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initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action. After December 1, 1993, any such OTC drug product containing lobeline (in the form of lobeline sulfate or natural lobelia alkaloids or *Lobelia inflata* herb), povidone-silver nitrate, silver acetate, or any other ingredients initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

[58 FR 31241, June 1, 1993]

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) A number of active ingredients have been present in 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
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

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Zinc sulfide

(2) *Anticaries drug products*—(i) *Approved as of May 7, 1991.*

Hydrogen fluoride
Sodium carbonate
Sodium monofluorophosphate (6 percent rinse)
Sodium phosphate

(ii) *Approved as of October 7, 1996.*

Calcium sucrose phosphate
Dicalcium phosphate dihydrate
Disodium hydrogen phosphate¹
Phosphoric acid¹
Sodium dihydrogen phosphate
Sodium dihydrogen phosphate monohydrate
Sodium phosphate, dibasic anhydrous reagent¹

(3) *Antidiarrheal drug products.*

Aluminum hydroxide
Atropine sulfate
Calcium carbonate
Carboxymethylcellulose sodium
Glycine
Homatropine methylbromide
Hyoscyamine sulfate
Lactobacillus acidophilus
Lactobacillus bulgaricus
Opium, powdered
Opium tincture
Paregoric
Phenyl salicylate
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)
Sodium aluminum chlorohydroxy lactate

(5) [Reserved]

(6) *Cold, cough, allergy, bronchodilator, and antiasthmatic drug products*—(i) *Antihistamine drug products*—(A) *Ingredients.*

Methapyrilene hydrochloride
Methapyrilene fumarate
Thenyldiamine hydrochloride

(B) *Ingredients.*

Phenyltoloxamine dihydrogen citrate
Methapyrilene hydrochloride

¹These ingredients are nonmonograph except when used to prepare acidulated phosphate fluoride treatment rinses identified in § 355.10(a)(3) of this chapter.

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Methapyrilene fumarate
 Thenyldiamine hydrochloride

(ii) *Nasal decongestant drug products—*
 (A) *Approved as of May 7, 1991.*

Allyl isothiocyanate
 Camphor (lozenge)
 Creosote, beechwood (oral)
 Eucalyptol (lozenge)
 Eucalyptol (mouthwash)
 Eucalyptus oil (lozenge)
 Eucalyptus oil (mouthwash)
 Menthol (mouthwash)
 Peppermint oil (mouthwash)
 Thenyldiamine hydrochloride
 Thymol
 Thymol (lozenge)
 Thymol (mouthwash)
 Turpentine oil

(B) *Approved as of August 23, 1995.*

Bornyl acetate (topical)
 Cedar leaf oil (topical)
 Creosote, beechwood (topical)
 Ephedrine (oral)
 Ephedrine hydrochloride (oral)
 Ephedrine sulfate (oral)
 Racephedrine hydrochloride (oral/topical)

(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, hydriodic acid syrup, iodized lime, potassium iodide)
 Ipecac
 Ipecac fluidextract
 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—*(A)
Approved as of October 2, 1987.

Aminophylline
 Belladonna alkaloids
 Euphorbia pilulifera
 Metaproterenol sulfate
 Methoxyphenamine hydrochloride
 Pseudoephedrine hydrochloride

Pseudoephedrine sulfate
 Theophylline, anhydrous
 Theophylline calcium salicylate
 Theophylline sodium glycinate

(B) *Approved as of January 29, 1996.*
 Any combination drug product containing theophylline (e.g., theophylline and ephedrine, or theophylline and ephedrine and phenobarbital).

(C) *Approved as of June 19, 1996.* Any ingredient(s) in a pressurized metered-dose inhaler container.

(D) *Approved as of October 29, 2001.* 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.

(7) *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

(8) *Digestive aid drug products—*(i) *Approved as of May 7, 1991.*

Bismuth sodium tartrate
 Calcium carbonate
 Cellulase
 Dehydrocholic acid
 Dihydroxyaluminum sodium carbonate
 Duodenal substance
 Garlic, dehydrated
 Glutamic acid hydrochloride
 Hemicellulase

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Homatropine methylbromide
 Magnesium hydroxide
 Magnesium trisilicate
 Ox bile extract
 Pancreatin
 Pancrelipase
 Papain
 Peppermint oil
 Pepsin
 Sodium bicarbonate
 Sodium citrate
 Sorbitol

(ii) *Approved as of November 10, 1993.*

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
 Black radish powder
 Blessed thistle (*cnicus benedictus*)
 Buckthorn
 Calcium gluconate
 Capsicum
 Capsicum, fluid extract of
 Carbon
 Cascara sagrada extract
 Catechu, tincture
 Catnip
 Chamomile flowers
 Charcoal, wood
 Chloroform
 Cinnamon oil
 Cinnamon tincture
 Citrus pectin
 Diastase
 Diastase malt
 Dog grass
 Elecampane
 Ether
 Fennel acid
 Galega
 Ginger
 Glycine
 Hydrastis canadensis (golden seal)
 Hectorite
 Horsetail
 Huckleberry
 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
 Mannitol
 Mycozyme
 Myrrh, fluid extract of
 Nettle
 Nickel-pectin
 Nux vomica extract
 Orthophosphoric acid
 Papaya, natural
 Pectin
 Peppermint
 Peppermint spirit
 Phenacetin
 Potassium bicarbonate
 Potassium carbonate
 Protease
 Prolase
 Rhubarb fluid extract
 Senna
 Sodium chloride
 Sodium salicylate
 Stem bromelain
 Strawberry
 Strychnine
 Tannic acid
 Trillium
 Woodruff

(iii) Charcoal, activated

(9) [Reserved]

(10) *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

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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
Tripeleminamine hydrochloride
Trolamine salicylate
Turpentine oil
Zinc sulfate

(vi) *Insect bite and sting drug products.*

Alcohol
Alcohol, ethoxylated alkyl
Benzalkonium chloride
Calamine
Ergot fluidextract
Ferric chloride
Panthenol
Peppermint oil
Pyriminamine 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
Pyriminamine maleate
Salicylamide
Salicylic acid
Simethicone
Sulfur
Tannic acid
Thymol
Trolamine salicylate
Turpentine oil
Zirconium oxide
Zyloxin

(11) [Reserved]

(12) *Laxative drug products—(i) Bulk laxatives.*

Agar
Carrageenan (degraded)
Carrageenan (native)
Guar gum

(ii) *Saline laxative.*

Tartaric acid

(iii) *Stool softener.*

Poloxamer 188

(iv)(A) *Stimulant laxatives—Approved as of May 7, 1991.*

Aloin
Bile salts/acids
Calcium pantothenate
Calomel
Colocynth
Elaterin resin
Frangula
Gamboge
Ipomea
Jalap
Ox bile
Podophyllum resin
Prune concentrate dehydrate
Prune powder
Rhubarb, Chinese
Sodium Oleate

(iv)(B) *Stimulant laxatives—Approved as of January 29, 1999.*

Danthron
Phenolphthalein

(C) *Stimulant laxatives—Approved as of November 5, 2002.*

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

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

(13) [Reserved]

(14) *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

(a) * * *

(15) *Topical otic drug products—(i) For the prevention of swimmer's ear and for the drying of water-clogged ears, approved as of May 7, 1991.*

Acetic acid

(ii) *For the prevention of swimmer's ear, approved as of August 15, 1995.*

Glycerin and anhydrous glycerin
Isopropyl alcohol

(16) *Poison treatment drug products.*

Ipecac fluidextract
Ipecac tincture
Zinc sulfate

(17) *Skin bleaching drug products.*

Mercury, ammoniated

(18) *Skin protectant drug products.* (i)
Ingredients.

Allantoin (wound healing claims only)
Sulfur
Tannic acid
Zinc acetate (wound healing claims only)

(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
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
Benzalkonium chloride
Camphor
Ergot fluidextract

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Ferric chloride
 Menthol
 Peppermint oil
 Phenol
 Pyrilamine maleate
 Sodium borate
 Trolamine
 Turpentine oil
 Zirconium oxide

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

Alcohol
 Anion and cation exchange resins buffered
 Benzethonium chloride
 Benzocaine
 Benzyl alcohol
 Bismuth subnitrate
 Bithionol
 Boric acid
 Camphor
 Cetalkonium chloride
 Chloral hydrate
 Chlorpheniramine maleate
 Creosote
 Dipiperodon hydrochloride
 Diphenhydramine hydrochloride
 Eucalyptus oil
 Ferric chloride
 Glycerin
 Hectorite
 Hydrogen peroxide
 Impatiens biflora tincture
 Iron oxide
 Isopropyl alcohol
 Lanolin
 Lead acetate
 Lidocaine
 Menthol
 Merbromin
 Mercuric chloride
 Panthenol
 Parethoxycaïne hydrochloride
 Phenol
 Phenyltoloxamine dihydrogen citrate
 Povidone-vinylacetate copolymers
 Salicylic acid
 Simethicone
 Tannic acid
 Topical starch
 Trolamine
 Turpentine oil
 Zirconium oxide
 Zyloxin

(19) [Reserved]
 (20) *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
 Cholecalciferol
 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

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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 mono-
nitrate)
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

(21) *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)

(22) *Topical antifungal drug products.*

(i) *Diaper rash drug products.* Any ingredient(s) labeled with claims or di-

rections for use in the treatment and/or prevention of diaper rash.

(ii) *Ingredients.*

Alcloxa
Alum, potassium
Aluminum sulfate
Amyltri cresols, secondary
Basic fuchsin
Benzethonium chloride
Benzoic acid
Benzoxiquine
Boric acid
Camphor
Candididin
Chlorothymol
Coal tar
Dichlorophen
Menthol
Methylparaben
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

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

(iv) *Ingredients.*

Camphorated metacresol
Chloroxylenol
m-cresol
Nystatin

(23) *Internal analgesic drug products.*

(i) *Approved as of November 10, 1993.*

Aminobenzoic acid
Antipyrine
Aspirin, aluminum
Calcium salicylate
Codeine
Codeine phosphate
Codeine sulfate
Iodoantipyrine
Lysine aspirin
Methapyrilene fumarate
Phenacetin
Pheniramine maleate
Pyrimilamine maleate
Quinine
Salsalate

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Sodium aminobenzoate

(ii) *Approved as of February 22, 1999.*

Any atropine ingredient
Any ephedrine ingredient

(24) *Orally administered menstrual drug products.* (i) *Approved as of November 10, 1993.*

Alcohol
Alfalfa leaves
Aloes
Asclepias tuberosa
Asparagus
Barosma
Bearberry (extract of uva ursi)
Bearberry fluidextract (extract of bearberry)
Blessed thistle (cnicus benedictus)
Buchu powdered extract (extract of buchu)
Calcium lactate
Calcium pantothenate
Capsicum oleoresin
Cascara fluidextract, aromatic (extract of cascara)
Chlorprophenpyridamine maleate
Cimicifuga racemosa
Codeine
Collinsonia (extract stone root)
Corn silk
Couch grass
Dog grass extract
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

(ii) *Approved as of February 22, 1999.*

Any atropine ingredient
Any ephedrine ingredient

(25) *Pediculicide drug products—(i) Approved as of November 10, 1993.*

Benzocaine
Benzyl alcohol
Benzyl benzoate
Chlorophenothane (dichlorodiphenyl trichloroethane)
Coconut oil soap, aqueous
Copper oleate
Docusate sodium
Formic acid
Isobornyl thiocynoacetate
Picrotoxin
Propylene glycol
Sabadilla alkaloids
Sulfur, sublimed
Thiocynoacetate

(ii) *Approved as of June 14, 1994.* The combination of pyrethrum extract (formerly named pyrethrins) and piperonyl butoxide in an aerosol dosage formulation.

(26) *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

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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

(27) *Topical antimicrobial drug products—(i) First aid antiseptic drug products.*

Ammoniated mercury
Calomel (mercurous chloride)
Merbromin (mercuochrome)
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

(28) *Vaginal contraceptive drug products—(i) Approved as of October 22, 1998.*

Dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate)
Laureth 10S
Methoxypolyoxyethyleneglycol 550 laurate
Phenylmercuric acetate
Phenylmercuric nitrate

Any other ingredient containing mercury

(ii) *Approved as of November 5, 2002.*

Octoxynol 9

(29) *Sunscreen drug products.*

Diethanolamine methoxycinnamate
Digalloyl trioleate
Ethyl 4-[bis(hydroxypropyl)] aminobenzoate
Glyceryl aminobenzoate
Lawsonite with dihydroxyacetone
Red petrolatum

(30) [Reserved]

(b) Any OTC drug product that is labeled, represented, or promoted for the uses specified and containing any active ingredient(s) as specified in paragraph (a) of this section is regarded as a new drug within the meaning of section 210(p) of the Federal Food, Drug, and Cosmetic Act (the Act), for which an approved new drug application under section 505 of the Act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application, such product is also misbranded under section 502 of the Act.

(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 paragraph (a) of this section 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 part 312 of this chapter.

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(29) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18) of this section.

(2) February 10, 1992, for products subject to paragraph (a)(20) of this section.

(3) December 4, 1992, for products subject to paragraph (a)(7) of this section

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that contain menthol as an anti-pruritic in combination with the anti-dandruff ingredient coal tar identified in § 358.710(a)(1) of this chapter.

(4) February 28, 1990, for products subject to paragraph (a)(6)(iii) of this section, except those that contain ipecac.

(5) September 14, 1993, for products subject to paragraph (a)(6)(iii) of this section that contain ipecac.

(6) December 9, 1993, for products subject to paragraph (a)(6)(i)(B) of this section.

(7) March 6, 1989, for products subject to paragraph (a)(21) of this section, except those that contain ophthalmic anti-infective ingredients listed in paragraph (a)(21)(ii).

(8) June 18, 1993, for products subject to paragraph (a)(21) of this section that contain ophthalmic anti-infective ingredients.

(9) June 18, 1993, for products subject to paragraph (a)(10)(iv) of this section.

(10) June 18, 1993, for products subject to paragraph (a)(22)(i) of this section.

(11) November 10, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) (except products that contain ferric subsulfate) through (a)(18)(vi), (a)(22)(ii), (a)(23)(i), (a)(24)(i), and (a)(25) of this section.

(12) March 2, 1994, for products subject to paragraph (a)(22)(iii) of this section.

(13) August 5, 1991, for products subject to paragraphs (a)(26) of this section, except for those that contain live yeast cell derivative.

(14) September 2, 1994, for products subject to paragraph (a)(26)(vii) and (a)(26)(x) of this section that contain live yeast cell derivative.

(15) September 23, 1994, for products subject to paragraph (a)(22)(iv) of this section.

(16) June 14, 1994, for products subject to paragraph (a)(25)(ii) of this section.

(17) [Reserved]

(18) August 15, 1995, for products subject to paragraph (a)(15)(ii) of this section.

(19) October 2, 1987, for products subject to paragraph (a)(6)(iv)(A) of this section.

(20) January 29, 1996, for products subject to paragraph (a)(6)(iv)(B) of this section.

(21) April 21, 1994, for products subject to paragraph (a)(8)(iii) of this section.

(22) April 21, 1993, for products subject to paragraph (a)(18)(ii) of this section that contain ferric subsulfate.

(23) August 23, 1995, for products subject to paragraph (a)(6)(ii)(B) of this section.

(24) October 7, 1996, for products subject to paragraph (a)(2)(ii) of this section.

(25) June 19, 1996, for products subject to paragraph (a)(6)(iv)(C) of this section.

(26) February 22, 1999, for products subject to paragraphs (a)(23)(ii) and (a)(24)(ii) of this section.

(27) [Reserved]

(28) October 22, 1998, for products subject to paragraphs (a)(27) and (a)(28)(i) of this section.

(29) January 29, 1999, for products subject to paragraph (a)(12)(iv)(B) of this section.

(30) November 5, 2002, for products subject to paragraph (a)(12)(iv)(C) of this section.

(31) December 31, 2002, for products subject to paragraph (a)(29) of this section.

(32) [Reserved]

(33) October 29, 2001, for products subject to paragraph (a)(6)(iv)(D) of this section.

(34)–(35)[Reserved]

(36) November 5, 2002, for products subject to paragraph (a)(28)(ii) of this section.

[55 FR 46919, Nov. 7, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 310.545, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EFFECTIVE DATE NOTE: At 61 FR 9571, Mar. 8, 1996, in § 310.545 in paragraph (a)(6)(ii)(B), the entry for “1-desoxyephedrine (topical)” was stayed until further notice.