

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
2-ethylhexyl-4-phenylbenzophenone-2-carboxylic acid	sunscreen		II	IISE		
acetaminophen	internal analgesic		I	I		
acetaminophen	menstrual/diuretic	analgesic	I			
acetaminophen	nighttime sleep aid		II	IISE		54 FR 6826
	overindulgence in alcohol/food					
acetaminophen	hangover reliever			I		
acetanilide	internal analgesic		II	IIS		
acetic acid	otic				310.545(a)(15)(i)	
acetic acid	wart remover		III	IIISE		[55 FR 33254]
acetic acid, glacial	corn/callus remover		II	IIISE		[55 FR 33254]
acetic acid, glacial	wart remover		III	IIISE		[55 FR 33254]
acetone	skin protectant	astringent			310.545(a)(18)(ii)	
acidulated phosphate fluoride	anticaries			I	355.10(a)(3)(i)	
acidulated phosphate fluoride	anticaries			I	355.10(a)(3)(ii)	
agar	laxative	bulk laxative		III	310.545(a)(12)(i)	
alcloxa	acne		II	II	310.545(a)(1)	
alcloxa	anorectal	keratolytic	I(e)	I(e)	346.20(a)	
alcloxa	antifungal		III	III	310.545(a)(22)(ii)	
alcohol	digestive aid				310.545(a)(8)(ii)	
alcohol	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
alcohol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
alcohol	menstrual/diuretic				310.545(a)(24)(i)	
alcohol	mercury			I		
alcohol	oral health care		III	IISE		
alcohol	skin protectant	astringent			310.545(a)(18)(ii)	
alcohol	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
alcohol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
alcohol	skin protectant			IISE		
alcohol	weight control			II	310.545(a)(20)	
alcohol, ethoxylated alkyl	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
alcohol, ethoxylated alkyl	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
aldioxa	skin protectant			IISE		
alfalfa	weight control			II	310.545(a)(20)	
alfalfa leaves	menstrual/diuretic				310.545(a)(24)(i)	
alginic acid	weight control		III		310.545(a)(20)	
alkyl dimethyl amine oxide and alkyl dimethyl glycine	gingivitis/plaque			IISE		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
alkyl isoquinolinium bromide	acne		II	II	310.545(a)(1)	
alkyl isoquinolinium bromide	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
allantoin	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
allantoin	external analgesic			IISE		
allantoin	skin protectant		I	I	347.10(a)	
allantoin (5-ureidohydantoin)	corn/callus remover		II	IISE		[55 FR 33261]
allantoin (with aminobenzoic acid)	sunscreen		II	IIIIE		[64 FR 27682]
allantoin (wound healing claims only)	skin protectant			III	310.545(a)(18)(i)(A)	
allyl isothiocyanate	cough/cold	nasal decongestant			310.545(a)(6)(ii)(A)	
allyl isothiocyanate	external analgesic	counterirritant	I	I		
allyl isothiocyanate	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
almadrate sulfate	digestive aid	antacid	III	I		
aloe ingredients (aloe, aloe extract, aloe flower extract)	laxative	stimulant laxative		I	310.545(a)(12)(iv)(C)	
aloe vera [see aloe]	gingivitis/plaque			IIIIE		
aloes	menstrual/diuretic				310.545(a)(24)(i)	
aloin	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
alpha cellulose	laxative	bulk laxative		III		
alum, ammonium	oral health care	astringent	I	I		
alum, ammonium	skin protectant	astringent			310.545(a)(18)(ii)	
alum, potassium	antifungal		III	III	310.545(a)(22)(ii)	
alum, potassium	antiperspirant		IIISE	IIISE	310.545(a)(4)(i)	
alum, potassium	oral health care			I		
alum, potassium	skin protectant	astringent			310.545(a)(18)(ii)	
alumina powder, hydrated	antidiarrheal		III	III		
aluminum acetate	external analgesic			I	347.12(a)	
aluminum acetate	skin protectant	astringent		I	347.12(a)	
aluminum acetate	skin protectant			IIISE		
aluminum bromohydrate	antiperspirant		IIISE	IISE	310.545(a)(4)(i)	
aluminum carbonate gel (basic)	antacid			I	331.11(a)(1)	
aluminum chlorhydroxy complex	skin protectant	astringent			310.545(a)(18)(ii)	
aluminum chloride (alcoholic solutions)	antiperspirant		IIS	IIS	310.545(a)(4)(i)	
aluminum chloride (aqueous solution) (aerosol only)	antiperspirant				310.545(a)(4)(i)	
aluminum chloride (nonaerosol aqueous solution)	antiperspirant		I	I	350.10(a)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
aluminum chloride hexahydrate	external analgesic			IIIIE		
aluminum chlorohydrate	antiperspirant		I	I	350.10(b)	
aluminum chlorohydrex	acne		II	II	310.545(a)(1)	
aluminum chlorohydrex polyethylene glycol	antiperspirant		I	I	350.10(c)	
aluminum chlorohydrex propylene glycol	antiperspirant		I	I	350.10(d)	
aluminum dichlorohydrate	antiperspirant		I	I	350.10(e)	
aluminum dichlorohydrex polyethylene glycol	antiperspirant		I	I	350.10(f)	
aluminum dichlorohydrex propylene glycol	antiperspirant		I	I	350.10(g)	
aluminum hydroxide	acne		II	II	310.545(a)(1)	
aluminum hydroxide	antacid			I	331.11(a)(2)	
aluminum hydroxide	antidiarrheal				310.545(a)(3)(i)	
aluminum hydroxide	digestive aid	antacid	III	I	310.545(a)(8)(ii)	
	overindulgence in alcohol/food	hangover reliever		I		
aluminum hydroxide	skin protectant	diaper rash			310.545(a)(18)(iii)	
aluminum hydroxide	skin protectant			I	347.10(b)	
aluminum hydroxide	topical analgesic					
aluminum hydroxide gel	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(1)	
	overindulgence in alcohol/food	hangover reliever		I		
aluminum hydroxide gel	skin protectant			I	347.10(b)	
aluminum hydroxide-hexitol, stabilized polymer	antacid			I	331.11(a)(2)	
aluminum hydroxide-magnesium carbonate, co-dried gel	antacid			I	331.11(a)(2)	
aluminum hydroxide-magnesium trisilicate, co-dried gel	antacid			I	331.11(a)(2)	
aluminum hydroxide-sucrose powder hydrated	antacid			I	331.11(a)(2)	
aluminum phosphate	antacid			I	331.11(i)(1)	
aluminum phosphate gel (in combination only)	antacid			I	331.11(a)(4)	
aluminum sesquichlorohydrate	antiperspirant		I	I	350.10(h)	
aluminum sesquichlorohydrate polyethylene glycol	antiperspirant		I	I	350.10(i)	
aluminum sesquichlorohydrate propylene glycol	antiperspirant		I	I	350.10(j)	
aluminum sulfate	antifungal				310.545(a)(22)(ii)	
aluminum sulfate	antiperspirant		IIISE	IIISE	310.545(a)(4)(i)	
aluminum sulfate	skin protectant	astringent		I	347.12(b)	

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aluminum sulfate buffered w/ sodium aluminum lactate	antiperspirant	w/ sales less than \$25,000	I	IIIS	310.545(a)(4)(ii)	
aluminum sulfate, buffered (aerosol only)	antiperspirant		I	IIIS	310.545(a)(4)(i)	
aluminum zirconium octachlorohydrate	antiperspirant		I	IIS	350.10(k)	
aluminum zirconium octachlorohydrex gly	antiperspirant		I	IIS	350.10(l)	
aluminum zirconium pentachlorohydrate	antiperspirant		I	IIS	350.10(m)	
aluminum zirconium pentachlorohydrex gly	antiperspirant		I	IIS	350.10(n)	
aluminum zirconium tetrachlorohydrate	antiperspirant		I	IIS	350.10(o)	
aluminum zirconium tetrachlorohydrex gly	antiperspirant		I	IIS	350.10(p)	
aluminum zirconium trichlorohydrate	antiperspirant		I	IIS	350.10(q)	
aluminum zirconium trichlorohydrex gly	antiperspirant		I	IIS	350.10(r)	
aminacrine hydrochloride	boil treatment			IISE	310.531(a)	
aminoacetic acid	antiemetic			II		
aminobenzoic acid	internal analgesic		II	II	310.545(a)(23)(i)	
aminobenzoic acid (PABA)	sunscreen		I	I	352.10(a)	
aminophylline	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
ammonia solution, strong	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
ammonia solution, strong (ammonia water, strong)	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
ammoniated mercury	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
ammonium bromide	nighttime sleep aid	bromide	II	IISE		[54 FR 6826]
ammonium chloride	cough/cold	expectorant		III	310.545(a)(6)(iii)	
ammonium chloride	menstrual/diuretic	diuretic	I	I		
ammonium chloride	nighttime sleep aid			II		
ammonium chloride	oral health care	expectorant	III			
ammonium chloride	stimulant			IIIE		[39 FR 6104]
ammonium hydroxide	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
amylase	digestive aid				310.545(a)(8)(ii)	
amyltricresols, secondary	oral health care			IIISE		
anion and cation exchange resins buffered	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
anise oil	weight control		II		310.545(a)(20)	
anise seed	digestive aid				310.545(a)(8)(ii)	
antimony potassium tartrate	cough/cold	expectorant		II	310.545(a)(6)(iii)	
antipyrine	internal analgesic		III	III	310.545(a)(23)(i)	
antipyrine	ophthalmic	anesthetic	II	II	310.545(a)(21)(i)	
antipyrine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
any atropine ingredient	internal analgesic				310.545(a)(23)(ii)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
any atropine ingredient	menstrual/diuretic				310.545(a)(24)(ii)	
any ephedrine ingredient	internal analgesic				310.545(a)(23)(ii)	
any ephedrine ingredient	menstrual/diuretic				310.545(a)(24)(ii)	
any other ingredient containing mercury	antimicrobial	diaper rash			310.545(a)(27)(ii)	
any other ingredients containing mercury	vaginal contraceptive				310.545(a)(28)(i)	
arginine	weight control			II	310.545(a)(20)	
aromatic powder	digestive aid				310.545(a)(8)(ii)	
aromatics	skin protectant	astringent			310.545(a)(18)(ii)	
asafetida	digestive aid				310.545(a)(8)(ii)	
asclepias tuberosa	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
ascorbic acid	corn/callus remover		II	IISE		[55 FR 33261]
ascorbic acid	wart remover		III	IIIIE		[55 FR 33254]
ascorbic acid	weight control			II	310.545(a)(20)	
asparagus	menstrual/diuretic				310.545(a)(24)(i)	
aspergillus oryza enzymes (except lactase enzyme derived from <i>Aspergillus oryzae</i>)	digestive aid				310.545(a)(8)(ii)	
aspirin	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
aspirin	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
aspirin	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
aspirin	internal analgesic	cardiovascular	I	I	343.12(a)	
aspirin	internal analgesic	rheumatologic	I	I	343.13(a)	
aspirin	menstrual/diuretic	analgesic		I		
aspirin	nighttime sleep aid		II	IIE		[54 FR 6826]
aspirin	oral health care	anesthetic/analgesic	I	IIIIE		
aspirin	overindulgence in alcohol/food	hangover reliever		I		
aspirin (buffered)	internal analgesic	cardiovascular	I	I	343.12(b)	
aspirin (buffered)	internal analgesic	rheumatologic	I	I	343.13(b)	
aspirin, aluminum	internal analgesic		III	III	310.545(a)(23)(i)	
aspirin, calcium	internal analgesic			I		
aspirin, calcium	internal analgesic			I		
aspirin, calcium	menstrual/diuretic			I		
atropa belladonna	cough/cold	anticholinergic		II	310.533	
atropine	anorectal	anticholinergic	II(e,i)	II(e,i)	310.545(a)(26)(i)	
atropine sulfate	antidiarrheal		III	III	310.545(a)(3)(i)	
atropine sulfate	cough/cold	anticholinergic		III	310.533	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
attapulgite, activated	antidiarrheal	w/ sales less than \$25,000	III	I	310.545(3)(ii)	
avobenzone	sunscreen				352.10(b)	
avobenzone				I	352.10(a)	
bacillus acidophilus	digestive aid				310.545(a)(8)(ii)	
bacitracin	first aid antibiotic	ointment		I	333.110(a)	
bacitracin zinc	first aid antibiotic	ointment		I	333.110(b)	
barosma	menstrual/diuretic				310.545(a)(24)(i)	
basic fuchsin	antifungal		III	III	310.545(a)(22)(ii)	
beachwood creosote	cough/cold	expectorant		III	310.545(a)(6)(iii)	
bean	digestive aid				310.545(a)(8)(ii)	
bearberry	weight control			II	310.545(a)(20)	
bearberry (extract of uva ursi)	menstrual/diuretic				310.545(a)(24)(i)	
bearberry fluidextract (extract of bearberry)	menstrual/diuretic				310.545(a)(24)(i)	
beeswax	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
beeswax	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
beeswax	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
belladonna alkaloids	corn/callus remover		II	IISE		[55 FR 33261]
belladonna alkaloids	cough/cold	anticholinergic		IIIE	310.533	
belladonna alkaloids	cough/cold	bronchodilator	II	II	310.545(a)(6)(iv)	
belladonna alkaloids	digestive aid				310.545(a)(8)(ii)	
belladonna extract	anorectal	anticholinergic	II(e,i)	II(e,i)	310.545(a)(26)(i)	
belladonna leaves, powdered extact	digestive aid				310.545(a)(8)(ii)	
benzalkonium chloride	antimicrobial			I		
benzalkonium chloride	antimicrobial			I		
benzalkonium chloride	antimicrobial			IISE		
benzalkonium chloride	antimicrobial			IISE		
benzalkonium chloride	antimicrobial			IISE		
benzalkonium chloride	antimicrobial			IISE		
benzalkonium chloride	antimicrobial			IISE		
benzalkonium chloride	dandruff/seborrheic					
benzalkonium chloride	dermatitis/psoriasis		III	III	310.545(a)(7)	
benzalkonium chloride	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
benzalkonium chloride	skin protectant	astringent			310.545(a)(18)(ii)	

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benzalkonium chloride	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
benzethonium chloride	antifungal				310.545(a)(22)(ii)	
benzethonium chloride	antimicrobial			I		
benzethonium chloride	antimicrobial			IIIE		
benzethonium chloride	antimicrobial			IIISE		
benzethonium chloride	antimicrobial			IIISE		
benzethonium chloride	antimicrobial			IIISE		
benzethonium chloride	antimicrobial			IIISE		
benzethonium chloride	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
benzethonium chloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
benzethonium chloride	skin protectant	astringent			310.545(a)(18)(ii)	
benzethonium chloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
benzocaine	acne		II	II	310.545(a)(1)	
benzocaine	anorectal	local anesthetic	I(e),III(i)	I(e),III(i)	346.10(a)	
benzocaine	dandruff/seborrheic dermatitis/psoriasis		II	IIIE		[56 FR 63567]
benzocaine	external analgesic	male genital desensitizer	I	I	348.10(a)(1)	
benzocaine	external analgesic	poison ivy/oak/sumac	I	I	310.545(a)(10)(vii)	
benzocaine	external analgesic		IIIE	IISE (0.5-1.25%)		
benzocaine	oral health care	anesthetic/analgesic	I	I		
benzocaine	otic			IISE		[51 FR 28660]
benzocaine	pediculicide		II	II	310.545(a)(25)(i)	
benzocaine	relief of oral discomfort			I		
benzocaine	relief of oral discomfort			IIIE		
benzocaine	skin protectant	astringent			310.545(a)(18)(ii)	
benzocaine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
benzocaine	wart remover		II	IISE		[55 FR 33254]
benzocaine	weight control			IISE		
benzoic acid	acne		II	II	310.545(a)(1)	
benzoic acid	antifungal		III	III	310.545(a)(22)(ii)	
benzoic acid	oral health care			IIIE		
benzoic acid	skin protectant	astringent			310.545(a)(18)(ii)	
benzoin preparations (compound tincture of benzoin, tincture of benzoin)	cough/cold	expectorant	III		310.545(a)(6)(iii)	

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benzoin tincture, compound	relief of oral discomfort			I		
benzonatate	cough/cold	antitussive		I		
benzoxiquine	antifungal		III	III	310.545(a)(22)(ii)	
benzoyl peroxide	acne		I	I-> IIIS	n/a	[56FR37622]
benzyl alcohol	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(b)	
benzyl alcohol	external analgesic	anesthetic	I	I		
benzyl alcohol	external analgesic	male genital desensitizer	I	I	310.545(a)(10)(iii)	
benzyl alcohol	oral health care	anesthetic/analgesic	I	I		
benzyl alcohol	pediculicide		II	II	310.545(a)(25)(i)	
benzyl alcohol	relief of oral discomfort			I		
benzyl alcohol	relief of oral discomfort			IIISE		
benzyl alcohol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
benzyl benzonate	pediculicide		II	II	310.545(a)(25)(i)	
betaine hydrochloride	digestive aid				310.545(a)(8)(ii)	
bicarbonate	antacid				331.11(b)	
bile salts/acids	laxative	stimulant laxative	III		310.545(a)(12)(iv)(A)	
bisacodyl	laxative			I		
bismuth aluminate	antacid			I	331.11(c)(1)	
bismuth carbonate	antacid			I	331.11(c)(2)	
bismuth oxide	anorectal	protectant	III(e,i)	III(e,i)	310.545(a)(26)(viii)	
bismuth sodium tartrate	digestive aid		II	II	310.545(a)(8)(i)	
bismuth sodium tartrate	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
bismuth subcarbonate	anorectal	protectant	III(e,i)	III(e,i)	310.545(a)(26)(viii)	
bismuth subcarbonate	antacid			I	331.11(c)(3)	
bismuth subcarbonate	digestive aid				310.545(a)(8)(ii)	
bismuth subgallate	anorectal	protectant	III(e,i)	III(e,i)	310.545(a)(26)(viii)	
bismuth subgallate	antacid			I	331.11(c)(4)	
bismuth subgallate	deodorants for internal use			I	357.810(a)	
bismuth subgallate	digestive aid				310.545(a)(8)(ii)	
bismuth subnitrate	anorectal	protectant	II(e,i)	II(e,i)	310.545(a)(26)(viii)	
bismuth subnitrate	antacid			I	331.11(c)(5)	
bismuth subnitrate	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
bismuth subnitrate	skin protectant	fever blister/cold sore	II	II	310.545(a)(18)(iv)	
bismuth subnitrate	skin protectant	insect bites/stings w/ sales less than \$25,000	II	II	310.545(a)(18)(v)(B)	

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bismuth subnitrate	skin protectant	poison ivy/oak/sumac	II	II	310.545(a)(18)(vi)(A)	
bismuth subnitrate	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000	II	II	310.545(a)(18)(vi)(B)	
bismuth subnitrate	skin protectant	w/ sales less than \$25,000	II	II	310.545(a)(18)(i)(B)	
bismuth subsalicylate	antidiarrheal		III	III	335.10(a)	
bismuth subsalicylate	antiemetic			III		
bismuth subsalicylate	antimicrobial			IIS		
bismuth subsalicylate	oral health care			IIS		
bismuth subsalicylate	overindulgence in alcohol/food	overindulgence		I		
bismuth subsalicylate	skin protectant			IIS		
bithionol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
bithionol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
black radish powder	digestive aid				310.545(a)(8)(ii)	
blessed thistle (<i>cnicus benedictus</i>)	digestive aid				310.545(a)(8)(ii)	
blessed thistle (<i>cnicus benedictus</i>)	menstrual/diuretic				310.545(a)(24)(i)	
boitin	weight control			II	310.545(a)(20)	
bomelone	sunscreen		III	III		[64 FR 27682]
bone marrow, red	weight control			II	310.545(a)(20)	
boric acid	acne		II	II	310.545(a)(1)	
boric acid	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
boric acid	antifungal		III		310.545(a)(22)(ii)	
boric acid	dandruff/seborrheic dermatitis/psoriasis			II	310.545(a)(7)	
boric acid	ophthalmic	anti-infective	III	II	310.545(a)(21)(ii)	
boric acid	skin protectant	astringent	II	II	310.545(a)(18)(ii)	
boric acid	skin protectant	fever blister/cold sore	II	II	310.545(a)(18)(iv)	
boric acid	skin protectant	insect bites/stings w/ sales less than \$25,000	II	II	310.545(a)(18)(v)(B)	
boric acid	skin protectant	poison ivy/oak/sumac	II	II	310.545(a)(18)(vi)(A)	
boric acid	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000	II	II	310.545(a)(18)(vi)(B)	
boric acid	skin protectant	w/ sales less than \$25,000	II	II	310.545(a)(18)(i)(B)	
bornyl acetate (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
boroglycerin	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
boroglycerin	oral health care			IIS		

I - GRASE; II - Not GRASE; III - Insufficient Data

S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
bran	laxative			I		
bromopheniramine maleate	cough/cold	antihistamine	I	I	341.12(a)	
buchu	weight control			II	310.545(a)(20)	
buchu powdered extract (extract of buchu)	menstrual/diuretic		II	II	310.545(a)(24)(i)	
buchu, potassium extract	weight control			II	310.545(a)(20)	
buckthorn	digestive aid				310.545(a)(8)(ii)	
butacaine sulfate	relief of oral discomfort			I		
butacaine sulfate	relief of oral discomfort			IIISE		
butaben benzoate	external analgesic		I	I		
caffeine	cough/cold	miscellaneous		IIIE		
caffeine	internal analgesic		III	IIIE		
caffeine	menstrual/diuretic	analgesic	III			
caffeine	menstrual/diuretic	diuretic	I	I		
caffeine	nighttime sleep aid	stimulant		I		
caffeine	overindulgence in alcohol/food	hangover reliever		I		
caffeine	stimulant			I	340.1	
caffeine	weight control			II	310.545(a)(20)	
caffeine citrate	weight control			II	310.545(a)(20)	
calamine	anorectal	astringent	I(e,i)	I(e,i)	346.18(a)	
calamine	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
calamine	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
calamine	skin protectant		I	I	347.10(c)	
calamine (in combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(1)	
calcium	weight control			II	310.545(a)(20)	
calcium (mono or dibasic salt)	antacid				331.11(i)(2)	
calcium acetate	skin protectant	astringent			310.545(a)(18)(ii)	
calcium carbonate	antacid			I	331.11(d)	
calcium carbonate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
calcium carbonate	weight control			II	310.545(a)(20)	
calcium carbonate precipitated	antidiarrheal		III	III	310.545(a)(3)(i)	
calcium caseinate	weight control			II	310.545(a)(20)	
calcium gluconate	digestive aid				310.545(a)(8)(ii)	
calcium hydroxide	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
calcium lactate	menstrual/diuretic				310.545(a)(24)(i)	
calcium lactate	weight control			II	310.545(a)(20)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
calcium pantothenate	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
calcium pantothenate	menstrual/diuretic				310.545(a)(24)(i)	
calcium pantothenate	wart remover		III	III E		[55 FR 33254]
calcium pantothenate	weight control			II	310.545(a)(20)	
calcium phosphate	antacid			I	331.11(d)	
calcium polycarbophil	antidiarrheal	w/ sales less than \$25,000	NC	I	310.545(a)(3)(ii)	
calcium polycarbophil	laxative	bulk laxative		I		
calcium polysulfide	acne		II	II	310.545(a)(1)	
calcium salicylate	internal analgesic				310.545(a)(23)(i)	
calcium sucrose phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
calcium thiosulfate	acne		II	II	310.545(a)(1)	
calcium undecylenate	antifungal		I	I	333.210(f)	
calcium undecylenate	antimicrobial			III E		
calcium undecylenate	dandruff/seborrheic dermatitis/psoriasis				310.545(a)(7)	
calomel	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
calomel (mercurous chloride)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
camphor	acne		II	II	310.545(a)(1)	
camphor	anorectal	analgesic, anesthetic, antipruritic		I(e)	346.16(a)	
camphor	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
camphor	antifungal		II	II	310.545(a)(22)(ii)	
camphor	cough/cold	antitussive	III	III E	341.14(b)(1)	steam inhalation
camphor	cough/cold	antitussive	III	I	341.14(b)(1)	topical
camphor	cough/cold	expectorant		III	310.545(a)(6)(iii)	topical/inhalant
camphor	cough/cold	nasal decongestant	III	III E		[59 FR 43408]
camphor	external analgesic		I	I		
camphor	external analgesic		I	II E		
camphor	oral health care	anesthetic/analgesic	II	II E		
camphor	oral health care	non-antimicrobial			310.545(a)(14)	
camphor	relief of oral discomfort			II E		
camphor	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
camphor	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
camphor	sunscreen		II	II E		[64 FR 27682]
camphor	wart remover		II	II E		[55 FR 33254]
camphor (exceeding 3 percent)	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
camphor (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
camphor gum	skin protectant	astringent			310.545(a)(18)(ii)	
camphorated metacresol	antifungal		III	III	310.545(a)(22)(iv)	
camphorated metacresol	external analgesic	anesthetic	I	I		
camphorated metacresol	external analgesic	male genital desensitizer	I	I	310.545(a)(10)(iii)	
candididin	antifungal		II	II	310.545(a)(22)(ii)	
capsaicin	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
capsicum	digestive aid				310.545(a)(8)(ii)	
capsicum	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
capsicum	relief of oral discomfort			III E		
capsicum	relief of oral discomfort			II S E		
capsicum oleoresin	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
capsicum oleoresin	menstrual/diuretic				310.545(a)(24)(i)	
capsicum, fluid extract of	digestive aid				310.545(a)(8)(ii)	
captan	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
caramiphen edisylate	cough/cold	antitussive	III	III E		[52 FR 30054]
carbamide peroxide	oral health care			III		
carbamide peroxide	oral health care			III E		
carbamide peroxide (in anhydrous glycerin)	oral health care	wound cleansing	I	I		
carbamide peroxide 6.5% (in anhydrous glycerin)	otic			I	344.1	
carbaspirin calcium	internal analgesic		I	I		
carbaspirin calcium	menstrual/diuretic	analgesic	I			
carbetapentane citrate	cough/cold	antitussive	III	III E		[52 FR 30054]
carbon	digestive aid				310.545(a)(8)(ii)	
carbon dioxide, released	laxative			I		
carboxymethylcellulose sodium	antidiarrheal				310.545(a)(3)(i)	
carboxymethylcellulose sodium	laxative			I		
carboxymethylcellulose sodium	ophthalmic	demulcents	I	I	349.12(a)(1)	
carboxymethylcellulose sodium	weight control		III		310.545(a)(20)	
carrageenan	weight control		III		310.545(a)(20)	
carrageenan (degraded)	laxative	bulk laxative	II		310.545(a)(12)(i)	
carrageenan (native)	laxative	bulk laxative	III		310.545(a)(12)(i)	
casanthranol	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
cascara fluidextract aromatic	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
cascara fluidextract, aromatic (extract of cascara)	menstrual/diuretic				310.545(a)(24)(i)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
cascara sagrada bark	laxative	stimulant laxative		I	310.545(a)(12)(iv)(C)	
cascara sagrada extract	digestive aid				310.545(a)(8)(ii)	
cascara sagrada extract	laxative	stimulant laxative		I	310.545(a)(12)(iv)(C)	
cascara sagrada fluidextract	laxative	stimulant laxative		I	310.545(a)(12)(iv)(C)	
castor oil	laxative	stimulant laxative		I		
castor oil	wart remover		II	IISE		[55 FR 33254]
catechu, tinctures	digestive aid				310.545(a)(8)(ii)	
catnip	digestive aid				310.545(a)(8)(ii)	
cedar leaf oil (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
cellulase	digestive aid		II/III	III	310.545(a)(8)(i)	
cellulose, microporous	skin protectant			IIISE		
cetalkonium chloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
cetalkonium chloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
cetyl alcohol	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
cetyl alcohol	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
cetyl alcohol	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
cetylpyridinium chloride	oral health care			IIISE		
chamomile flowers	digestive aid				310.545(a)(8)(ii)	
charcoal (activated)	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
charcoal, activated	acute toxic ingestion			I		
Charcoal, activated	antacid			IIIE		
charcoal, activated	deodorants for internal use			IIIE		[55 FR 19864]
charcoal, activated	overindulgence in alcohol/food	hangover minimizer		IIIE		[48 FR 32873]
charcoal, activated	poison treatment			I		
charcoal, wood/activated	digestive aid		III	III	310.545(a)(8)(ii)	
chlorphedianol hydrochloride	cough/cold	antitussive		I	341.14(a)(1)	oral
chloral hydrate	external analgesic	anesthetic	II	II	310.545(a)(10)(i)	
chloral hydrate	external analgesic	counter irritant	I	I	310.545(a)(10)(ii)	
chloral hydrate	external analgesic	fever blister/cold sore	II	II	310.545(a)(10)(v)	
chloral hydrate	external analgesic	poison ivy/oak/sumac	II	II	310.545(a)(10)(vii)	
chloral hydrate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
chlorcyclizine hydrochloride	cough/cold	antihistamine		I	341.12(b)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
chlorhydroxyquinoline (cloxyquin)	acne		II	II	310.545(a)(1)	
chlorobutanol	corn/callus remover		II	IISE		[55 FR 33261]
chlorobutanol	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
chlorobutanol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
chlorobutanol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
chloroform	cough/cold	expectorant		II	310.545(a)(6)(iii)	
chloroform	digestive aid				310.545(a)(8)(ii)	
chlorophenothane (dichlorodiphenyl trichloroethane)	pediculicide				310.545(a)(25)(i)	
chlorophyllin	relief of oral discomfort			IISE		
chlorophyllin copper complex	deodorants for internal use			I	357.810(b)	
chlorophyllin copper complex	oral health care			IIIE		
chlorothymol	antifungal		III	III	310.545(a)(22)(ii)	
chloroxlyneol	antimicrobial			IIIE		
chloroxlyneol	antimicrobial			IIIE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	antimicrobial			IIISE		
chloroxlyneol	acne		II	II	310.545(a)(1)	
chloroxlyenol	antifungal		III	III	310.545(a)(22)(iv)	
chloroxlyenol	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
chlorpheniramine maleate	cough/cold	antihistamine	I	I	341.12(c)	
chlorpheniramine maleate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
chlorpheniramine maleate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
chlorprophenpyridamine maleate	menstrual/diuretic				310.545(a)(24)(i)	
chlortetracycline hydrochloride	first aid antibiotic	ointment		I	333.110(c)	
cholecalciferol	skin protectant			IISE		
cholecalciferol	weight control			II	310.545(a)(20)	
cholecalciferol (vitamin D)	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
choline	weight control			II	310.545(a)(20)	
choline salicylate	internal analgesic		I	I		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
choline salicylate	menstrual/diuretic	analgesic	I			
chondrus	weight control			III	310.545(a)(20)	
cimicifuga racemosa	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
cinnamedrine hydrochloride	menstrual/diuretic	muscle relaxant	III	III E		
cinnamon oil	digestive aid				310.545(a)(8)(ii)	
cinnamon tincture	digestive aid				310.545(a)(8)(ii)	
cinoxate	sunscreen		I	I	352.10(c)	
citrate (containing active ingredients: citrate ion, as citric acid or salt)	antacid			I	331.11(e)	
citric acid	relief of oral discomfort			III E		
citric acid	weight control			II	310.545(a)(20)	
citrus pectin	digestive aid				310.545(a)(8)(ii)	
clioquinol						
clioquinol (iodochlorhydroxyquin)	antifungal		I	I	333.210(a)	
clofucarban	antimicrobial			III S		
clofucarban	antimicrobial			III SE		
clofucarban	antimicrobial			III SE		
clofucarban	antimicrobial			III SE		
clofucarban	antimicrobial			III SE		
clofucarban	antimicrobial			III SE		
clofucarban	antimicrobial			III SE		
clofucarban	antimicrobial			III SE		
clotrimazole	antifungal			I	333.210(g)	
clotrimazole	n/a			I		[67 FR 5942]
clove oil	skin protectant	astringent			310.545(a)(18)(ii)	
cloxyquin (chlorhydroxyquinoline)	acne				310.545(a)(1)	
cnicus benedictus	menstrual/diuretic		II	II		
cnicus benedictus	weight control			II	310.545(a)(20)	
coal tar	acne		II	II	310.545(a)(1)	
coal tar	antifungal		II	II	310.545(a)(22)(ii)	
coal tar	dandruff/seborrheic dermatitis/psoriasis		IS III	I	358.710(a)(1)	
coal tar	dandruff/seborrheic dermatitis/psoriasis		IS III	I	358.710(b)(1)	
coal tar	dandruff/seborrheic dermatitis/psoriasis		IS III	I	358.710(c)(1)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
cocoa butter	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(2)	
cocoa butter	skin protectant	diaper rash	I	I	310.545(a)(18)(iii)	
cocoa butter	skin protectant		I	I	346.14(2)	
cocoa butter	skin protectant		I	I	347.10(d)	
coconut oil soap, aqueous	pediculicide		II	II	310.545(a)(25)(i)	
cod liver oil	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
cod liver oil	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
cod liver oil	skin protectant				347.10(e)	
cod liver oil (in combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(2)	
codeine	cough/cold	antitussive	I	I	341.14(a)(2)(i)	oral
codeine	internal analgesic		II	II	310.545(a)(23)(i)	
codeine	menstrual/diuretic	analgesic	II		310.545(a)(24)(i)	
codeine phosphate	cough/cold	antitussive	I	I	341.14(a)(2)(ii)	oral
codeine phosphate	internal analgesic				310.545(a)(23)(i)	
codeine sulfate	cough/cold	antitussive	I	I	341.14(a)(2)(iii)	oral
codeine sulfate	internal analgesic				310.545(a)(23)(i)	
collinsonia (extract stone root)	menstrual/diuretic				310.545(a)(24)(i)	
collinsonia extract	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
colloidal oatmeal	dandruff/seborrheic dermatitis/psoriasis		II	II	310.545(a)(7)	
colloidal oatmeal	skin protectant	astringent			310.545(a)(18)(ii)	
colloidal oatmeal	skin protectant			I	347.10(f)	
colloidal oatmeal	skin protectant				347.10(f)	
colocynth	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
copper	weight control			II	310.545(a)(20)	
copper gluconate	weight control			II	310.545(a)(20)	
copper oleate	pediculicide		II	II	310.545(a)(25)(i)	
copper undecylenate	antifungal		I	I	333.210(f)	
corn oil	weight control			II	310.545(a)(20)	
corn oil, aqueous emulsion	cholecystokinetic			I	357.210(a)	
corn silk	menstrual/diuretic		II	II	310.545(a)(24)(i)	
corn silk, potassium extract	weight control			II	310.545(a)(20)	
corn starch	skin protectant		I	NA		
corn syrup	weight control			II	310.545(a)(20)	
couch grass	menstrual/diuretic				310.545(a)(24)(i)	
creosote	relief of oral discomfort			IIIIE		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
creosote	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
creosote, beechwood	cough/cold	antitussive	III	IIIE		[52 FR 30054]
creosote, beechwood	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
creosote, beechwood	relief of oral discomfort			IIISE		
creosote, beechwood (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
creosote, beechwood (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
cresol	oral health care	anesthetic/analgesic	II	IISE		
cresol	oral health care	non antimicrobial			310.545(a)(14)	
cresol	relief of oral discomfort			IIISE		
cresol	relief of oral discomfort			IIISE		
cresol	skin protectant	astringent			310.545(a)(18)(ii)	
cresol, saponated	dandruff/seborrheic dermatitis/psoriasis		II	II	310.545(a)(7)	
cupric sulfate	external analgesic					
cupric sulfate	skin protectant	astringent			310.545(a)(18)(ii)	
cupric sulfate	weight control			II	310.545(a)(20)	
cyanocobalamin (vitamin B12)	weight control			II	310.545(a)(20)	
cyclizine hydrochloride	antiemetic			I	336.10(a)	
cyclomethycaine sulfate	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
cyclomethycaine sulfate	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
cyclomethycaine sulfate	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
cysteine hydrochloride	skin protectant	diaper rash			310.545(a)(18)(iii)	
cystine	weight control			II	310.545(a)(20)	
danthon	laxative	stimulant laxative		I	310.545(a)(12)(iv)(B)	
datura stramonium	cough/cold	anticholinergic		II	310.533	
dehydrocholic acid	digestive aid		II	II	310.545(a)(8)(i)	
dequalinium chloride	oral health care			IIIE		
dexbrompheniramine maleate	cough/cold	antihistamine		I	341.12(d)	
dexchlorpheniramine maleate	cough/cold	antihistamine		I	341.12(e)	
dexpanthenol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
dexpanthenol	external analgesic			IIIE		
dexpanthenol	skin protectant			IIIE		
dextran 70	ophthalmic	demulcents	I	I	349.12(b)	
dextromethorphan	cough/cold	antitussive	I	I	341.14(a)(3)	oral
dextromethorphan hydrobromide	cough/cold	antitussive	I	I	341.14(a)(4)	oral
dextrose	weight control			II	310.545(a)(20)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
diastase	digestive aid				310.545(a)(8)(ii)	
dibenzothiophene	acne		II	II	310.545(a)(1)	
dibucaine	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(c)	
dibucaine	external analgesic		I	I		
dibucaine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
dibucaine hydrochloride	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(d)	
dibucaine hydrochloride	external analgesic		I	I		
dibucaine hydrochloride	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
dicalcium phosphate dihydrate	anticaries		II	NC	310.545(a)(2)(ii)	
dicalcium phosphate dihydrate [see calcium phosphate, dibasic]	gingivitis/plaque			III(E)		
dichlorodiphenyl trichloroethane (DDT)	pediculicide		II	II		
dichlorophen	antifungal		III	III	310.545(a)(22)(ii)	
diethanolamine methoxycinnamate	sunscreen		I	I	310.545(a)(29)	
digalloyl trioleate	sunscreen		I	I	310.545(a)(29)	
dihydroxyaluminum aminoacetate	antacid			I	331.11(a)(3)	
dihydroxyaluminum aminoacetic acid	antacid				331.11(a)(3)	
dihydroxyaluminum sodium carbonate	antacid			I	331.11(a)(5)	
dihydroxyaluminum sodium carbonate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
dimenhydrinate	antiemetic			I	336.10(b)	
dimethicone	skin protectant		I	I	347.10(g)	
dimethicone	skin protectant		I	I		
dimethicone	skin protectant		I	I		
dimethisoquin hydrochloride	external analgesic		I	I		
dioctyl sodium sulfosuccinate	pediculicide		II	II		
dioxybenzone	sunscreen		I	I	352.10(e)	
diperodon	anorectal	anesthetic			310.545(a)(26)(vi)	
diperodon hydrochloride	corn/callus remover		II	IISE		[55 FR 33261]
diperodon hydrochloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
diperodon hydrochloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
diphenhydramine citrate	cough/cold	antihistamine			341.12(f)	
diphenhydramine citrate	cough/cold	antitussive			341.14(a)(5)	oral
diphenhydramine citrate	nighttime sleep aid				338.10(b)	
diphenhydramine hydrochloride	antiemetic			III(E)	336.10(c)	
diphenhydramine hydrochloride	cough/cold	antihistamine	I	I	341.12(g)	
diphenhydramine hydrochloride	cough/cold	antitussive	III	III(E)	341.14(a)(6)	oral

I - GRASE; II - Not GRASE; III - Insufficient Data

S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
diphenhydramine hydrochloride	external analgesic		I	I		
diphenhydramine hydrochloride	nighttime sleep aid	antihistamine	III	IIIE	338.10(a)	
diphenhydramine hydrochloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
dipropylene glycol salicylate	sunscreen		III	IIIE		[64 FR 27682]
disodium hydrogen phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
distase malt	digestive aid				310.545(a)(8)(ii)	
docusate calcium sulfosuccinate	laxative	stool softener				
docusate potassium sulfosuccinate	laxative	stool softener				
docusate sodium	pediculicide				310.545(a)(25)(i)	
docusate sodium	weight control			II	310.545(a)(20)	
docusate sodium sulfosuccinate	laxative	stool softener				
dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate)	vaginal contraceptive			IIIE	310.545(a)(28)(i)	
dog grass	digestive aid				310.545(a)(8)(ii)	
dog grass extract	menstrual/diuretic		II	II	310.545(a)(24)(i)	
domiphen bromide	oral health care			IIIE		
doxylamine succinate	cough/cold	antihistamine		I	341.12(h)	
doxylamine succinate	nighttime sleep aid	antihistamine	III	IIIE		[5 FR 6828]
duodenal substance	digestive aid		II	II	310.545(a)(8)(i)	
dyclonine hydrochloride	anorectal	local anesthetic		I	346.10(e)	
dyclonine hydrochloride	external analgesic		I	I		
dyclonine hydrochloride	oral health care	anesthetic/analgesic	I	I		
edetate disodium	relief of oral discomfort			IIIE		
elaterin resin	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
elecampane	digestive aid				310.545(a)(8)(ii)	
elm bark	cough/cold	antitussive	III	IIIE		[52 FR 30054]
elm bark	oral health care	demulcents	I	I		
ensulizole (phenylbenzimidazole sulfonic acid)	sunscreen		I	I	352.10(n)	
ephedrine	cough/cold	bronchodilator	I	I	341.16(a)	
ephedrine (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(2)	
ephedrine (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(2)	
ephedrine (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
ephedrine hydrochloride	cough/cold	bronchodilator	I	I	341.16(b)	
ephedrine hydrochloride	external analgesic	male genital desensitizer			310.545(a)(10)(iii)	
ephedrine hydrochloride	ophthalmic	vasoconstrictor	I	I	349.18(a)	
ephedrine hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(3)	

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
ephedrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(3)	
ephedrine hydrochloride (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
ephedrine sulfate	anorectal	vasoconstrictor	I	I	346.12(a)	
ephedrine sulfate	cough/cold	bronchodilator	I	I	341.16(c)	
ephedrine sulfate (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(4)	
ephedrine sulfate (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(4)	
ephedrine sulfate (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
epinephrine	anorectal	vasoconstrictor	III(e,i)	I(e),III(i)	346.12(b)	
epinephrine	cough/cold	bronchodilator	I	I	341.16(d)	inhalation
epinephrine	cough/cold	bronchodilator	I	I	341.16(d)	rubber bulb
epinephrine bitartrate	cough/cold	bronchodilator	I	I	341.16(e)	inhalation
epinephrine bitartrate	cough/cold	bronchodilator	I	I	341.16(e)	rubber bulb
epinephrine hydrochloride	anorectal	vasoconstrictor	I(e),II(i)	I(e),II(i)	346.12(c)	
epinephrine hydrochloride	cough/cold	bronchodilator	I	I		
epinephrine undecylenate	anorectal	vasoconstrictor	I	I	310.545(a)(26)(ix)	
ergocalciferol	weight control			II	310.545(a)(20)	
ergot fluid extract	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
ergot fluidextract	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
Escherichia coli vaccine	anorectal	other			310.545(a)(26)(vii)	
estrone	acne		II	II	310.545(a)(1)	
ether	digestive aid				310.545(a)(8)(ii)	
	dandruff/seborrheic					
ethohexadiol	dermatitis/psoriasis		III	III	310.545(a)(7)	
ethyl 4-[bis(hydroxypropyl)] aminobenzoate	sunscreen		I	I	310.545(a)(29)	
ethyl nitrate	menstrual/diuretic				310.545(a)(24)(i)	
ethylmorphine hydrochloride	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
eucalyptol	cough/cold	antitussive		IIIIE		[52 FR 30055]
eucalyptol	cough/cold	antitussive		IIIIE		[52 FR 30055]
	dandruff/seborrheic					
eucalyptol	dermatitis/psoriasis		III	III	310.545(a)(7)	
eucalyptol	oral health care	anesthetic/analgesic	III	III	310.545(a)(14)	
eucalyptol (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
eucalyptol (mouthwash)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
eucalyptol/eucalyptus oil	cough/cold	expectorant		III	310.545(a)(6)(iii)	
eucalyptus oil	cough/cold	antitussive	III	IIIIE		[52 FR 30055]
eucalyptus oil	cough/cold	antitussive	III	IIIIE		[52 FR 30054]

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
eucalyptus oil	cough/cold	antitussive	III	IIIE		[52 FR 30055]
eucalyptus oil	cough/cold	nasal decongestant	III	IIIE		[59 FR 43408]
eucalyptus oil	external analgesic	counter irritant	I	I	310.545(a)(10)(ii)	
eucalyptus oil	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
eucalyptus oil	external analgesic	poison ivy/oak/sumac	I	I	310.545(a)(10)(vii)	
eucalyptus oil	skin protectant	astringent			310.545(a)(18)(ii)	
eucalyptus oil	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
eucalyptus oil (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
eucalyptus oil (mouthwash)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
eugenol	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
eugenol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
eugenol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
eugenol	relief of oral discomfort			IIISE		
eugenol	skin protectant	astringent			310.545(a)(18)(ii)	
euphorbia pilulifera	cough/cold	bronchodilator	III	III	310.545(a)(6)(iv)	
fennel acid	digestive aid				310.545(a)(8)(ii)	
ferric acid	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
ferric ammonium citrate	weight control			II	310.545(a)(20)	
ferric chloride	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
ferric chloride	menstrual/diuretic				310.545(a)(24)(i)	
ferric chloride	oral health care			IISE		
ferric chloride	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
ferric pyrophosphate	weight control			II	310.545(a)(20)	
ferric subsulfate (Monsel's solution)	skin protectant	astringent			310.545(a)(18)(ii)	
ferrous fumarate	weight control			II	310.545(a)(20)	
ferrous gluconate	weight control			II	310.545(a)(20)	
ferrous sulfate	menstrual/diuretic				310.545(a)(24)(i)	
ferrous sulfate (iron)	weight control			II	310.545(a)(20)	
flax seed	weight control			II	310.545(a)(20)	
fluorosalan	antimicrobial			IIS		
folic acid	weight control			II	310.545(a)(20)	
formaldehyde solution	relief of oral discomfort			IIIE		
formic acid	pediculicide				310.545(a)(25)(i)	
frangula	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
fructose	overindulgence in alcohol/food	inebriation minimizer		IIIE		[48 FR 32873]

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
fructose	weight control			II	310.545(a)(20)	
galega	digestive aid				310.545(a)(8)(ii)	
gamboge	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
garlic, dehydrated	digestive aid		II	II	310.545(a)(8)(i)	
gelatin	ophthalmic	demulcents	I	I	349.12(c)	
gelatin	oral health care	demulcents	I	I		
gentian violet	oral health care			III E		
gentian violet	anthelmintic		I	II		
gentiana lutea (gentian)	menstrual/diuretic				310.545(a)(24)(i)	
ginger	digestive aid				310.545(a)(8)(ii)	
ginseng	nighttime sleep aid			II		
ginseng	stimulant			III E		[39 FR 6104]
glutamic acid hydrochloride	digestive aid	stomach acidifier	II	II	310.545(a)(8)(i)	
glycerin	anorectal	protectant	I(e)	I(e)	346.14(a)(3)	
glycerin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
glycerin	laxative	hyperosmotic		I		
glycerin	ophthalmic	demulcents	I	I	349.12(d)(1)	
glycerin	oral health care			I		
glycerin	otic			III E		[51 FR 28660]
glycerin	skin protectant		I	I	347.10(h)	
glycerin	skin protectant		I	I		
glycerine and anhydrous glycerine	otic				310.545(a)(15)(ii)	
glycerine and anhydrous glycerine	skin protectant	diaper rash			310.545(a)(18)(iii)	
glycerine and anhydrous glycerine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
glyceryl aminobenzoate	sunscreen		I	I	310.545(a)(29)	
glyceryl stearate	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
glyceryl stearate	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
glyceryl stearate	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
glycine	antidiarrheal		II	II	310.545(a)(3)(i)	
glycine	digestive aid				310.545(a)(8)(ii)	
glycine (aminoacetic acid)	antacid		I		331.11(f)	
glycol salicylate	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
glycol salicylate	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
glycyrrhiza (licorice)	menstrual/diuretic				310.545(a)(24)(i)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
gramicidin	first aid antibiotic			III		
guaifenesin	cough/cold	expectorant		IIIIE	341.18	
guar gum	weight control			III	310.545(a)(20)	
guar gun	laxative	bulk laxative		III	310.545(a)(12)(i)	
haloprogin	antifungal		I	I	333.210(b)	
hard fat	anorectal	protectant			346.14(a)(4)	
hard fat	skin protectant				347.10(i)	
hectorite	digestive aid				310.545(a)(8)(ii)	
hectorite	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
hectorite	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
hemicellulase	digestive aid		III	III	310.545(a)(8)(i)	
hexachlorophene	antimicrobial					[37 FR 20163]
hexylresorcinol	antimicrobial		I			
hexylresorcinol	antimicrobial		I			
hexylresorcinol	antimicrobial		IIIE			
hexylresorcinol	antimicrobial		IIIIE			
hexylresorcinol	antimicrobial		IIIIE			
hexylresorcinol	antimicrobial		IIIIE			
hexylresorcinol	antimicrobial		IIIIE			
hexylresorcinol	antimicrobial		IIIIE			
hexylresorcinol	antimicrobial		IIIIE			
hexylresorcinol	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
hexylresorcinol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
hexylresorcinol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
hexylresorcinol	oral health care	anesthetic/analgesic	I	I		
histamine dihydrochloride	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
histidine	weight control			II	310.545(a)(20)	
homatropine methylbromide	antidiarrheal		III	III	310.545(a)(3)(i)	
homatropine methylbromide	digestive aid		II/III	III	310.545(a)(8)(i)	
homatropine methylbromide	menstrual/diuretic	muscle relaxant	II	II	310.545(a)(24)(i)	
homosalate	sunscreen		I	I	352.10(f)	
honey	skin protectant	astringent			310.545(a)(18)(ii)	
horehound	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
horehound	cough/cold	expectorant			310.545(a)(6)(iii)	
horehound	oral health care	expectorant	III			
horsetail	digestive aid				310.545(a)(8)(ii)	
huckleberry	digestive aid				310.545(a)(8)(ii)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
hydrastis	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
hydrastis	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
hydrastis canadensis	weight control			II	310.545(a)(20)	
hydrastis canadensis (golden seal)	digestive aid				310.545(a)(8)(ii)	
hydrastis canadensis (golden seal)	menstrual/diuretic		II	II	310.545(a)(24)(i)	
hydrastis fluid extract	digestive aid				310.545(a)(8)(ii)	
hydrate magnesium aluminate activated sulfate	antacid				331.11(g)(1)	
hydrochloric acid	digestive aid				310.545(a)(8)(ii)	
hydrocodone bitartrate	cough/cold	antitussive	II	IIS		[52 FR 30054]
hydrocortisone	external analgesic		I	I		
hydrocortisone (0.25-5%)	external analgesic		I	I		
hydrocortisone (0.5-1%)	external analgesic			IISE		
hydrocortisone (combination)	anorectal				310.545(a)(26)(xi)	
hydrocortisone acetate	external analgesic		I	I		
hydrocortisone acetate	external analgesic		I	I		
hydrocortisone acetate (0.25-5.0%)	external analgesic		I	I		
hydrocortisone acetate (0.25%-0.5%)	external analgesic		I	I		
hydrocortisons preparations	dandruff/seborrheic dermatitis/psoriasis		III	IS		
hydrogen fluoride	anticaries		NC	III	310.545(a)(2)(i)	
hydrogen peroxide	antimicrobial			I		
hydrogen peroxide	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
hydrogen peroxide	oral health care	wound cleansing	I	I		
hydrogen peroxide	oral health care			III		
hydrogen peroxide	oral health care			IIIE		
hydrogen peroxide	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
hydrogen peroxide and povidone iodine	gingivitis/plaque			IISE		
hydrogen peroxide and sodium bicarbonate	gingivitis/plaque			IISE		
hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc chloride	gingivitis/plaque			IIISE		
hydroquinone	skin bleach			I		
hydroxyethylcellulose	ophthalmic	demulcents	I	I	349.12(a)(2)	
hydroxypropyl methylcellulose	ophthalmic	demulcents	I	I		
hyocamine sulfate	antidiarrheal		III	III	310.545(a)(3)(i)	
hyoscyamine sulfate	menstrual/diuretic				310.545(a)(24)(i)	
hypromellose	ophthalmic	demulcents		I	349.12(a)(3)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
ibuprofen	internal analgesic			I		[67 FR 54139]
ibuprofen	internal analgesic			I		[67 FR 54139]
ichthammol	corn/callus remover		II	IISE		[55 FR 33261]
impatiens biflora tincture	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
impatiens biflora tincture	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
infusion of rose petals	ophthalmic	astringent	III	III	310.545(a)(21)(iii)	
inositol	weight control			II	310.545(a)(20)	
iodides (calcium iodide anhydrous, hydroiodic acid syrup, iodized lime, potassium iodide)	cough/cold	expectorant		II	310.545(a)(6)(iii)	
iodine	corn/callus remover		II	IISE		[55 FR 33261]
iodine	digestive aid				310.545(a)(8)(ii)	
iodine	oral health care			IIISE		
iodine	wart remover		II	IISE		[55 FR 33254]
iodine	weight control			II	310.545(a)(20)	
iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IIISE		
iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IIISE		
iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IIISE		
iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IIISE		
iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IIISE		
iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IIISE		
iodine tincture	antimicrobial			I		
iodine tincture	antimicrobial			I		
iodine tincture	antimicrobial			IIIS		
iodine tincture	antimicrobial			IIIS		
iodine tincture	antimicrobial			IIISE		
iodine tincture	antimicrobial			IIS		
iodine tincture	antimicrobial			IISE		
iodine tincture	antimicrobial			IISE		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
iodine topical solution	antimicrobial			I		
iodoantipyrine (idopyrine)	internal analgesic		II	II	310.545(a)(23)(i)	
ipecac	cough/cold	expectorant			310.545(a)(6)(iii)	
ipecac fluidextract	cough/cold	expectorant	II		310.545(a)(6)(iii)	
ipecac fluidextract	poison treatment		II		310.545(a)(16)	
ipecac syrup	cough/cold	expectorant	III		310.545(a)(6)(iii)	
ipecac syrup	digestive aid		III E			[58 FR 54454]
ipecac syrup	emetic		I			
ipecac syrup	poison treatment		I			
ipecac tincture	poison treatment		II		310.545(a)(16)	
ipomea	laxative	stimulant laxative	II		310.545(a)(12)(iv)(A)	
iron ox bile	digestive aid				310.545(a)(8)(ii)	
iron oxide	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
iron oxide	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
isobornyl thiocycanoacetate	pediculicide		II	II	310.545(a)(25)(i)	
isoleucine	weight control			II	310.545(a)(20)	
isopropyl alcohol	alcohols (topical)		I	I		
isopropyl alcohol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
isopropyl alcohol	mercury			I		
isopropyl alcohol	otic				344.12	
isopropyl alcohol	otic				310.545(a)(15)(ii)	
isopropyl alcohol	skin protectant	astringent			310.545(a)(18)(ii)	
isopropyl alcohol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
isopropyl palmitate	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
isopropyl palmitate	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
isopropyl palmitate	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
jalap	laxative	stimulant laxative	II		310.545(a)(12)(iv)(A)	
johnswort	digestive aid				310.545(a)(8)(ii)	
juniper oil (oil of juniper)	menstrual/diuretic		II	II	310.545(a)(24)(i)	
juniper tar	anorectal	analgesic, anesthetic, antipruritic	III(e,i)	I(e)	346.16(b)	
juniper tar	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
juniper tar	digestive aid				310.545(a)(8)(ii)	

I - GRASE; II - Not GRASE; III - Insufficient Data

S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
juniper tar	external analgesic		I	I		
juniper, potassium extract	weight control			II	310.545(a)(20)	
kaolin	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(5)	
kaolin	antidiarrheal		III	III E	335.10(b)	
kaolin	skin protectant		I	I	347.10(j)	
kaolin	skin protectant		I	I		
kaolin, colloidal	digestive aid				310.545(a)(8)(ii)	
karaya gum	laxative			I		
karaya gum	weight control			III	310.545(a)(20)	
kelp	weight control			III	310.545(a)(20)	
knotgrass	digestive aid				310.545(a)(8)(ii)	
lactic acid	digestive aid				310.545(a)(8)(ii)	
lactic acid	wart remover		III	III E		[55 FR 33254]
Lactobacillus acidophilis	antidiarrheal		III	III	310.545(a)(3)(i)	
Lactobacillus bulgaricus	antidiarrheal		III	III	310.545(a)(3)(i)	
lactose	digestive aid				310.545(a)(8)(ii)	
lactose	weight control			II	310.545(a)(20)	
lanolin	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(6)	
lanolin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
lanolin	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
lanolin	skin protectant				347.10(k)	
lanolin	skin protectant			I		
lanolin (in combination)	ophthalmic	emollient	I	I	349.14(a)(2)	
lanolin alcohols	anorectal	protectant	I(e,i)	III(e,i)	310.545(a)(26)(viii)	
lanolin nonionic derivatives	ophthalmic		I	I	349.14	
lanolin, anhydrous (in combination)	ophthalmic	emollient	I	I	349.14(a)(1)	
lappa extract	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
laureth 10S	vaginal contraceptive			III E	310.545(a)(28)(i)	
lauryl isoquinolinium chloride	dandruff/seborrheic					
lavender compound, tincture of	dermatitis/psoriasis		III	III	310.545(a)(7)	
lawsone w/ dihydroxyacetone	digestive aid				310.545(a)(8)(ii)	
lawsone w/ dihydroxyacetone	sunscreen		I	I	310.545(a)(29)	
lead acetate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
lead acetate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
lecithin	weight control			II	310.545(a)(20)	
leptandra extract	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
leucine	weight control			II	310.545(a)(20)	
levmetamfetamine	cough/cold	nasal decongestant		I	341.20(b)(1)	inhalant
levmetamfetamine	cough/cold	nasal decongestant		I	341.20(b)(1)	topical
lidocaine	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(f)	
lidocaine	external analgesic	male genital desensitizer		I	348.10(a)(2)	
lidocaine	external analgesic		I	I		
lidocaine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
lidocaine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
lidocaine hydrochloride	external analgesic		I	I		
lidocaine hydrochloride	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
linden	digestive aid				310.545(a)(8)(ii)	
lipase	digestive aid				310.545(a)(8)(ii)	
live yeast cell derivative	anorectal	other			310.545(a)(26)(vii)	
live yeast cell derivative	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
live yeast cell derivative	skin protectant	insect bites/stings w/ sales less than \$25,000	III	III	310.545(a)(18)(v)(B)	
live yeast cell derivative	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000	III	III	310.545(a)(18)(vi)(B)	
live yeast cell derivative	skin protectant	w/ sales less than \$25,000	III	III	310.545(a)(18)(i)(B)	
liver concentrate	weight control			II	310.545(a)(20)	
lysine	weight control			II	310.545(a)(20)	
lysine aspirin	internal analgesic				310.545(a)(23)(i)	
lysine hydrochloride	digestive aid				310.545(a)(8)(ii)	
lysine hydrochloride	weight control			II	310.545(a)(20)	
magaldrate	antacid			I	331.11(g)(2)	
magnesium	weight control			II	310.545(a)(20)	
magnesium aluminosilicate	antacid			I	331.11(g)(3)	
magnesium aluminosilicate	antacid			I	331.11(l)(1)	
magnesium aluminum silicate	acne				310.545(a)(1)	
magnesium carbonate	antacid			I	331.11(g)(4)	
magnesium carbonate	overindulgence in alcohol/food	hangover reliever		I		
magnesium citrate (oral)	laxative	saline laxative		I		
magnesium glycinate	antacid			I	331.11(g)(5)	
magnesium hydroxide	antacid			I	331.11(g)(6)	
magnesium hydroxide	digestive aid	antacid	III	I	310.545(a)(8)(i)	

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
magnesium hydroxide	laxative	saline laxative		I		
magnesium oxide	antacid			I	331.11(g)(7)	
magnesium oxide	weight control			II	310.545(a)(20)	
magnesium salicylate	internal analgesic		I	I		
magnesium salicylate	menstrual/diuretic	analgesic	I			
magnesium sulfate	acne		II	II	310.545(a)(1)	
magnesium sulfate	laxative	saline laxative		I		
magnesium sulfate	menstrual/diuretic				310.545(a)(24)(i)	
magnesium trisilicate	antacid			I	331.11(g)(8)	
magnesium trisilicate	antacid			I	331.11(l)(2)	
magnesium trisilicate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
magnesium trisilicate	overindulgence in alcohol/food	hangover reliever		I		
malt	weight control			II	310.545(a)(20)	
malt soup extract	laxative			I		
maltodextrin	weight control			II	310.545(a)(20)	
manganese citrate	weight control			II	310.545(a)(20)	
mannitol	digestive aid				310.545(a)(8)(ii)	
mannitol	weight control			II	310.545(a)(20)	
m-cresol	antifungal				310.545(a)(22)(iv)	
meclizine hydrochloride	antiemetic			I	336.10(d)	
menfegol	vaginal contraceptive			I		
menthol	anorectal	analgesic, anesthetic, antipruritic		I(e)	346.16(c)	
menthol	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
menthol	antifungal		II	II	310.545(a)(22)(ii)	
menthol	cough/cold	antitussive		IIIIE	341.14(b)(2)	steam inhalation
menthol	cough/cold	antitussive	III	IIIIE	341.14(b)(2)	lozenge
menthol	cough/cold	antitussive	III	I	341.14(b)(2)	lozenge
menthol	cough/cold	antitussive	III	I	341.14(b)(2)	topical
menthol	cough/cold	nasal decongestant	III	IIIIE		[59 FR 43408]
menthol	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
menthol	external analgesic		I	I		
menthol	oral health care	anesthetic/analgesic	I	I		
menthol	relief of oral discomfort			IIS		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
menthol	skin protectant	astringent			310.545(a)(18)(ii)	
menthol	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
menthol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
menthol	wart remover		II	IISE		[55 FR 33254]
menthol (0.1 to 1.0%)	external analgesic		I	I		
menthol (exceeding 1 percent)	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
menthol (mouthwash)	cough/cold	antihistamine	III	III	310.545(a)(6)(ii)(A)	
menthol/peppermint oil	cough/cold	expectorant		III	310.545(a)(6)(iii)	
menthyl anthranilate (future meradimate)	sunscreen		I	I	352.10(h)	
meralein sodium	oral health care			IISE		
merbromin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
merbromin	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
merbromin (mercurochrome)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercufenol chloride (orthochloromercuriphenol, orthohydroxyphenylmercuric chloride)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercuric chloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
mercuric chloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
mercuric chloride (bichloride of mercury, mercury chloride)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercuric oxide, yellow	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercuric salicylate	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercuric sulfide, red	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercury	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercury oleate	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercury oleate	dandruff/seborrheic dermatitis/psoriasis		II	II	310.545(a)(7)	
mercury sulfide	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
mercury, ammoniated	skin bleach				310.545(a)(17)	
metaproterenol sulfate	cough/cold	antihistamine	I	I	310.545(a)(6)(iv)	
methapyrilene fumarate	cough/cold	antihistamine	I	II	310.545(a)(6)(i)	
methapyrilene fumarate	internal analgesic		III	II	310.545(a)(23)(i)	
methapyrilene fumarate	nighttime sleep aid	antihistamine	II	IIS		[54 FR 6826]
methapyrilene hydrochloride	cough/cold	antihistamine	I	II	310.545(a)(6)(i)	
methapyrilene hydrochloride	external analgesic	anesthetic	I	II	310.545(a)(10)(i)	
methapyrilene hydrochloride	external analgesic	fever blister/cold sore	I	II	310.545(a)(10)(v)	
methapyrilene hydrochloride	external analgesic	poison ivy/oak/sumac	I	II	310.545(a)(10)(vii)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
methapyrilene hydrochloride	menstrual/diuretic				310.545(a)(24)(i)	
methapyrilene hydrochloride	nighttime sleep aid	antihistamine	II	IIS		[54 FR 6826]
methenamine	menstrual/diuretic				310.545(a)(24)(i)	
methionine	weight control			II	310.545(a)(20)	
methoxyphenamine hydrochloride	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
methoxypolyoxyethyleneglycol 550 laurate	vaginal contraceptive			IIIIE	310.545(a)(28)(i)	
methyl nicotinate	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
methyl salicylate	corn/callus remover		II	IISE		[55 FR 33261]
methyl salicylate	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
methyl salicylate	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
methyl salicylate	oral health care	anesthetic/analgesic	III	III	310.545(a)(14)	
methyl salicylate	relief of oral discomfort			IISE		
methyl salicylate	relief of oral discomfort			IISE		
methyl saliscylate	skin protectant	astringent			310.545(a)(18)(ii)	
methylbenzethonium chloride	antimicrobial		I			
methylbenzethonium chloride	antimicrobial		I			
methylbenzethonium chloride	antimicrobial		IIIIE			
methylbenzethonium chloride	antimicrobial		IIISE			
methylbenzethonium chloride	antimicrobial		IIISE			
methylbenzethonium chloride	antimicrobial		IIISE			
methylbenzethonium chloride	antimicrobial		IIISE			
methylbenzethonium chloride	antimicrobial		IIISE			
methylbenzethonium chloride	antimicrobial		IIISE			
methylbenzethonium chloride	corn/callus remover		II	IISE		[55 FR 33261]
methylbenzethonium chloride	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
methylcellulose	laxative			I		
methylcellulose	ophthalmic	demulcents	I	I	349.12(a)(4)	
methylcellulose	weight control			III	310.545(a)(20)	
methylene blue	menstrual/diuretic				310.545(a)(24)(i)	
methylparaben	antifungal		III	III	310.545(a)(22)(ii)	
miconazole nitrate	antifungal		I	I	333.210(c)	
mild silver protein	ophthalmic	anti-infective	III	II	310.545(a)(21)(ii)	
milk solids, dried	antacid			I	331.11(h)	
mineral oil	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(7)	
mineral oil	laxative	lubricant		I		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
mineral oil	ophthalmic	emollient	I	I	349.14(b)(2)	
mineral oil	skin protectant			I	347.10(l)	
mineral oil, light	ophthalmic	emollient	I	I	349.14(b)(1)	
mono- and di-glycerides	weight control			II	310.545(a)(20)	
mullein	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
mustard oil (alltlishthiocyanate) (topical/inhalant)	cough/cold	nasal decongestant	II	II		
mycozyme	digestive aid				310.545(a)(8)(ii)	
myrrh	digestive aid				310.545(a)(8)(ii)	
myrrh	relief of oral discomfort			IISE		
myrrh tincture	oral health care	astringent	II	II	310.545(a)(14)	
naphazoline hydrochloride	cough/cold	nasal decongestant		I	341.20(b)(6)	
naphazoline hydrochloride	cough/cold	nasal decongestant		I	341.20(b)(6)	
naphazoline hydrochloride	ophthalmic	vasoconstrictor	I	I	349.18(b)	
naphazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(6)	
naphazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(6)	
natural estrogenic horomone	menstrual/diuretic				310.545(a)(24)(i)	
neomycin ointment (combination only)	first aid antibiotic			I	333.120	
neomycin sulfate	first aid antibiotic	ointment		I	333.110(d)	
neomycin sulfate cream	first aid antibiotic			I	333.110(e)	
nettle	digestive aid				310.545(a)(8)(ii)	
niacinamide	menstrual/diuretic				310.545(a)(24)(i)	
niacinamide	nighttime sleep aid			II		
niacinamide	weight control			II	310.545(a)(20)	
nickel-pectin	digestive aid				310.545(a)(8)(ii)	
nitromersol	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
nitromersol	oral health care			IISE		
nonoxynol 9	vaginal contraceptive			I		
nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial			IISE		
nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial			IISE		
nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial			IISE		
nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial			IISE		
nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial			IISE		
nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial			IISE		
noscapine	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
noscapine hydrochloride	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
nutmeg oil (oil of nutmeg)	menstrual/diuretic				310.545(a)(24)(i)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
nux vomica extract	digestive aid				310.545(a)(8)(ii)	
nystatin	antifungal		I	III	310.545(a)(22)(iv)	
obtundia surgical dressing	external analgesic			IISE		
obtundia surgical dressing	skin protectant			IISE		
octinoxate (octyl methoxycinnamate)	sunscreen		I	I	352.10(j)	
octisalate (octyl salicylate)	sunscreen		I	I	352.10(k)	
octocrylene	sunscreen		I	I	352.10(i)	
octoxynol 9	vaginal contraceptive			I	310.545(a)(28)(ii)	
oil of erigeron	menstrual/diuretic				310.545(a)(24)(i)	
Opium powder	antidiarrheal		I	III	310.545(a)(3)(i)	
Opium tincture	antidiarrheal		I	III	310.545(a)(3)(i)	
organic vegetables	weight control			II	310.545(a)(20)	
orthophosphoric acid	digestive aid				310.545(a)(8)(ii)	
ox bile	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
ox bile extract	digestive aid		II	II	310.545(a)(8)(i)	
oxybenzone (benzophenone-3)	sunscreen		I	I	352.10(l)	
oxymetazoline hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(7)	
oxymetazoline hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(7)	
oxymetazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(7)	
oxyquinoline	antifungal			III	310.545(a)(22)(ii)	
oxyquinoline	antimicrobial			IISE		
oxyquinoline	oral health care			IISE		
oxyquinoline sulfate	antifungal		III	III	310.545(a)(22)(ii)	
oxyquinoline sulfate	skin protectant	astringent			310.545(a)(18)(ii)	
oxytetracycline hydrochloride (combination only)	first aid antibiotic	ointment		I	333.120	
padimate a	sunscreen		I	IISE		
padimate a	sunscreen			IISE		
padimate o	sunscreen		I	I	352.10(m)	
pamabrom	menstrual/diuretic	antihistamine	I	I		
pancreatin	digestive aid	exocrine pancreatic insufficiency	II/III	I	310.545(a)(8)(i)	
pancreatin	weight control			II	310.545(a)(20)	
pancrelipase	digestive aid	exocrine pancreatic insufficiency	II/III	I	310.545(a)(8)(i)	
panthenol	corn/callus remover		II	IISE		[55 FR 33261]
panthenol	external analgesic	insect bite/sting			310.545(a)(10)(vi)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
panthenol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
panthenol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
pantothenic acid	weight control			II	310.545(a)(20)	
papain	digestive aid		II	II	310.545(a)(8)(i)	
papain	weight control			II	310.545(a)(20)	
papaya enzymes	weight control			II	310.545(a)(20)	
papaya, natural	digestive aid				310.545(a)(8)(ii)	
para-chloromercuriphenol	antimicrobial	diaper rash			310.545(a)(27)(ii)	
para-chloromercuriphenol	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
paraffin	ophthalmic	emollient	I	I	349.14(b)(3)	
paregoric	antidiarrheal		I	III	310.545(a)(3)(i)	
parethoxycaine hydrochloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
parethoxycaine hydrochloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
parsley	menstrual/diuretic				310.545(a)(24)(i)	
passion flower extract	nighttime sleep aid		II			
pectin	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
pectin	digestive aid				310.545(a)(8)(ii)	
pectin	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
pectin	oral health care	demulcents	I	I		
peppermint	digestive aid				310.545(a)(8)(ii)	
peppermint oil	cough/cold	antitussive		IIIIE		[52 FR 30054]
peppermint oil	cough/cold	nasal decongestant		IIIIE		[59 FR 43408]
peppermint oil	cough/cold	nasal decongestant		IIIIE		[59 FR 43408]
peppermint oil	cough/cold	nasal decongestant		IIIIE		[59 FR 43408]
peppermint oil	digestive aid		III	III	310.545(a)(8)(i)	
peppermint oil	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
peppermint oil	skin protectant	astringent			310.545(a)(18)(ii)	
peppermint oil	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
peppermint oil (mouthwash)	cough/cold	antihistamine			310.545(a)(6)(ii)(A)	
peppermint oil and sage oil	gingivitis/plaque			IIIIE		
peppermint spirit	digestive aid				310.545(a)(8)(ii)	
peppermint spirit	menstrual/diuretic				310.545(a)(24)(i)	
pepsin	digestive aid		II	II	310.545(a)(8)(i)	
pepsin	weight control			II	310.545(a)(20)	
pepsin, essence	menstrual/diuretic				310.545(a)(24)(i)	
Peruvian balsam	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
peruvian balsam	skin protectant			III E		
peruvian balsam oil	ophthalmic			I		
peruvian balsam oil	skin protectant			I	347.10(m)	
peruvian balsam oil	skin protectant			I		
peruvian balsam oil	skin protectant			I		
peruvian balsam oil	skin protectant			III E		
petrolatum	anorectal	protectant		I(e,i)	346.14(a)(8)	
petrolatum	ophthalmic	emollient	NA		349.14(b)(4)	
petrolatum	skin protectant			I	I	347.10(m)
petrolatum, white	ophthalmic	emollient		I	I	349.14(b)(6)
petrolatum, white	skin protectant			I	I	347.10(r)
phenacaine hydrochloride	anorectal	anesthetic	II(e,i)	II(e,i)	310.545(a)(26)(vi)	
phenacetin	digestive aid				310.545(a)(8)(ii)	
phenacetin	internal analgesic			II	II	310.545(a)(23)(i)
phenacetin	menstrual/diuretic				310.545(a)(24)(i)	
phenacetin	weight control				II	310.545(a)(20)
phenindamine tartrate	cough/cold	antihistamine		I	I	341.12(i)
phenindamine tartrate	menstrual/diuretic				310.545(a)(24)(i)	
pheniramine maleate	cough/cold	antihistamine			I	341.12(j)
pheniramine maleate	internal analgesic			III	III	310.545(a)(23)(i)
phenobarbital	cough/cold	miscellaneous			IIS	
phenol	acne			II	II	310.545(a)(1)
phenol	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
phenol	antifungal			II	III	310.545(a)(22)(ii)
phenol	antimicrobial				I	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				III E	
phenol	antimicrobial				IISE	
phenol	antimicrobial				IIS	
phenol	antimicrobial				IIS	
phenol	antimicrobial				IIS	

I - GRASE; II - Not GRASE; III - Insufficient Data

S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
phenol	antimicrobial			IIS		
phenol	antimicrobial			IIS		
phenol	antimicrobial			IIS		
phenol	antimicrobial			IIS		
phenol	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
phenol	external analgesic		I	I		
phenol	oral health care	anesthetic/analgesic	I	I		
phenol	relief of oral discomfort			I		
phenol	relief of oral discomfort			IIISE		
phenol	skin protectant	astringent			310.545(a)(18)(ii)	
phenol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
phenol sulfonate (Zn phenol sulfonate)	sunscreen					[64 FR 27682]
phenolate sodium	acne		II	II	310.545(a)(1)	
phenolate sodium	antifungal		II	III	310.545(a)(22)(ii)	
phenolate sodium	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
phenolate sodium	external analgesic		I	I		
phenolate sodium	oral health care	anesthetic/analgesic	I	I		
phenolate sodium	relief of oral discomfort			I		
phenolate sodium	relief of oral discomfort			IIISE		
phenolphthalein	laxative	stimulant laxative		I	310.545(a)(12)(iv)(B)	
phenoxyacetic acid	corn/callus remover		III	IIIIE		[55 FR 33261]
phenyl salicylate	corn/callus remover		II	II		
phenyl salicylate	acne		II	II	310.545(a)(1)	
phenyl salicylate	antiemetic			II		
phenyl salicylate	antifungal		III	III	310.545(a)(22)(ii)	
phenyl salicylate	menstrual/diuretic				310.545(a)(24)(i)	
phenyl salicylate (salo)	antidiarrheal		III	III	310.545(a)(3)(i)	
phenylalanine	weight control			II	310.545(a)(20)	
phenylephrine bitartrate (effervescent)	cough/cold	nasal decongestant			341.20(a)(4)	
phenylephrine hydrochloride	anorectal	vasoconstrictor		I	346.12(d)	
phenylephrine hydrochloride	cough/cold	nasal decongestant		I	341.20(a)(1)	oral
phenylephrine hydrochloride	ophthalmic	vasoconstrictor	III	III	310.545(a)(21)(v)	
phenylephrine hydrochloride	oral health care		III			
phenylephrine hydrochloride (0.08 to 0.2%)	ophthalmic	vasoconstrictor	I	I	349.18(c)	

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylephrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylephrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylephrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
phenylmercuric acetate	vaginal contraceptive			IIS	310.545(a)(28)(i)	
phenylmercuric nitrate	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
phenylmercuric nitrate	vaginal contraceptive			IIS	310.545(a)(28)(i)	
phenylpropanolamine bitartrate	cough/cold	nasal decongestant	I			
phenylpropanolamine hydrochloride	oral health care		III			
phenylpropanolamine hydrochloride	weight control			I/IIS		
phenylpropanolamine hydrochloride (oral)	cough/cold	nasal decongestant	I			
phenylpropanolamine hydrochloride (topical)	cough/cold	nasal decongestant	III			
phenylpropanolamine maleate	cough/cold	nasal decongestant	I			
phenyltoloxamine citrate	internal analgesic			IIIE		
phenyltoloxamine citrate	menstrual/diuretic	antihistamine	NA	III		
phenyltoloxamine dihydrogen citrate	cough/cold	antihistamine			310.545(a)(6)(i)	
phenyltoloxamine dihydrogen citrate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
phenyltoloxamine dihydrogen citrate	internal analgesic		III	III		
phenyltoloxamine dihydrogen citrate	nighttime sleep aid	antihistamine	III	IISE		[54 FR 6826]
phenyltoloxamine dihydrogen citrate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
phenyltoloxamine hydrochloride	cough/cold	antihistamine			310.545(a)(6)(i)	
phosphorated carbohydrate	antiemetic			III		
phosphoric acid	anticaries		II	NC	310.545(a)(2)(ii)	
phosphorus	weight control			II	310.545(a)(20)	
phytolacca	weight control			II	310.545(a)(20)	
picrotoxin	pediculicide		II	II	310.545(a)(25)(i)	
pine tar	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
pine tar preparations (extract white pine compound, pine tar, syrup of pine tar, compound white pine syrup, white pine)	cough/cold	expectorant		III	310.545(a)(6)(iii)	
pineapple enzymes	weight control			II	310.545(a)(20)	
piperazine citrate	anthelminthic		II	IIS		[51 FR 27758]

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
piperocaine hydrochloride	ophthalmic	anesthetic	II	II	310.545(a)(21)(i)	
piperonyl butoxide (combination)	pediculicide				310.545(a)(25)(ii)	
pipsissewa	menstrual/diuretic		II	II	310.545(a)(24)(i)	
piscidia erythrina	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
plantago ovata husks	laxative	bulk laxative		I		
plantago seed	laxative	bulk laxative		I		
plantago seed	weight control			III	310.545(a)(20)	
plantago seed husks [see psyllium seed husks]				IISE		
plantago seed, blond [see plantago seed]				IISE		
podophyllum resin (podophyllin)	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
poloxamer	laxative	stool softener		III	310.545(a)(12)(iii)	
poloxamer 188	antimicrobial			I		
poloxamer 407	relief of oral discomfort			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
poloxamer-iodine complex	antimicrobial			IIIE		
polycarbophil	antidiarrheal	w/ sales less than \$25,000	I	I	310.545(a)(3)(ii)	
polycarbophil	laxative			I		
polydimethylsiloxane and poloxamer	gingivitis/plaque			IIIE		
polyethylene glycol 300	ophthalmic	demulcents	I	I	349.12(d)(2)	
polyethylene glycol 400	ophthalmic	demulcents	I	I	349.12(d)(3)	
polyethylene glycol 6000	ophthalmic	demulcents	NA	III	310.545(a)(21)(iv)	
polymyxin b sulfate (combination only)	first aid antibiotic	ointment		I	333.120	
polyols, liquid	ophthalmic	demulcents			349.12(d)	
polyoxyethylene laurate	skin protectant	astringent			310.545(a)(18)(ii)	
polysorbate 80	ophthalmic	demulcents	I	I	349.12(d)(4)	
polyvinyl alcohol	ophthalmic	demulcents	I	I	349.12(e)	
potassium acetate	menstrual/diuretic				310.545(a)(24)(i)	
potassium bicarbonate	antacid				331.11(j)(1)	
potassium bicarbonate	digestive aid				310.545(a)(8)(ii)	
potassium bromide	nighttime sleep aid	bromide	II	IISE		[54 FR 6826]
potassium carbonate	antacid				331.11(j)(1)	

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S - Safety; E - Efficacy

Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
potassium carbonate	antidiarrheal	w/ sales less than \$25,000	II	II	310.545(a)(3)(ii)	
potassium carbonate	digestive aid				310.545(a)(8)(ii)	
potassium chlorate	oral health care			IISE		
potassium citrate	weight control			II	310.545(a)(20)	
potassium ferrocyanide	skin protectant	astringent			310.545(a)(18)(ii)	
potassium guaiacolsulfonate	cough/cold	expectorant		III	310.545(a)(6)(iii)	
potassium iodide	oral health care	expectorant	II			
potassium nitrate	menstrual/diuretic				310.545(a)(24)(i)	
potassium salicylate	internal analgesic			III		
povidone	ophthalmic	demulcents	I	I	349.12(f)	
povidone-iodine	acne		III	III	310.545(a)(1)	
povidone-iodine	antifungal		III	I	333.210(d)	
povidone-iodine	antimicrobial			I		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	antimicrobial			IISE		
povidone-iodine	dandruff/seborrheic					
povidone-iodine	dermatitis/psoriasis		III	III	310.545(a)(7)	
povidone-iodine	oral health care			IISE		
povidone-vinylacetate copolymers	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
povidone-vinylacetate copolymers	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
pramoxine hydrochloride	anorectal	local anesthetic	I(e),III(i)	I(e),III(i)	346.10(g)	
pramoxine hydrochloride	external analgesic		I	I		
pramoxine hydrochloride	skin protectant			n/a		
pramoxine hydrochloride (combination)	anorectal				310.545(a)(26)(xi)	
precipitated sulfur	anorectal	keratolytic	III(e),II(i)	III(e),II(i)	310.545(a)(26)(v)	
prolase	digestive aid				310.545(a)(8)(ii)	
propionic acid	antifungal		III	III	310.545(a)(22)(ii)	
propylene glycol	ophthalmic	demulcents	I	I	349.12(d)(5)	
propylene glycol	pediculicide		II	II	310.545(a)(25)(i)	
propylhexedrine	cough/cold	nasal decongestant	I	I	341.20(b)(9)	inhalant
propylparaben	antifungal		III	III	310.545(a)(22)(ii)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
protease	digestive aid				310.545(a)(8)(ii)	
protein hydrolysate	skin protectant	diaper rash			310.545(a)(18)(iii)	
prune concentrate dehydrate	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
prune powder	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
pseudoephedrine hydrochloride	cough/cold	bronchodilator	II	II	310.545(a)(6)(iv)	
pseudoephedrine hydrochloride	cough/cold	nasal decongestant	I	I	341.20(a)(2)	oral
pseudoephedrine sulfate	cough/cold	bronchodilator	II	II	310.545(a)(6)(iv)	
pseudoephedrine sulfate	cough/cold	nasal decongestant		I	341.20(a)(3)	oral
pseudoephedrine sulfate (oral)	cough/cold	nasal decongestant	I	I		
psyllium (hemicellulose) [see plantago seed]				IISE		
psyllium hydrophilic mucilloid	laxative			I		
psyllium seed	laxative			I		
psyllium seed (blond)	laxative			I		
psyllium seed husks	laxative			I		
psyllium (hemicellulose)	laxative	bulk laxative		I		
p-t-butyl-m-cresol	skin protectant	astringent			310.545(a)(18)(ii)	
pyrantel pamoate	anthelmintic		I	I	357.11	
pyrethrum extract (combination)	pediculicide	aresol		I	310.545(a)(25)(ii)	
pyrethrum extract (combination)	pediculicide	non-aresol	I	I	358.61	
pyridoxine hydrochloride	menstrual/diuretic	vitamine	III	IIIIE		
pyridoxine hydrochloride	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
pyridoxine hydrochloride (vitamin B6)	weight control			II	310.545(a)(20)	
pyrilamine maleate	acne		II	II	310.545(a)(1)	
pyrilamine maleate	cough/cold	antihistamine	I	I	341.12(k)	
pyrilamine maleate	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
pyrilamine maleate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
pyrilamine maleate	internal analgesic		III	III	310.545(a)(23)(i)	
pyrilamine maleate	menstrual/diuretic	antihistamine	I	IISE		
pyrilamine maleate	nighttime sleep aid	antihistamine	III	IISE		[54 FR 6826]
pyrilamine maleate	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
pyrilamine maleate	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
pyrilamine maleate	skin protectant			IISE		
pyrithione zinc	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(a)(2)	
pyrithione zinc	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(a)(3)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
pyrithione zinc	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(b)(2)	
pyrithione zinc	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(b)(3)	
quinine	antimalarial				310.547	
quinine	internal analgesic		II	II	310.545(a)(23)(i)	
racemethionine	skin protectant	diaper rash			310.545(a)(18)(iii)	
racephedrine hydrochloride	cough/cold	bronchodilator		I	341.16(f)	
racephedrine hydrochloride (oral/topical)	cough/cold	nasal decongestant	I	I	310.545(a)(6)(ii)(B)	
racepinephrine hydrochloride	cough/cold	bronchodilator	I	I	341.16(g)	inhalation
racepinephrine hydrochloride	cough/cold	bronchodilator	I	I	341.16(g)	rubber bulb
red petrolatum	sunscreen		I	I	310.545(a)(29)	
reosote	relief of oral discomfort			IIISE		
resorcinol	acne				333.310(a)	
resorcinol	anorectal	antiseptic	III(e),II(i)	III(e),II(i)	310.545(a)(26)(ii)	
resorcinol	anorectal	keratolytic	I(e),II(i)	I(e),II(i)	346.20(b)	
resorcinol	antifungal		II	II	310.545(a)(22)(ii)	
resorcinol	antimicrobial			IIISE		
resorcinol	dandruff/seborrheic dermatitis/psoriasis		II	II	310.545(a)(7)	
resorcinol	dandruff/seborrheic dermatitis/psoriasis		II	II		[56 FR 63567]
resorcinol	external analgesic		I	I		
resorcinol	skin protectant					
resorcinol (as single ingredient only)	acne		III	II	310.545(a)(1)	
resorcinol monoacetate	acne				333.310(b)	
resorcinol monoacetate (as single ingredient only)	acne		III	II	310.545(a)(1)	
rhubarb fluid extract	digestive aid				310.545(a)(8)(ii)	
rhubarb fluidextract	antidiarrheal	w/ sales less than \$25,000	II	II	310.545(a)(3)(ii)	
rhubarb, Chinese	laxative	stimulant laxative	III		310.545(a)(12)(iv)(A)	
riboflavin	menstrual/diuretic				310.545(a)(24)(i)	
riboflavin	weight control		II		310.545(a)(20)	
rice polishings	weight control		II		310.545(a)(20)	
sabadilla, alkaloids	pediculicide		II	II	310.545(a)(25)(i)	
saccharin	weight control			II	310.545(a)(20)	
sage oil	skin protectant	astringent			310.545(a)(18)(ii)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
salicyl alcohol	oral health care		I	I		
salicylamide	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
salicylamide	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
salicylamide	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
salicylamide	internal analgesic		III	IIISE		
salicylamide	menstrual/diuretic			IIISE		
salicylamide	nighttime sleep aid		II	IIIE		[54 FR 6826]
salicylic acid	acne		III	I	333.310(c)	
salicylic acid	acne		III	III	310.545(a)(1)	
salicylic acid	antifungal		III	III	310.545(a)(22)(ii)	
salicylic acid	corn/callus remover	collodoin-like vehicle	I	I	358.510(b)	
salicylic acid	corn/callus remover	plaster vehicle	I	I	358.510(a)	
salicylic acid	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(a)(4)	
salicylic acid	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(b)(4)	
salicylic acid	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(c)(2)	
salicylic acid	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
salicylic acid	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
salicylic acid	wart remover	collodoin-like vehicle	I	I	358.110(b)	
salicylic acid	wart remover	karaya gum, glycol plaster vehicle	I	I	358.110(c)	
salicylic acid	wart remover	plaster vehicle		IISE	358.110(a)	
salsalate	internal analgesic		III	III	310.545(a)(23)(i)	
sanguinaria extract	gingivitis/plaque			IIIE		
saw palmetto	menstrual/diuretic				310.545(a)(24)(i)	
scopolamine aminoxyde hydrobromide	nighttime sleep aid	scopolamine compound	II	IIS		[54 FR 6826]
scopolamine hydrobromide	antidiarrheal		II	II	310.545(a)(3)(i)	
scopolamine hydrobromide	nighttime sleep aid	scopolamine compound	II	IIS		[54 FR 6826]
sea minerals	weight control			II	310.545(a)(20)	
secondary amyliocresols	antifungal		III	III		
	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(a)(5)	
	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(b)(5)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
selenium sulfide, micronized	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(a)(6)	
senecio aureus	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
senna	digestive aid				310.545(a)(8)(ii)	
senna fluidextract	laxative			I/IIIS		
senna pod concentrate	laxative			I/IIIS		
senna syrup	laxative			I/IIIS		
sennosides a and b	laxative			I		
sesame seed	weight control			II	310.545(a)(20)	
shark liver oil	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
shark liver oil	antimicrobial			n/a		
shark liver oil	skin protectant	insect bites/stings w/ sales less than \$25,000	I	I	310.545(a)(18)(v)(B)	
shark liver oil	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000	I	I	310.545(a)(18)(vi)(B)	
shark liver oil	skin protectant	w/ sales less than \$25,000	I	I	310.545(a)(18)(i)(B)	
shark liver oil (combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(3)	
silver nitrate	skin protectant	astringent			310.545(a)(18)(ii)	
simethicone	antiflatulent			I	332.10	
simethicone	digestive aid	antiflatulent	III	IIIIE		[58 FR 54454]
simethicone	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
simethicone	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
sodium	weight control			II	310.545(a)(20)	
sodium 3, 4-dimethylphenyl-glyoxylate	sunscreen		II	IISE		[64 FR 27682]
sodium acetylsalicylate (in solution)	overindulgence in alcohol/food	hangover reliever		I		
sodium aluminum chlorohydroxy lactate	antiperspirant		IIISE	IIISE	310.545(a)(4)(i)	
sodium benzoate	menstrual/diuretic				310.545(a)(24)(i)	
sodium bicarbonate	antacid			I	331.11(k)(1)	
sodium bicarbonate	anticaries		II	II		
sodium bicarbonate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
sodium bicarbonate	external analgesic			n/a		
sodium bicarbonate	gingivitis/plaque			IIIIE		
sodium bicarbonate	oral health care	wound cleansing	I	I		
sodium bicarbonate	skin protectant		I	NA	347.10(o)	
sodium bicarbonate	weight control			III	310.545(a)(20)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
sodium borate	acne		II	II	310.545(a)(1)	
sodium borate	antifungal		III		310.545(a)(22)(ii)	
sodium borate	dandruff/seborrheic dermatitis/psoriasis				310.545(a)(7)	
sodium borate	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
sodium borate	oral health care			IIE		
sodium borate	skin protectant	astringent			310.545(a)(18)(ii)	
sodium borate	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
sodium borate monohydrate	oral health care			IIE		
sodium bromide	daytime sedative			IIE	310.519(a)	
sodium bromide	nighttime sleep aid	bromide	II	IIE		[54 FR 6826]
sodium caprylate	antifungal		III	III	310.545(a)(22)(ii)	
sodium caprylate	oral health care			IIIIE		
sodium carbonate	antacid			I	331.11(k)(1)	
sodium carbonate	anticaries				310.545(a)(2)(i)	
sodium carboxymethylcellulose	antidiarrheal		III	III		
sodium carboxymethylcellulose	laxative	bulk laxative		I		
sodium caseinate	weight control			II	310.545(a)(20)	
sodium chloride	digestive aid				310.545(a)(8)(ii)	
sodium chloride	ophthalmic	hypertonic agent	I	I	349.16	
sodium chloride (salt)	weight control			II	310.545(a)(20)	
sodium citrate	cough/cold	expectorant		III	310.545(a)(6)(iii)	
sodium citrate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
sodium citrate	relief of oral discomfort			IIIIE		
sodium citrate in solution	overindulgence in alcohol/food	hangover reliever/overindulgence		I		
sodium diacetate	skin protectant	astringent			310.545(a)(18)(ii)	
sodium dichromate	oral health care			IIE		
sodium dihydrogen phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
sodium dihydrogen phosphate monohydrate	anticaries		II	NC	310.545(a)(2)(ii)	
sodium fluoride	relief of oral discomfort			IIIIE		
sodium fluoride	relief of oral discomfort			IIE		
sodium fluoride (aqueous)	anticaries		I/NC	I	355.10(a)(3)(iii)-(v)	
sodium fluoride (aqueous) (acidulated phosphate fluoride with .01% fluoride ion)	anticaries		NC	I		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
sodium fluoride (aqueous) (acidulated phosphate fluoride with .02% fluoride ion)	anticaries		I	I		
sodium fluoride gel or paste	anticaries	dentifrices	I	I	355.10(a)(1)	
sodium fluoride powder	anticaries	dentifrices	I	I	355.10(a)(2)	
sodium monofluorophosphate	anticaries				310.545(a)(2)(i)	
sodium monofluorophosphate (rinse)	anticaries		II	II		
sodium monofluorophosphate	relief of oral discomfort			IIIIE		
sodium monofluorophosphate (gel or paste)	anticaries	dentifrices	I	I	355.10(b)(1)	
sodium monofluorophosphate (gel or paste)	anticaries	dentifrices		I	355.10(b)(2)	
sodium nitrate	menstrual/diuretic				310.545(a)(24)(i)	
sodium oleate	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
sodium para-aminobenzoate	internal analgesic		II	II	310.545(a)(23)(i)	
sodium perborate	oral health care			IIISE		
sodium perborate monohydrate	oral health care	wound cleansing	II	I		
sodium phosphate	anticaries		II	NC	310.545(a)(2)(i)	
sodium phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
sodium phosphate, dibasic	laxative	saline laxative	I			
sodium phosphate, monobasic	laxative	saline laxative	I			
sodium potassium tartrate	antacid			I	331.11(j)(2)	
sodium potassium tartrate	antacid			I	331.11(k)(2)	
sodium propionate	antifungal		III	III	310.545(a)(22)(ii)	
sodium propionate	antimicrobial			IIISE		
sodium salicylate	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
sodium salicylate	digestive aid				310.545(a)(8)(ii)	
sodium salicylate	internal analgesic		I	I		
sodium salicylate	menstrual/diuretic	analgesic	I			
sodium salicylate	overindulgence in alcohol/food			I		
sodium salicylic acid phenolate	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
sodium sulfide (aqueous)	ingrown toenail	gel vehicle		I	538.31	
sodium thiosulfate	acne		II	II	310.545(a)(1)	
soopolamine hydrobromide	antiemetic			III		
sorbitol	digestive aid		II	II	310.545(a)(8)(i)	
sorbitol	laxative	hyperosmotic		I		
sorbitol	oral health care	demulcents		III	310.545(a)(14)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
soy meal	weight control			II	310.545(a)(20)	
soybean oil, hydrogenated (powder)	cholecystokinetic				357.210(b)	
soybean protein	weight control			II	310.545(a)(20)	
squill preparations (squill, squill extract)	cough/cold	expectorant		II	310.545(a)(6)(iii)	
stannous fluoride	anticaries	dentifrices	I	I	355.10(c)(1)(i)	
stannous fluoride	anticaries	dentifrices	I	I	355.10(c)(1)(ii)	
stannous fluoride	relief of oral discomfort			III(E)		
stannous fluoride (gel)	anticaries		I	I	355.10(c)(2)	
stannous fluoride (rinse)	anticaries		I	I	355.10(c)(3)	
stannous pyrophosphate and zinc citrate	gingivitis/plaque			III(E)		
stearyl alcohol	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
stearyl alcohol	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
stearyl alcohol	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
stem bromelain	digestive aid				310.545(a)(8)(ii)	
strawberry	digestive aid				310.545(a)(8)(ii)	
strontium chloride	relief of oral discomfort			III(E)		
strontium chloride	relief of oral discomfort			II(S,E)		
strychnine	digestive aid				310.545(a)(8)(ii)	
sublimed sulfur	anorectal	keratolytic	III(e),II(i)	III(e),II(i)	310.545(a)(26)(v)	
sucrose	menstrual/diuretic				310.545(a)(24)(i)	
sucrose	weight control			II	310.545(a)(20)	
sugars	oral health care	demulcents		III	310.545(a)(14)	
sulfacetamide sodium	ophthalmic	anti-infective	II	II		
sulferated oils of turpentine	menstrual/diuretic				310.545(a)(24)(i)	
sulfur	acne		I	I	333.310(d)	
sulfur	antifungal		III		310.545(a)(22)(ii)	
sulfur	dandruff/seborrheic dermatitis/psoriasis		I	I	358.710(a)(7)	
sulfur	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
sulfur	skin protectant	diaper rash	II	II	310.545(a)(18)(iii)	
sulfur	skin protectant	fever blister/cold sore	II	II	310.545(a)(18)(iv)	
sulfur	skin protectant		II	II	310.545(a)(18)(i)(A)	
sulfur (combination)	acne		I	I	333.310(e)	
sulfur, sublimed	pediculicide		II	II	310.545(a)(25)(i)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
sulisobenzone	sunscreen		I	I	352.10(o)	
talc	skin protectant	astringent			310.545(a)(18)(ii)	
talc	skin protectant			I		
tannic acid	anorectal	astringent	II(e,i)	II(e,i)	310.545(a)(26)(iii)	
tannic acid	antifungal		II		310.545(a)(22)(ii)	
tannic acid	digestive aid				310.545(a)(8)(ii)	
tannic acid	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
tannic acid	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
tannic acid	skin protectant	diaper rash	II	II	310.545(a)(18)(iii)	
tannic acid	skin protectant	fever blister/cold sore	II	II	310.545(a)(18)(iv)	
tannic acid	skin protectant	poison ivy/oak/sumac	II	II	310.545(a)(18)(vi)(A)	
tannic acid	skin protectant		II	II	310.545(a)(18)(i)(A)	
tannic acid glycerite	skin protectant	astringent			310.545(a)(18)(ii)	
taraxacum officinale	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
tartaric acid	laxative	saline laxative			310.545(a)(12)(ii)	
tartrate (acid or salt)	antacid			I	331.11(m)	
terpin hydrate prearations (terpin hydrate, terpin hydrate elixer)	cough/cold	expectorant		III	310.545(a)(6)(iii)	
tetracaine	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(h)	
tetracaine	external analgesic	anesthetic	I	I		
tetracaine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
tetracaine hydrochloride	acne		II	II	310.545(a)(1)	
tetracaine hydrochloride	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(i)	
tetracaine hydrochloride	external analgesic		I	I		
tetracaine hydrochloride	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
tetracycline hydrochloride	first aid antibiotic	ointment		I	333.110(f)	
tetrahydrozoline hydrochloride	ophthalmic	vasoconstrictor	I	I	349.18(d)	
thaimine hydrochloride (vitamin B1)	weight control			II	310.545(a)(20)	
thaimine mononitrate (vitamine B1 mononitrate)	weight control			II	310.545(a)(20)	
thenyldiamine hydrochloride	cough/cold	antihistamine	III	III	310.545(a)(6)(i)	
thenyldiamine hydrochloride	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
thenyldiamine hydrochloride	cough/cold	nasal decongestant	III	III E		[59 FR 43408]
theobromine sodium salicylate	menstrual/diuretic	antihistamine	III	III	310.545(a)(24)(i)	
theophylline	menstrual/diuretic	antihistamine	III	III	310.545(a)(24)(i)	
theophylline (in combination)	cough/cold	bronchodilator			310.545(a)(6)(iv)(B)	
theophylline calcium salicylate	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
theophylline sodium glycinate	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
theophylline, anhydrous	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
thiamine hydrochloride	menstrual/diuretic				310.545(a)(24)(i)	
thiamine hydrochloride	nighttime sleep aid		II	II		
thimerosal	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
thiocyanacetate	pediculicide		II	II	310.545(a)(25)(i)	
thonzylamine hydrochloride	cough/cold	antihistamine	I	I	341.12(l)	
threonine	weight control			II	310.545(a)(20)	
thymol	acne		II	III	310.545(a)(1)	
thymol	antifungal		II		310.545(a)(22)(ii)	
thymol	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
thymol	dandruff/seborrheic dermatitis/psoriasis			III	310.545(a)(7)	
thymol	external analgesic	anesthetic	III	III	310.545(a)(10)(i)	
thymol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
thymol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
thymol	oral health care	anesthetic/analgesic	III	III	310.545(a)(14)	
thymol	relief of oral discomfort			IIIIE		
thymol	relief of oral discomfort			IIIIE		
thymol	skin protectant	astringent			310.545(a)(18)(ii)	
thymol (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
thymol (mouthwash)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
thymol iodide	oral health care			IIISE		
thymol iodide	relief of oral discomfort			IIIIE		
thymol iodide	relief of oral discomfort			IIIIE		
titanium dioxide	sunscreen		I	I	352.10(p)	
tolindate	antifungal		II	II	310.545(a)(22)(ii)	
tolnaftate	antifungal		I	I	333.210(e)	
tolu balsam	oral health care		III			
tolu preparations (tolu, tolu balsalm, tolu balsalm tincture)	cough/cold	expectorant		III	310.545(a)(6)(iii)	
topical starch	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(9)	
topical starch	external analgesic			IIISE		
topical starch	skin protectant	astringent			310.545(a)(18)(ii)	
topical starch	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
topical starch	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
topical starch	skin protectant				347.10(q)	
topical starch	skin protectant			I		
triacetin	antifungal		III	III	310.545(a)(22)(ii)	
tricalcium phosphate	antacid				331.11(i)(3)	
tricalcium phosphate	weight control			II	310.545(a)(20)	
triclocarban	antimicrobial			IIIE		
triclocarban	antimicrobial			IIIE		
triclocarban	antimicrobial			IIIE		
triclocarban	antimicrobial			IIIE		
triclocarban	antimicrobial			IIIE		
triclocarban	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
triclosan	antimicrobial			IIIE		
trillium	digestive aid				310.545(a)(8)(ii)	
tripelennamine hydrochloride	external analgesic	fever blister/cold sore	I		310.545(a)(10)(v)	
tripelennamine hydrochloride	external analgesic		I			
triple dye	antimicrobial			IIIE		
triple dye	antimicrobial			IIIE		
triple dye	antimicrobial			IIIE		
triple dye	antimicrobial			IISE		
triple dye	antimicrobial			IISE		
triple dye	antimicrobial			IISE		
triple dye	antimicrobial			IISE		
triprolidine hydrochloride	cough/cold	antihistamine	I		341.12(m)	
triticum	menstrual/diuretic		II	II	310.545(a)(24)(i)	
trolamine	external analgesic			IISE		

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
trolamine	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
trolamine	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
trolamine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
trolamine salicylate	sunscreen		I	I	352.10(q)	
trolamine salicylate (triethanolamine salicylate)	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
trolamine salicylate (triethanolamine salicylate)	external analgesic	insect bite/sting	III	III	310.545(a)(10)(vi)	
trolamine salicylate (triethanolamine salicylate)	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
tryptophan	weight control			II	310.545(a)(20)	
turpentine oil	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
turpentine oil	external analgesic	insect bite/sting	I	I	310.545(a)(10)(vi)	
turpentine oil	external analgesic	poison ivy/oak/sumac	I	I	310.545(a)(10)(vii)	
turpentine oil	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
turpentine oil	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
turpentine oil (oral)	cough/cold	antitussive	III	IISE		
turpentine oil (rectified)	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
turpentine oil (spirits of turpentine)	cough/cold	expectorant			310.545(a)(6)(iii)	
turpentine oil (spirits of turpentine) (oral)	cough/cold	nasal decongestant	II	II	310.545(a)(6)(ii)(A)	
turpentine oil (spirits of turpentine) (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
turpentine oil (topical/inhalant)	cough/cold	antitussive	III	IIIE		[52 FR 30055]
turpentine, venice (venice turpentine)	menstrual/diuretic				310.545(a)(24)(i)	
tyrosine	weight control			II	310.545(a)(20)	
undecylium chlorideiodine complex	antimicrobial			IIIE		
undecylium chlorideiodine complex	antimicrobial			IIISE		
undecylium chlorideiodine complex	antimicrobial			IIISE		
undecylium chlorideiodine complex	antimicrobial			IIISE		
undecylium chlorideiodine complex	antimicrobial			IIISE		
undecylium chlorideiodine complex	antimicrobial			IIISE		
undecylium chlorideiodine complex	antimicrobial			IIISE		
undecylium chlorideiodine complex	antimicrobial			IISE		
undecylenic acid	antifungal		I	I	333.210(f)	
undecylenic acid	dandruff/seborrheic dermatitis/psoriasis		III	III	310.545(a)(7)	
urea	menstrual/diuretic				310.545(a)(24)(i)	
uva ursi, extract of	menstrual/diuretic		II	II		
uva ursi, potassium extract	weight control			II	310.545(a)(20)	
valine	weight control			II	310.545(a)(20)	
vegetable (green)	weight control			II	310.545(a)(20)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
vitamin A	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
vitamin A	corn/callus remover		II	IISE		[55 FR 33261]
vitamin A	skin protectant			IISE		
vitamin A	weight control			II	310.545(a)(20)	
vitamin A acetate	weight control			II	310.545(a)(20)	
vitamin A palmitate	weight control			II	310.545(a)(20)	
vitamin E	acne		II	II	310.545(a)(1)	
vitamin E	nighttime sleep aid			II		
vitamin E	stimulant			IIIE		[39 FR 6104]
vitamin E	weight control			II	310.545(a)(20)	
vitromersol	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
water and additives	ophthalmic		I			
water, purified	ophthalmic				349.2	
wax, white	ophthalmic	emollient	I	I	349.14(b)(7)	
wax, yellow	ophthalmic	emollient	NA	I	349.14(b)(8)	
wheat germ	weight control			II	310.545(a)(20)	
white ointment	ophthalmic	emollient	I	I	349.14(b)(5)	
white petrolatum	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(10)	
witch hazel	skin protectant	astringent		I	347.12(c)	
witch hazel (haramelis water)	anorectal	astringent	I(e)	I(e)	346.18(b)	
woodruff	digestive aid				310.545(a)(8)(ii)	
xanthan gum	weight control			III	310.545(a)(20)	
xylometazoline hydrochloride (aqueous)	cough/cold	nasal decongestant	I		341.20(b)(10)	
xylometazoline hydrochloride (aqueous)	cough/cold	nasal decongestant	I		341.20(b)(10)	
xylometazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(10)	
xylometazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(10)	
yeast	weight control			II	310.545(a)(20)	
yeast cell derivative, live	skin protectant			IIIE		
yeast cell derivative, live	skin protectant			IIISE		
yellow mercuric oxide	ophthalmic	anti-infective	III	II	310.545(a)(21)(ii)	
zinc acetate	external analgesic			IISE		
zinc acetate	skin protectant	diaper rash	I	I	310.545(a)(18)(iii)	
zinc acetate	skin protectant		I	I	347.10(s)	
zinc acetate (wound healing claims only)	skin protectant		I	I	310.545(a)(18)(i)(A)	
zinc caprylate	antifungal		III	III	310.545(a)(22)(ii)	
zinc carbonate	skin protectant	diaper rash	I	I	310.545(a)(18)(iii)	

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Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
zinc carbonate	skin protectant		I	I	347.10(t)	
zinc chloride	corn/callus remover		III	III E		[55 FR 33261]
zinc chloride	oral health care		I	I		
zinc chloride	skin protectant	astringent			310.545(a)(18)(ii)	
zinc citrate	gingivitis/plaque			III E		
zinc oxide	acne		II	II	310.545(a)(1)	
zinc oxide	anorectal	astringent	I(e,i)	I(e,i)	346.18(c)	
zinc oxide	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
zinc oxide	external analgesic			II SE		
zinc oxide	n/a			I	352.10(r)	
zinc oxide	skin protectant	astringent	I	I	310.545(a)(18)(ii)	
zinc oxide	skin protectant		I	I	347.10(u)	
zinc oxide	sunscreen			III	352.10(r)	
zinc oxide (combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(4)	
zinc phenolsulfonate	antidiarrheal		III	III	310.545(a)(3)(i)	
zinc phenolsulfonate	antiemetic			II		
zinc phenolsulfonate	skin protectant	astringent			310.545(a)(18)(ii)	
zinc propionate	antifungal		III	III	310.545(a)(22)(ii)	
zinc stearate	acne		II	II	310.545(a)(1)	
zinc stearate	skin protectant	astringent			310.545(a)(18)(ii)	
zinc sulfate	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
zinc sulfate	ophthalmic	astringent	I	I	349.1	
zinc sulfate	poison treatment			II	310.545(a)(16)	
zinc sulfate	skin protectant	astringent			310.545(a)(18)(ii)	
zinc sulfate	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
zinc sulfide	acne		II	II	310.545(a)(1)	
zinc undecylenate	antifungal		I	I	333.210(f)	
zirconium oxide	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
zirconium oxide	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
zirconium oxide	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
zirconium oxide	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
zyloxin	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
zyloxin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
zyloxin	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	aphrodisiac				310.528	

I - GRASE; II - Not GRASE; III - Insufficient Data

S - Safety; E - Efficacy