toltrazuril

- Tolu balsam
- Tolu preparations (tolu, tolu balsam tincture)
- Tommy gel
- Topical starch
- Triacetin
- Tricalcium phosphate
- Tricaprylin
- Triclocarban
- Triclosan
- Triethanolamine
- Triglycerides
- Trillium
- Trilostane
- Triolein
- Tripelennamine Hydrochloride
- Triple dye
- Triprolidine Hydrochloride
- Triticum
- Trolamine salicylate (triethanolamine salicylate)
- Tryptophan
- 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 oil (topical)
- Turpentine, venice
- Tyrosine
- Uinolinium bromide
- Ulose
- Undecoylium chlorideiodine complex
- Undecylenic acid
- Uva ursi, extract of
- Uva ursi, potassium extract
- Valic acid
- Valine
- Vegetable (green)
- Verapamil
- Vitamin A
- Vitamin A palmitate
- Vitamin A Palmitate, in Corn Oil
- Vitamin B Complex
- 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 Hydrochloride
- Xylometazoline Hydrochloride (aqueous)
- Xylometazoline Hydrochloride (jelly)
- Yeast
- Yellow mercuric oxide
- Zinc
- Zinc acetate
- Zinc caprylate
- Zinc carbonate
- Zinc citrate
- Zinc phenol sulfonate
- Zinc picolinate
- Zinc propionate
- Zinc stearate
- Zinc sulfide
- Zinc undecylenate
- Zirconium oxide
- Zyloxin