

## **U.S. Food and Drug Administration**

### **Non-Monograph Conditions NM900: Drug Products Containing Certain Active Ingredients Offered Over-the-Counter for Certain Uses (Posted September 24, 2021)<sup>1</sup>**

(a) A number of active ingredients have been present in over-the-counter (OTC) drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses:

#### **(1) Topical acne drug products**

Alcloxa

Alkyl isoquinolinium bromide

Aluminum chlorohydrate

Aluminum hydroxide

Benzocaine

Benzoic acid

Boric acid

Calcium polysulfide

Calcium thiosulfate

Camphor

Chloroxylenol

Cloxyquin

Coal tar

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<sup>1</sup> Final Administrative Order (OTC000007), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

Dibenzothiophene

Estrone

Magnesium aluminum silicate

Magnesium sulfate

Phenol

Phenolate sodium

Phenyl salicylate

Povidone-iodine

Pyrilamine maleate

Resorcinol (as single ingredient)

Resorcinol monoacetate (as single ingredient)

Salicylic acid (over 2 up to 5 percent)

Sodium borate

Sodium thiosulfate

Tetracaine hydrochloride

Thymol

Vitamin E

Zinc oxide

Zinc stearate

Zinc sulfide

**(2) Anticaries drug products**

Calcium sucrose phosphate

Dicalcium phosphate dihydrate

Disodium hydrogen phosphate<sup>2</sup>

Hydrogen fluoride

Phosphoric acid<sup>1</sup>

Sodium carbonate

Sodium dihydrogen phosphate

Sodium dihydrogen phosphate monohydrate

Sodium monofluorophosphate (6 percent rinse)

Sodium phosphate

Sodium phosphate, dibasic anhydrous reagent<sup>1</sup>

**(3) Antidiarrheal drug products**

Aluminum hydroxide

Atropine sulfate

Attapulgate, activated

Bismuth subnitrate

Calcium carbonate

Calcium hydroxide

Calcium polycarbophil

Carboxymethylcellulose sodium

Charcoal (activated)

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<sup>2</sup> These ingredients are non-monograph except when used to prepare acidulated phosphate fluoride treatment rinses identified in § M021.10(a)(3) of OTC Monograph M021.

Glycine

Homatropine methylbromide

Hyoscyamine sulfate

Lactobacillus acidophilus

Lactobacillus bulgaricus

Opium, powdered

Opium tincture

Paregoric

Pectin

Phenyl salicylate

Polycarbophil

Potassium carbonate

Rhubarb fluid extract

Scopolamine hydrobromide

Zinc phenolsulfonate

**(4) Antiperspirant drug products**

Alum, potassium

Aluminum bromohydrate

Aluminum chloride (alcoholic solutions)

Aluminum chloride (aqueous solution) (aerosol only)

Aluminum sulfate

Aluminum sulfate, buffered (aerosol only)

Aluminum sulfate buffered with sodium aluminum lactate

Sodium aluminum chlorohydroxy lactate

**(5) Cold, cough, allergy, bronchodilator, and antiasthmatic drug products**

(i) Antihistamine drug products

Methapyrilene hydrochloride

Methapyrilene fumarate

Phenyltoloxamine dihydrogen citrate

Thenyldiamine hydrochloride

(ii) Nasal decongestant drug products

Allyl isothiocyanate

Bornyl acetate (topical)

Camphor (lozenge)

Cedar leaf oil (topical)

Creosote, beechwood (oral)

Creosote, beechwood (topical)

Ephedrine (oral)

Ephedrine hydrochloride (oral)

Ephedrine sulfate (oral)

Eucalyptol (lozenge)

Eucalyptol (mouthwash)

Eucalyptus oil (lozenge)

Eucalyptus oil (mouthwash)

Menthol (mouthwash)

Peppermint oil (mouthwash)

Racephedrine hydrochloride (oral/topical)

Thenyldiamine hydrochloride

Thymol

Thymol (lozenge)

Thymol (mouthwash)

Turpentine oil

Any ingredient(s) labeled with claims or directions for use for sinusitis or for relief of nasal congestion associated with sinusitis.

(iii) Expectorant drug products.

Ammonium chloride

Antimony potassium tartrate

Beechwood creosote

Benzoin preparations (compound tincture of benzoin, tincture of benzoin)

Camphor

Chloroform

Eucalyptol/eucalyptus oil

Horehound

Iodides (calcium iodide anhydrous, hydroiodic acid syrup, iodized lime, potassium iodide)

Ipecac

Ipecac fluid extract

Ipecac syrup

Menthol/peppermint oil

Pine tar preparations (extract white pine compound, pine tar, syrup of pine tar, compound white pine syrup, white pine)

Potassium guaiacolsulfonate

Sodium citrate

Squill preparations (squill, squill extract)

Terpin hydrate preparations (terpin hydrate, terpin hydrate elixir)

Tolu preparations (tolu, tolu balsam, tolu balsam tincture)

Turpentine oil (spirits of turpentine)

(iv) Bronchodilator drug products

Aminophylline

Belladonna alkaloids

Euphorbia pilulifera

Metaproterenol sulfate

Methoxyphenamine hydrochloride

Pseudoephedrine hydrochloride

Pseudoephedrine sulfate

Theophylline, anhydrous

Theophylline calcium salicylate

Theophylline sodium glycinate

Any combination drug product containing theophylline (e.g., theophylline and ephedrine, or theophylline and ephedrine and phenobarbital).

Any ingredient(s) in a pressurized metered-dose inhaler container.

Any oral bronchodilator active ingredient (e.g., ephedrine, ephedrine hydrochloride, ephedrine sulfate, racephedrine hydrochloride, or any other ephedrine salt) in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient.

**(6) Dandruff/seborrheic dermatitis/psoriasis drug products**

Alkyl isoquinolinium bromide

Allantoin

Benzalkonium chloride

Benzethonium chloride

Boric acid

Calcium undecylenate

Captan

Chloroxylenol

Colloidal oatmeal

Cresol, saponated

Ethohexadiol

Eucalyptol

Juniper tar

Lauryl isoquinolinium bromide

Menthol

Mercury oleate

Methylbenzethonium chloride

Methyl salicylate

Phenol



Phenolate sodium

Pine tar

Povidone-iodine

Resorcinol

Sodium borate

Sodium salicylate

Thymol

Undecylenic acid

**(7) Digestive aid drug products**

Alcohol

Aluminum hydroxide

Amylase

Anise seed

Aromatic powder

Asafetida

Aspergillus oryza enzymes (except lactase enzyme derived from *Aspergillus oryzae*)

Bacillus acidophilus

Bean

Belladonna alkaloids

Belladonna leaves, powdered extract

Betaine hydrochloride

Bismuth subcarbonate

Bismuth subgallate

Bismuth sodium tartrate  
Black radish powder  
Blessed thistle (cnicus benedictus)  
Buckthorn  
Calcium carbonate  
Calcium gluconate  
Capsicum  
Capsicum, fluid extract of  
Carbon  
Cascara sagrada extract  
Catechu, tincture  
Catnip  
Cellulase  
Chamomile flowers  
Charcoal, activated  
Charcoal, wood  
Chloroform  
Cinnamon oil  
Cinnamon tincture  
Citrus pectin  
Dehydrocholic acid  
Diastase  
Diastase malt

Dog grass

Dihydroxyaluminum sodium carbonate

Duodenal substance

Elecampane

Ether

Fennel acid

Galega

Garlic, dehydrated

Ginger

Glutamic acid hydrochloride

Glycine

Hectorite

Hemicellulase

Homatropine methylbromide

Horsetail

Huckleberry

Hydrastis canadensis (golden seal)

Hydrastis fluid extract

Hydrochloric acid

Iodine

Iron ox bile

Johnswort

Juniper

Kaolin, colloidal

Knotgrass

Lactic acid

Lactose

Lavender compound, tincture of

Linden

Lipase

Lysine hydrochloride

Magnesium hydroxide

Magnesium trisilicate

Mannitol

Mycozyme

Myrrh, fluid extract of

Nettle

Nickel-pectin

Nux vomica extract

Orthophosphoric acid

Ox bile extract

Papaya, natural

Pancreatin

Pancrelipase

Papain

Pectin

Peppermint

Peppermint oil

Peppermint spirit

Pepsin

Phenacetin

Potassium bicarbonate

Potassium carbonate

Protease

Prolase

Rhubarb fluid extract

Senna

Sodium bicarbonate

Sodium chloride

Sodium citrate

Sodium salicylate

Sorbitol

Stem bromelain

Strawberry

Strychnine

Tannic acid

Trillium

Woodruff

**(8) External analgesic drug products**

(i) Analgesic and anesthetic drug products.

Aspirin

Chloral hydrate

Chlorobutanol

Cyclomethycaine sulfate

Eugenol

Hexylresorcinol

Methapyrilene hydrochloride

Salicylamide

Thymol

(ii) Counterirritant drug products.

Chloral hydrate

Eucalyptus oil

(iii) Male genital desensitizer drug products.

Benzyl alcohol

Camphorated metacresol

Ephedrine hydrochloride

(iv) Diaper rash drug products. Any ingredient(s) labeled with claims or directions for use in the treatment and/or prevention of diaper rash.

(v) Fever blister and cold sore treatment drug products.

Allyl isothiocyanate

Aspirin

Bismuth sodium tartrate

Camphor (exceeding 3 percent)

Capsaicin

Capsicum

Capsicum oleoresin

Chloral hydrate

Chlorobutanol

Cyclomethycaine sulfate

Eucalyptus oil

Eugenol

Glycol salicylate

Hexylresorcinol

Histamine dihydrochloride

Menthol (exceeding 1 percent)

Methapyrilene hydrochloride

Methyl nicotinate

Methyl salicylate

Pectin

Salicylamide

Strong ammonia solution

Tannic acid

Thymol

Tripelennamine hydrochloride

Trolamine salicylate

Turpentine oil

Zinc sulfate

(vi) Insect bite and sting drug products.

Alcohol

Alcohol, ethoxylated alkyl

Benzalkonium chloride

Calamine

Ergot fluid extract

Ferric chloride

Panthenol

Peppermint oil

Pyrilamine maleate

Sodium borate

Trolamine salicylate

Turpentine oil

Zinc oxide

Zirconium oxide

(vii) Poison ivy, poison oak, and poison sumac drug products.

Alcohol

Aspirin

Benzethonium chloride

Benzocaine (0.5 to 1.25 percent)

Bithionol



Calamine  
Cetalkonium chloride  
Chloral hydrate  
Chlorobutanol  
Chlorpheniramine maleate  
Creosote, beechwood  
Cyclomethycaine sulfate  
Dexpanthenol  
Diperodon hydrochloride  
Eucalyptus oil  
Eugenol  
Glycerin  
Glycol salicylate  
Hectorite  
Hexylresorcinol  
Hydrogen peroxide  
Impatiens biflora tincture  
Iron oxide  
Isopropyl alcohol  
Lanolin  
Lead acetate  
Merbromin  
Mercuric chloride

Methapyrilene hydrochloride  
Panthenol  
Parethoxycaine hydrochloride  
Phenyltoloxamine dihydrogen citrate  
Povidone-vinylacetate copolymers  
Pyrilamine maleate  
Salicylamide  
Salicylic acid  
Simethicone  
Sulfur  
Tannic acid  
Thymol  
Trolamine salicylate  
Turpentine oil  
Zirconium oxide  
Zyloxin

**(9) Laxative drug products**

(i) Bulk laxatives.

Agar  
Carrageenan (degraded)  
Carrageenan (native)  
Guar gum

Granular dosage forms containing psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), psyllium seed husks, plantago husks, or plantago seed including, but not limited to, any granules that are:

- (1) Swallowed dry prior to drinking liquid,
- (2) Dispersed, suspended, or partially dissolved in liquid prior to swallowing,
- (3) Chewed, partially chewed, or unchewed, and then washed down (or swallowed) with liquid, or
- (4) Sprinkled over food.

(ii) Saline laxative.

Tartaric acid

(iii) Stool softener.

Poloxamer 188

(iv) Stimulant laxatives

Aloe ingredients (aloe, aloe extract, aloe flower extract)

Aloin

Bile salts/acids

Calcium pantothenate

Calomel

Cascara sagrada ingredients (casanthranol, cascara fluid extract aromatic, cascara sagrada bark, cascara sagrada extract, cascara sagrada fluid extract).

Colocynth

Danthron

Elaterin resin

Frangula

Gamboge

Ipomea

Jalap

Ox bile

Phenolphthalein

Podophyllum resin

Prune concentrate dehydrate

Prune powder

Rhubarb, Chinese

Sodium Oleate

**(10) Oral health care drug products (nonantimicrobial)**

Antipyrine

Camphor

Cresol

Dibucaine

Dibucaine hydrochloride

Eucalyptol

Lidocaine

Lidocaine hydrochloride

Methyl salicylate

Myrrh tincture

Pyrilamine maleate

Sorbitol

Sugars

Tetracaine

Tetracaine hydrochloride

Thymol

**(11) Topical otic drug products**

(i) For the prevention of swimmer's ear and for the drying of water-clogged ears.

Acetic acid

(ii) For the prevention of swimmer's ear.

Glycerin and anhydrous glycerin

Isopropyl alcohol

**(12) Poison treatment drug products**

Ipecac fluid extract

Ipecac tincture

Zinc sulfate

**(13) Skin bleaching drug products**

Mercury, ammoniated

**(14) Skin protectant drug products**

(i) Ingredients.

Allantoin (wound healing claims only)

Sulfur

Tannic acid

Zinc acetate (wound healing claims only)

Beeswax

Bismuth subnitrate

Boric acid

Cetyl alcohol

Glyceryl stearate

Isopropyl palmitate

Live yeast cell derivative

Shark liver oil

Stearyl alcohol

(ii) Astringent drug products.

Acetone

Alcohol

Alum, ammonium

Alum, potassium

Aluminum chlorhydroxy complex

Aromatics

Benzalkonium chloride

Benzethonium chloride

Benzocaine

Benzoic acid

Boric acid

Calcium acetate (except calcium acetate monohydrate when combined with aluminum sulfate tetradecahydrate to provide an aluminum acetate solution as described in § M016.20(b) of OTC Monograph M016.

Camphor gum

Clove oil

Colloidal oatmeal

Cresol

Cupric sulfate

Eucalyptus oil

Eugenol

Ferric subsulfate (Monsel's Solution)

Honey

Isopropyl alcohol

Menthol

Methyl salicylate

Oxyquinoline sulfate

P-t-butyl-m-cresol

Peppermint oil

Phenol

Polyoxyethylene laurate

Potassium ferrocyanide

Sage oil

Silver nitrate

Sodium borate

Sodium diacetate

Talc

Tannic acid glycerite

Thymol

Topical starch

Zinc chloride

Zinc oxide

Zinc phenolsulfonate

Zinc stearate

Zinc sulfate

(iii) Diaper rash drug products.

Aluminum hydroxide

Cocoa butter

Cysteine hydrochloride

Glycerin

Protein hydrolysate

Racemethionine

Sulfur

Tannic acid

Zinc acetate

Zinc carbonate

(iv) Fever blister and cold sore treatment drug products.

Bismuth subnitrate

Boric acid

Pyridoxine hydrochloride

Sulfur



Tannic acid

Topical starch

Trolamine

Zinc sulfate

(v) Insect bite and sting drug products.

Alcohol

Alcohol, ethoxylated alkyl

Ammonia solution, strong

Ammonium hydroxide

Beeswax

Benzalkonium chloride

Bismuth subnitrate

Boric acid

Camphor

Cetyl alcohol

Ergot fluid extract

Ferric chloride

Glyceryl stearate

Isopropyl palmitate

Live yeast cell derivative

Menthol

Peppermint oil

Phenol

Pyrilamine maleate

Shark liver oil

Stearyl alcohol

Sodium borate

Trolamine

Turpentine oil

Zirconium oxide

(vi) Poison ivy, poison oak, and poison sumac drug products.

Alcohol

Anion and cation exchange resins buffered

Beeswax

Benzethonium chloride

Benzocaine

Benzyl alcohol

Bismuth subnitrate

Bithionol

Boric acid

Camphor

Cetalkonium chloride

Cetyl alcohol

Chloral hydrate

Chlorpheniramine maleate

Creosote

Diperodon hydrochloride  
Diphenhydramine hydrochloride  
Eucalyptus oil  
Ferric chloride  
Glycerin  
Glyceryl stearate  
Hectorite  
Hydrogen peroxide  
Impatiens biflora tincture  
Iron oxide  
Isopropyl alcohol  
Isopropyl palmitate  
Lanolin  
Lead acetate  
Lidocaine  
Live yeast cell derivative  
Menthol  
Merbromin  
Mercuric chloride  
Panthenol  
Parethoxycaine hydrochloride  
Phenol  
Phenyltoloxamine dihydrogen citrate

Povidone-vinylacetate copolymers

Salicylic acid

Shark liver oil

Simethicone

Stearyl alcohol

Tannic acid

Topical starch

Trolamine

Turpentine oil

Zirconium oxide

Zyloxin

**(15) Weight control drug products**

Alcohol

Alfalfa

Alginic acid

Anise oil

Arginine

Ascorbic acid

Bearberry

Biotin

Bone marrow, red

Buchu

Buchu, potassium extract

Caffeine

Caffeine citrate

Calcium

Calcium carbonate

Calcium caseinate

Calcium lactate

Calcium pantothenate

Carboxymethylcellulose sodium

Carrageenan

Cholecalcierol

Choline

Chondrus

Citric acid

Cnicus benedictus

Copper

Copper gluconate

Corn oil

Corn syrup

Corn silk, potassium extract

Cupric sulfate

Cyanocobalamin (vitamin B12)

Cystine

Dextrose

Docusate sodium

Ergocalciferol

Ferric ammonium citrate

Ferric pyrophosphate

Ferrous fumarate

Ferrous gluconate

Ferrous sulfate (iron)

Flax seed

Folic acid

Fructose

Guar gum

Histidine

Hydrastis canadensis

Inositol

Iodine

Isoleucine

Juniper, potassium extract

Karaya gum

Kelp

Lactose

Lecithin

Leucine

Liver concentrate

Lysine

Lysine hydrochloride

Magnesium

Magnesium oxide

Malt

Maltodextrin

Manganese citrate

Mannitol

Methionine

Methylcellulose

Mono- and di-glycerides

Niacinamide

Organic vegetables

Pancreatin

Pantothenic acid

Papain

Papaya enzymes

Pepsin

Phenacetin

Phenylalanine

Phosphorus

Phytolacca

Pineapple enzymes

Plantago seed

Potassium citrate

Pyridoxine hydrochloride (vitamin B6)

Riboflavin

Rice polishings

Saccharin

Sea minerals

Sesame seed

Sodium

Sodium bicarbonate

Sodium caseinate

Sodium chloride (salt)

Soybean protein

Soy meal

Sucrose

Thiamine hydrochloride (vitamin B1)

Thiamine mononitrate (vitamin B1 mononitrate)

Threonine

Tricalcium phosphate

Tryptophan

Tyrosine

Uva ursi, potassium extract

Valine



Vegetable

Vitamin A

Vitamin A acetate

Vitamin A palmitate

Vitamin E

Wheat germ

Xanthan gum

Yeast

**(16) Ophthalmic drug products**

(i) Ophthalmic anesthetic drug products.

Antipyrine

Piperocaine hydrochloride

(ii) Ophthalmic anti-infective drug products.

Boric acid

Mild silver protein

Yellow mercuric oxide

(iii) Ophthalmic astringent drug products.

Infusion of rose petals

(iv) Ophthalmic demulcent drug products.

Polyethylene glycol 6000

(v) Ophthalmic vasoconstrictor drug products.

Phenylephrine hydrochloride (less than 0.08 percent)

**(17) Topical antifungal drug products**

(i) Diaper rash drug products.

Any ingredient(s) labeled with claims or directions for use in the treatment and/or prevention of diaper rash.

(ii) Any ingredient(s) labeled with claims or directions for use on the scalp or on the nails.

(iii) Ingredients.

Alcloxa

Alum, potassium

Aluminum sulfate

Amyltricresols, secondary

Basic fuchsin

Benzethonium chloride

Benzoic acid

Benzoxiquine

Boric acid

Camphor

Camphorated metacresol

Candicidin

Chlorothymol

Chloroxylonol

Coal tar

Dichlorophen

m-cresol

Menthol  
Methylparaben  
Nystatin  
Oxyquinoline  
Oxyquinoline sulfate  
Phenol  
Phenolate sodium  
Phenyl salicylate  
Propionic acid  
Propylparaben  
Resorcinol  
Salicylic acid  
Sodium borate  
Sodium caprylate  
Sodium propionate  
Sulfur  
Tannic acid  
Thymol  
Tolindate  
Triacetin  
Zinc caprylate  
Zinc propionate

**(18) Internal analgesic drug products**

Aminobenzoic acid  
Antipyrine  
Any atropine ingredient  
Aspirin, aluminum  
Calcium salicylate  
Codeine  
Codeine phosphate  
Codeine sulfate  
Any ephedrine ingredient  
Iodoantipyrine  
Lysine aspirin  
Methapyrilene fumarate  
Phenacetin  
Pheniramine maleate  
Pyrilamine maleate  
Quinine  
Salsalate  
Sodium aminobenzoate

**(19) Orally administered menstrual drug products**

Alcohol  
Alfalfa leaves  
Aloes

Asclepias tuberosa

Asparagus

Any atropine ingredient

Barosma

Bearberry (extract of uva ursi)

Bearberry fluid extract (extract of bearberry)

Blessed thistle (cnicus benedictus)

Buchu powdered extract (extract of buchu)

Calcium lactate

Calcium pantothenate

Capsicum oleoresin

Cascara fluid extract, aromatic (extract of cascara)

Chlorprophenpyridamine maleate

Cimicifuga racemosa

Codeine

Collinsonia (extract stone root)

Corn silk

Couch grass

Dog grass extract

Any ephedrine ingredient

Ethyl nitrite

Ferric chloride

Ferrous sulfate

Gentiana lutea (gentian)  
Glycyrrhiza (licorice)  
Homatropine methylbromide  
Hydrangea, powdered extract (extract of hydrangea)  
Hydrastis canadensis (golden seal)  
Hyoscyamine sulfate  
Juniper oil (oil of juniper)  
Magnesium sulfate  
Methapyrilene hydrochloride  
Methenamine  
Methylene blue  
Natural estrogenic hormone  
Niacinamide  
Nutmeg oil (oil of nutmeg)  
Oil of erigeron  
Parsley  
Peppermint spirit  
Pepsin, essence  
Phenacetin  
Phenindamine tartrate  
Phenyl salicylate  
Piscidia erythrina  
Pipsissewa

Potassium acetate

Potassium nitrate

Riboflavin

Saw palmetto

Senecio aureus

Sodium benzoate

Sodium nitrate

Sucrose

Sulferated oils of turpentine

Taraxacum officinale

Theobromine sodium salicylate

Theophylline

Thiamine hydrochloride

Triticum

Turpentine, venice (venice turpentine)

Urea

**(20) Pediculicide drug products**

Benzocaine

Benzyl alcohol

Benzyl benzoate

Chlorophenothane (dichlorodiphenyl trichloroethane)

Coconut oil soap, aqueous

Copper oleate

Docusate sodium

Formic acid

Isobornyl thiocynoacetate

Picrotoxin

Propylene glycol

The combination of pyrethrum extract (formerly named pyrethrins) and piperonyl butoxide in an aerosol dosage formulation.

Sabadilla alkaloids

Sulfur, sublimed

Thiocynoacetate

**(21) Anorectal drug products**

(i) Anticholinergic drug products.

Atropine

Belladonna extract

(ii) Antiseptic drug products.

Boric acid

Boroglycerin

Hydrastis

Phenol

Resorcinol

Sodium salicylic acid phenolate

(iii) Astringent drug products.

Tannic acid

(iv) Counterirritant drug products.



Camphor (greater than 3 to 11 percent)

Hydrastis

Menthol (1.25 to 16 percent)

Turpentine oil (rectified) (6 to 50 percent)

(v) Keratolytic drug products.

Precipitated sulfur

Sublimed sulfur

(vi) Local anesthetic drug products.

Diperodon

Phenacaine hydrochloride

(vii) Other drug products.

Collinsonia extract

Escherichia coli vaccines

Lappa extract

Leptandra extract

Live yeast cell derivative

Mullein

(viii) Protectant drug products.

Bismuth oxide

Bismuth subcarbonate

Bismuth subgallate

Bismuth subnitrate

Lanolin alcohols

(ix) Vasoconstrictor drug products.

Epinephrine undecylenate

(x) Wound healing drug products.

Cholecalciferol

Cod liver oil

Live yeast cell derivative

Peruvian balsam

Shark liver oil

Vitamin A

(xi) Combination drug products.

Any combination drug product containing hydrocortisone and pramoxine hydrochloride.

**(22) Topical antimicrobial drug products**

(i) First aid antiseptic drug products.

Ammoniated mercury

Calomel (mercurous chloride)

Merbromin (mercurochrome)

Mercufenol chloride (ortho-chloromercuriphenol, ortho-hydroxyphenylmercuric chloride)

Mercuric chloride (bichloride of mercury, mercury chloride)

Mercuric oxide, yellow

Mercuric salicylate

Mercuric sulfide, red

Mercury

Mercury oleate

Mercury sulfide

Nitromersol

Para-chloromercuriphenol

Phenylmercuric nitrate

Thimerosal

Vitromersol

Zyloxin

(ii) Diaper rash drug products.

Para-chloromercuriphenol

Any other ingredient containing mercury

(iii) Consumer antiseptic hand wash drug products.

Cloflucarban

Fluorosalan

Hexachlorophene

Hexylresorcinol

Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)

Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)

Methylbenzethonium chloride

Nonylphenoxypoly (ethyleneoxy) ethaniodine

Phenol (greater than 1.5 percent)

Phenol (less than 1.5 percent)

Poloxamer iodine complex

Povidone-iodine (5 to 10 percent)

Secondary amyltr cresols

Sodium oxychlorosene

Tribromsalan

Triclocarban

Triclosan

Triple Dye

Undecoylium chloride iodine complex

(iv) Consumer antiseptic body wash drug products.

Cloflucarban

Fluorosalan

Hexachlorophene

Hexylresorcinol

Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)

Iodine tincture

Methylbenzethonium chloride

Nonylphenoxypoly (ethyleneoxy) ethanoliiodine

Phenol (greater than 1.5 percent)

Phenol (less than 1.5 percent)

Poloxamer iodine complex

Povidone-iodine (5 to 10 percent)

Secondary amyltr cresols

Sodium oxchlorosene

Tribromsalan

Triclocarban

Triclosan

Triple Dye

Undecoylium chloride iodine complex

(v) Health care personnel hand wash drug products.

Cloflucarban

Fluorosalan

Hexachlorophene

Hexylresorcinol

Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)

Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)

Methylbenzethonium chloride

Nonylphenoxypoly (ethyleneoxy) ethanoliiodine

Phenol

Poloxamer-iodine complex

Secondary amyltricrosols

Sodium oxchlorosene

Tribromsalan

Triclocarban

Triclosan

Undecoylium chloride iodine complex

(vi) Surgical hand scrub drug products.

Cloflucarban

Fluorosalan

Hexachlorophene

Hexylresorcinol

Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)

Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)

Methylbenzethonium chloride

Nonylphenoxypoly (ethyleneoxy) ethanoliiodine

Phenol

Poloxamer-iodine complex

Secondary amyltr cresols

Sodium oxychlorosene

Tribromsalan

Triclocarban

Triclosan

Undecoylium chloride iodine complex

(vii) Patient antiseptic skin preparation drug products.

Combination of calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative

Cloflucarban

Fluorosalan

Hexachlorophene

Hexylresorcinol

Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)

Iodine tincture (USP)

Iodine topical solution (USP)

Mercufenol chloride

Combination of mercufenol chloride and secondary amyltr cresols in 50 percent alcohol

Methylbenzethonium chloride

Nonylphenoxypoly (ethyleneoxy) ethanoliiodine

Phenol

Poloxamer-iodine complex

Secondary amyltr cresols

Sodium oxychlorosene

Tribromsalan

Triclocarban

Triclosan

Triple dye

Undecoylium chloride iodine complex

**(23) Vaginal contraceptive drug products**

Dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate)

Laureth 10S

Methoxypolyoxyethyleneglycol 550 laurate

Octoxynol 9

Phenylmercuric acetate

Phenylmercuric nitrate

Any other ingredient containing mercury

**(24) Sunscreen drug products**

(i) Ingredients.

Diethanolamine methoxycinnamate

Digalloyl trioleate

Ethyl 4-[bis(hydroxypropyl)] aminobenzoate

Glyceryl aminobenzoate

Lawsone with dihydroxyacetone

Red petrolatum

(ii) Any ingredients labeled with any of the following or similar claims. Instant protection or protection immediately upon application.

Claims for "all-day" protection or extended wear claims citing a specific number of hours of protection that is inconsistent with the directions for application in OTC Monograph M020.

(b) Any OTC drug product that is labeled, represented, or promoted for the uses specified and containing any active ingredient(s) as specified in § NM900(a) is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(p)), for which an approved new drug application under section 505 of the FD&C Act (21 U.S.C. 355) and 21 CFR 314 is required for marketing. In the absence of an approved new drug application, such product is also misbranded under section 502 of the FD&C Act (21 U.S.C. 352).

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for the OTC uses and containing any active ingredient(s) as specified in § NM900(a) is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in 21 CFR part 312.

(d) Any OTC drug product that is not in compliance with Non-Monograph Conditions NM900 is subject to regulatory action if introduced or delivered for introduction into interstate commerce.