



U.S. Food and Drug Administration

Final Administrative Order (OTC000007)

Non-Monograph Conditions NM900: Drug Products Containing Certain Active Ingredients Offered Over-the-Counter for Certain Uses (Posted September 24, 2021)

I. Summary

Non-Monograph Conditions NM900: Drug Products Containing Certain Active Ingredients Offered Over-the-Counter for Certain Uses, as set forth in this document, is a final administrative order (final order) deemed by section 505G(k)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(k)(2)(A)), and effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

II. Background

The CARES Act added section 505G of the FD&C Act, which revised the framework for the regulation of over-the-counter (OTC) monograph drug products.

In section 505G(k)(2)(A) of the FD&C Act, Congress provided that the provisions of 21 CFR 310.545 (§ 310.545), as in effect on the day before the date of enactment of the CARES Act, are deemed to be a final order. The final order may be amended, revoked, or otherwise modified in accordance with the procedures under section 505G of the FD&C Act.

In the *Federal Register* of November 7, 1990 (55 FR 46914 at 46919), FDA issued a final rule under the procedure of 21 CFR part 330, establishing that certain active ingredients in OTC drug products for various uses are not generally recognized as safe and effective (GRASE). This final rule was codified in § 310.545 and then amended by subsequent final rules (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 at www.govinfo.gov). However, § 310.545, which is often referred to as the negative monograph, did not include all active ingredients and conditions that are not GRASE.

This final order incorporates the provisions of § 310.545 as in effect on March 26, 2020, with technical amendments including the removal of the compliance dates, which are no longer relevant because any unexpired product will have been introduced or initially delivered for introduction into interstate commerce after such dates. As a result of the removal of the compliance dates in various provisions, some reordering of the active ingredients within such provisions was necessary so that they generally appear in alphabetical order. While this final order specifies certain active ingredients in OTC drug products for various uses are not GRASE

and cannot be legally marketed under section 505G of the FD&C Act, the absence from this final order of an active ingredient for a specific use does not establish or otherwise convey that such active ingredient for a specific use can or cannot be legally marketed under section 505G of the FD&C Act.

III. Final Administrative Order

Non-Monograph Conditions

NM900: Drug Products Containing Certain Active Ingredients Offered Over-the-Counter for Certain Uses

(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
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 phosphate¹
Hydrogen fluoride
Phosphoric acid¹
Sodium carbonate
Sodium dihydrogen phosphate
Sodium dihydrogen phosphate monohydrate
Sodium monofluorophosphate (6 percent rinse)
Sodium phosphate
Sodium phosphate, dibasic anhydrous reagent¹

(3) Antidiarrheal drug products

Aluminum hydroxide
Atropine sulfate
Attapulgate, activated
Bismuth subnitrate
Calcium carbonate
Calcium hydroxide
Calcium polycarbophil
Carboxymethylcellulose sodium
Charcoal (activated)
Glycine
Homatropine methylbromide
Hyoscyamine sulfate

¹ 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.

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
Tripelethamine 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

Candididin

Chlorothymol

Chloroxylenol

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

Thiocyanoacetate

(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 amyltricrosols

Sodium oxychlorosene

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) ethaniodine

Phenol

Poloxamer-iodine complex

Secondary amyltricrosols

Sodium oxychlorosene

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.