

OTC Ingredient List
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Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
paba [see aminobenzoic acid]						
=====	=====		=====	=====	=====	=====
padimate a						
miscellaneous external	external analgesic		fever blister (topical)	defer	defer	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	defer	pending
topical analgesic	sunscreen		sunscreen (≥ 5%)	I	IISE	pending
topical analgesic	sunscreen		sunscreen (< 5%)	I	IIISE	pending
padimate o						
topical analgesic	sunscreen		sunscreen	I	I	352.10(m)
pamabrom						
miscellaneous internal	menstrual/diuretic		diuretic	I	I	pending
pancreatin						
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	exocrine pancreatic insufficiency		exocrine pancreatic insufficiency	I	I	310.543(a)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
pancrelipase						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)

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miscellaneous internal	exocrine pancreatic insufficiency	exocrine pancreatic insufficiency	I	I	310.543(a)
panthenol					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic	insect bite/sting	n/a	IIIE	310.545(a)(10)(vi)
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIIE	310.545(a)(10)(vii)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
pantothenic acid					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
papain					
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIIE	withdraw	n/a
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(8)(i)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
papaya enzymes					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

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papaya, natural					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
para-chloromercuriphenol					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	IISE	310.545(a)(27)(ii)
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	mercury	first aid antiseptic	IISE	n/a	310.545(a)(27)(i)
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
miscellaneous external	skin protectant	diaper rash	defer	n/a	310.545(a)(27)(ii)
para-t-butyl-m-cresol					
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
para-tertiary-butyl-meta-cresol [see para-t-butyl-m-cresol]					
=====	=====	=====	=====	=====	=====
paraffin					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
ophthalmic	ophthalmic	emollient	I	I	349.14(b)(3)

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para-t-butyl-m-cresol					
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
para-tertiary-butyl-meta-cresol [see p-t-butyl-m-cresol]					
=====	=====	=====	=====	=====	=====
paregoric					
laxative	antidiarrheal	antidiarrheal	I	IIISE	310.545(a)(3)(i)
parethoxycaine hydrochloride					
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
parsley					
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
passion flower extract					
sedative	nighttime sleep aid	sleep aid	IIE	IIE	[54 FR 6826]
pectin					
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(ii)
miscellaneous external	external analgesic	fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	skin protectant	fever blister (topical)	defer	defer	pending
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

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oral cavity	oral health care	demulcent	I	I	pending	
pega palo						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
peppermint						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
peppermint oil						
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	IIIE	IIIE	[52 FR 30054]	
cough/cold	cough/cold (expectorant)	expectorant (lozenge)	IIIE	IIIE	310.545(a)(6)(iii)	
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	IIIE	IIIE	310.545(a)(6)(iii)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (inhalant room spray)	IIIE	IIIE	[59 FR 43408]	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIE	[59 FR 43408]	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIE	IIIE	310.545(a)(6)(ii)(A)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	IIIE	[59 FR 43408]	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	

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miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)
peppermint oil and sage oil					
=====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIIE	pending
peppermint spirit					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
pepsin					
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	stomach acidifier	stomach acidifier	IIE	IIE	310.540(a)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
pepsin, essence					
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
peruvian balsam					
hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIIE	IIIE	310.545(a)(26)(x)

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hemorrhoidal	anorectal	wound healing agent (external)	IIIE	IIIE	310.545(a)(26)(x)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	IIIE	pending	
peruvian balsam oil						
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	IIIE	pending	
petrolatum						
hemorrhoidal	anorectal	protectant (external)	n/a	I	346.14(8)	
hemorrhoidal	anorectal	protectant (intrarectal)	n/a	I	346.14(8)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	

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miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending	
ophthalmic	ophthalmic	emollient	n/a	I	349.14(b)(4)	
topical analgesic	skin protectant	skin protectant	I	I	347.10(m)	
petrolatum, red						
topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)	
petrolatum, white						
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(10)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(10)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending	
ophthalmic	ophthalmic	emollient	I	I	349.14(b)(6)	
topical analgesic	skin protectant	skin protectant	I	I	347.10(r)	
phenacaine hydrochloride						
hemorrhoidal	anorectal	anesthetic (external)	IIS	IIS	310.545(a)(26)(vi)	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIS	IIS	310.545(a)(26)(vi)	

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phenacetin						
internal analgesic	internal analgesic	analgesic	IIS	IIS	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antipyretic	IIS	IIS	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	310.545(a)(23)(i)	
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
miscellaneous internal	menstrual/diuretic	analgesic	IIS	IISE	310.545(a)(24)(i)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
phenindamine tartrate						
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(i)	
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)	
pheniramine maleate						
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(j)	
internal analgesic	internal analgesic	analgesic adjuvant	IIIE	IIIE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antipyretic adjuvant	IIIE	IIIE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic adjuvant	IIIE	n/a	310.545(a)(23)(i)	
phenobarbital						
cough/cold	cough/cold (miscellaneous)	corrective	IIIE	IIS	pending	
phenol						
antimicrobial I	antimicrobial	first aid antiseptic	n/a	n/a	pending	

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antimicrobial I	antimicrobial	surgical hand scrub	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIS	IIS	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIS	IIS	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIS	IIS	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	skin wound protectant	n/a	IIISE	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIS	IIS	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIS	IIS	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIS	IIS	pending	
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIS	IIS	pending	
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IISE	IIISE	310.545(a)(22)(ii)	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	

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dental	relief of oral discomfort	toothache relief	IIISE	IIISE	pending
dental	relief of oral discomfort	oral mucosal analgesic	I	I	pending
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)
miscellaneous external	antimicrobial	diaper rash	defer	IISE	310.545(a)(27)(ii)
miscellaneous external	boil treatment	boil treatment	IISE	IIISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIE	310.545(a)(7)
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
miscellaneous external	external analgesic	insect bite/sting	IISE	I	pending
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	diaper rash	defer	n/a	310.545(a)(27)(ii)
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending
oral cavity	oral health care	analgesic/anesthetic	I	I	pending

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topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
phenol sulfonate						
laxative	antiemetic	antiemetic	IIIE	IIE	[52 FR 15891]	
topical analgesic	sunscreen	sunscreen	n/a	n/a	[64 FR 27682]	
phenolate sodium						
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IISE	IIISE	310.545(a)(22)(ii)	
contraceptive/vaginal	vaginal	minor irritations	IISE	withdraw	n/a	
dental	relief of oral discomfort	toothache relief	IIISE	IIISE	pending	
dental	relief of oral discomfort	oral mucosal analgesic	I	I	pending	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending	
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
phenolathalain, yellow						
laxative	laxative	stimulant laxative	I	I/IIS	310.545(a)(12)(iv)(B)	

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phenolphthalein, white						
laxative		laxative	stimulant laxative	I	I/IS	310.545(a)(12)(iv)(B)
phenolphthalein, white [see phenolphthalein]						
=====		=====	=====	=====	=====	=====
phenoxyacetic acid						
miscellaneous external		corn/callus remover	corn/callus remover	IIIE	IIIE	[55 FR 33261]
phenyl salicylate						
antimicrobial II		acne	acne	IIE	IIE	310.545(a)(1)
antimicrobial II		antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
laxative		antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(i)
laxative		antiemetic	antiemetic	IIIE	IIE	[52 FR 15891]
miscellaneous external		corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
miscellaneous internal		menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
phenylalanine						
miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
phenylbenzimidazole sulfonic acid [see ensulizole]						
=====		=====	=====	=====	=====	=====
phenylephrine bitartrate (in an effervescent dosage form)						
n/a		=====	nasal decongestant (oral)	n/a	n/a	341.20(a)(4)

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phenylephrine hydrochloride						
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (oral)	I	I	341.20(a)(1)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical/inhalant))	I	I	341.20(b)(8)
hemorrhoidal	anorectal		vasoconstrictor (intrarectal)	I	I	346.10(d)
hemorrhoidal	anorectal		vasoconstrictor (external)	I	I	346.10(d)
oral cavity	oral health care		oral mucosal decongestant	IIIE	IIIE	pending
phenylephrine hydrochloride (0.08 to 0.2%)						
ophthalmic	ophthalmic		vasoconstrictor	I	I	349.18(c)
phenylephrine hydrochloride (less than 0.08%)						
ophthalmic	ophthalmic		vasoconstrictor	IIIE	IIIE	310.545(a)(21)(v)
phenylmercuric acetate						
contraceptive/vaginal	contraceptive (vaginal)		contraceptive	IIS	withdraw	310.545(a)(28)
phenylmercuric nitrate						
contraceptive/vaginal	contraceptive (vaginal)		contraceptive	IIS	withdraw	310.545(a)(28)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	mercury		first aid antiseptic	n/a	IIIE	310.545(a)(27)(i)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending

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		miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
phenylpropanolamine bitartrate							
		cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	II	pending
phenylpropanolamine hydrochloride							
		cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	II	pending
		cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	II	pending
		miscellaneous internal	weight control	anorectic	I	I/IIS	pending
		oral cavity	oral health care	oral mucosal decongestant	IIIE	IIIE	pending
phenylpropanolamine maleate							
		cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	II	pending
phenyltoloxamine citrate							
		internal analgesic	internal analgesic	antipyretic adjuvant	IIIE	IIIE	pending
		internal analgesic	internal analgesic	antirheumatic adjuvant	IIIE	n/a	n/a
phenyltoloxamine citrate [see phenyltoloxamine dihydrogen citrate]							
		=====	=====	=====	=====	=====	=====
phenyltoloxamine dihydrogen citrate							
		cough/cold	cough/cold (antihistamine)	antihistamine	IIIE	IIIE	310.545(a)(6)(i)(B)
		miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)

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sedative	nighttime sleep aid	sleep aid	IIISE	IIISE	[54 FR 6826]
sedative	nighttime sleep aid	sleep aid	IIISE	IIISE	[54 FR 6826]
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
phosphate, disodium [see sodium phosphate, dibasic]					
=====	=====	=====	=====	=====	=====
phosphate, monosodium [see sodium phosphate, monobasic]					
=====	=====	=====	=====	=====	=====
phosphorated carbohydrate					
laxative	antiemetic	antiemetic	IIIE	IIIE	52 FR 15891]
phosphoric acid					
dental	anticaries	anticavity agent	IIE	n/a	310.545(a)(2)(ii)
phosphorus					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
phytolacca					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
picrotoxin					
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
pine tar					
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)

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miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIE	310.545(a)(7)
pine tar syrup					
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
pineapple enzymes					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
piperazine citrate					
miscellaneous internal	anthelmintic	anthelmintic	IIS	IIS	[51 FR 27758]
piperocaine hydrochloride					
ophthalmic	ophthalmic	analgesic/anesthetic	IIS	IIS	310.545(a)(21)(i)
pipsissewa					
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
piroctone olamine					
n/a	TEA	dandruff	n/a		
piscidia erythrina					
miscellaneous internal	menstrual/diuretic	dysmenorrhea	IIE	IIE	310.545(a)(24)(i)
plantago ovata husks [see psyllium husk]					
=====	=====	=====	=====	=====	=====
plantago seed					

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
laxative	laxative	bulk laxative	I	IISE	pending	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
plantago seed husks [see psyllium seed husks]						
=====	=====	=====	=====	IISE	pending	
plantago seed, blond [see plantago seed]						
=====	=====	=====	=====	IISE	pending	
podophyllum resin						
laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)	
poloxalkol [see polxamer 188]						
=====	=====	=====	=====	=====	=====	
poloxamer 188						
antimicrobial I	antimicrobial	skin wound cleanser	n/a	I	pending	
laxative	laxative	stool softener	IIIE	IIIE	310.545(a)(12)(iii)	
poloxamer 407						
dental	relief of oral discomfort	tooth desensitizer (in combination only)	IIIE	IIIE	pending	
poloxamer-iodine complex						
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	

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Ingredient					
Review Panel	Report	Drug Category	ANPR	PR	FR
antimicrobial I	antimicrobial	skin wound cleanser	III SE	III SE	pending
antimicrobial I	antimicrobial	skin antiseptic	III SE	III SE	pending
antimicrobial I	antimicrobial	skin protectant	III SE	III SE	pending
antimicrobial I	antimicrobial	health care personnel handwash	III SE	III SE	pending
polycarbophil					
laxative	antidiarrheal	antidiarrheal	I	I	310.545(a)(3)(ii)
laxative	laxative	bulk laxative	I	I	pending
polycarbophil, calcium					
laxative	antidiarrheal	antidiarrheal	n/a	I	310.545(a)(3)(ii)
laxative	laxative	bulk laxative	n/a	n/a	n/a
polydimethylsiloxane and poloxamer					
====	gingivitis/plaque	antiplaque/gingivitis	n/a	III E	pending
polyethylene glycol 300					
ophthalmic	ophthalmic	demulcent	I	I	349.12(d)(2)
polyethylene glycol 400					
ophthalmic	ophthalmic	demulcent	I	I	349.12(d)(3)
polyethylene glycol 6000					
ophthalmic	ophthalmic	demulcent	n/a	III E	310.545(a)(21)(iv)
polymyxin b sulfate					

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Ingredient		Review Panel	Report	Drug Category	ANPR	PR	FR
	antimicrobial II		antibiotic	skin wound protectant	I	defer	n/a
	antimicrobial II		antibiotic	first aid antibiotic	IIIE	I	333.120 [combos]
	antimicrobial II		antibiotic	skin wound antibiotic	I	defer	n/a
polyoxyethylene laurate							
	miscellaneous external	external	analgesic	astringent	IISE	n/a	n/a
	miscellaneous external	skin	protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
polyoxyethylene monolaurate [see polyoxyethylene laurate]							
	=====		=====	=====	=====	=====	=====
polysorbate 20							
	miscellaneous external	hair	growth/loss	hair grower	n/a	IIIE	310.527(a)
polysorbate 60							
	miscellaneous external	hair	growth/loss	hair grower	n/a	IIIE	310.527(a)
polysorbate 80							
	ophthalmic		ophthalmic	demulcent	I	I	349.12(d)(4)
polyvinyl alcohol							
	ophthalmic		ophthalmic	demulcent	I	I	349.12(e)
polyvinylpyrrolidone [see povidone]							
	=====		=====	=====	=====	=====	=====

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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
potassium acetate						
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
potassium alum [see alum, potassium]						
	=====	=====	=====	=====	=====	=====
potassium aluminum sulfate [see alum, potassium]						
	=====	=====	=====	=====	=====	=====
potassium bicarbonate						
	antacid	antacid	antacid	n/a	n/a	331.11(j)(1)
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
potassium bromide						
	sedative	nighttime sleep aid	sleep aid	IISE	IISE	[54 FR 6826]
	sedative	daytime sedative	sedative	IIS	IISE	310.519(a)
potassium carbonate						
	antacid	antacid	antacid	n/a	n/a	331.11(j)(1)
	laxative	antidiarrheal	antidiarrheal	IIE	IIE	310.545(a)(3)(ii)
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
potassium chlorate						
	oral cavity	oral health care	antimicrobial	IISE	IISE	pending
potassium citrate						

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Ingredient						
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miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
potassium extract						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
potassium ferrocyanide						
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
potassium guaiacolsulfonate						
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)	
potassium iodide						
cough/cold	cough/cold (expectorant)	expectorant	IIS	IISE	310.545(a)(6)(iii)	
oral cavity	oral health care	expectorant	IIS	IIS	310.545(a)(6)(iii)	
potassium nitrate						
dental	relief of oral discomfort	tooth desensitizer	IIIE	I	pending	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
potassium sorbate						
contraceptive/vaginal	vaginal	minor irritations	I	withdraw	n/a	
povidone						
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)	

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIE	310.545(a)(18)(vi)(A)	
ophthalmic	ophthalmic	demulcent	I	I	349.12(f)	
povidone silver nitrate						
miscellaneous internal	smoking deterrent	smoking deterrent	n/a	n/a	310.544(d)	
povidone vinylacetate copolymers						
miscellaneous external	skin protectant	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(A)	
povidone-iodine						
antimicrobial I	antimicrobial	antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	surgical hand scrub	III SE	III SE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	III SE	pending	
antimicrobial I	antimicrobial	skin protectant	III SE	III SE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	III SE	III SE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	III SE	III SE	pending	
antimicrobial I	antimicrobial	skin antiseptic	III SE	III SE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	III SE	III SE	pending	
antimicrobial II	acne	acne	III E	III E	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	III E	I	333.210(d)	
contraceptive/vaginal	vaginal	minor irritations	I	withdraw	n/a	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	III E	III E	310.545(a)(7)	

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
povidone-iodine complex [see povidone-iodine]						
====	====	====	====	====	====	
pramoxine hydrochloride						
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
hemorrhoidal	anorectal	anesthetic (external)	I	I	346.10(g)	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
pregnenolone						
miscellaneous external	hormone	hormone	IISE	IIIE	310.530(a)	
pregnenolone acetate						
miscellaneous external	hormone	hormone	IISE	IIIE	310.530(a)	
progesterone						

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Ingredient		Review Panel	Report	Drug Category	ANPR	PR	FR
miscellaneous external hormone				hormone	IIE	IIE	310.530(a)
prolase							
miscellaneous internal digestive aid				digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
promethazine hydrochloride							
cough/cold		cough/cold (antihistamine)		antihistamine	I	IIIS	[57 FR 58373]
propionic acid							
antimicrobial II		antifungal		antifungal	IIIE	IIIE	310.545(a)(22)(ii)
propyl benzoate							
miscellaneous external skin protectant				fever blister (topical)	defer	n/a	n/a
propyl p-benzoate							
miscellaneous external external analgesic				fever blister (topical)	defer	n/a	n/a
propylene glycol							
miscellaneous external pediculicide				pediculicide	IISE	IISE	310.545(a)(25)(i)
ophthalmic		ophthalmic		demulcent	I	I	349.12(d)(5)
miscellaneous external hair growth/loss				hair grower	IISE	n/a	310.527(a)
propylhexidrine							
cough/cold		cough/cold (nasal decongestant)		nasal decongestant (topical/inhalant))	I	I	341.20(b)(9)
propylparaben							

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Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
protease					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
protein					
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
protein hydrolysate					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)
proteins [see protein]					
=====	=====	=====	=====	=====	=====
prune concentrate dehydrate					
laxative	laxative	stimulant laxative	IIIE	IIIE	310.545(a)(12)(iv)(A)
prune powder					
laxative	laxative	stimulant laxative	IIIE	IIIE	310.545(a)(12)(iv)(A)
pseudoephedine sulfate					
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	I	341.20(a)(3)

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Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
pseudoephedrine hydrochloride						
cough/cold	cough/cold (bronchodilator)		bronchodilator	IIE	IIE	310.545(a)(6)(iv)(A)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (oral)	I	I	341.20(a)(2)
pseudoephedrine sulfate						
cough/cold	cough/cold (bronchodilator)		bronchodilator	IIE	IIE	310.545(a)(6)(iv)(A)
psyllium (hemicellulose) [see plantago seed]						
=====	=====		=====	=====	IISE	pending
psyllium hydrophilic mucilloid						
laxative	laxative		bulk laxative	I	IISE	pending
psyllium seed						
laxative	laxative		bulk laxative	I	IISE	pending
psyllium seed (blond)						
laxative	laxative		bulk laxative	I	IISE	pending
psyllium seed husks						
laxative	laxative		bulk laxative	I	IISE	pending
pyrantel pamoate						
miscellaneous internal	antihelmintic		anthelmintic	I	I	357.110
pyrethins [see pyrethrum extract]						

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Ingredient		Drug Category	ANPR	PR	FR
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=====	=====	=====	=====	=====	=====
pyrethrum extract (aerosol) with piperonyl butoxide					
=====	pediculicide	pediculicide	n/a	n/a	310.545(a)(25)(ii)
pyrethrum extract (nonaerosol) with piperonyl butoxide					
miscellaneous external	pediculicide	pediculicide	I	I	358.610
pyridoxine hydrochloride					
miscellaneous external	external analgesic	fever blister (topical)	defer	DEF	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	IISE	310.545(a)(18)(iv)
miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	IIIE	IIIE	pending
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
pyrilamine maleate					
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(k)
internal analgesic	internal analgesic	analgesic adjuvant	IIIE	IIIE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antipyretic adjuvant	IIIE	IIIE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antirheumatic adjuvant	IIIE	n/a	310.545(a)(23)(i)
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)

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Ingredient						
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miscellaneous external	skin protectant	poison ivy/oak/sumac	n/a	IISE	pending	
miscellaneous internal	menstrual/diuretic	antihistamine	I	IIISE	pending	
oral cavity	oral health care	analgesic/anesthetic	IIE	IIE	310.545(a)(14)	
sedative	nighttime sleep aid	sleep aid	IIISE	IIISE	[54 FR 6826]	
sedative	daytime sedative	sedative	IIISE	IISE	310.519(a)	
pyrithione zinc						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	I	I	358.710(a)(2)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	I	I	358.710(a)(3)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	I	I	358.710(b)(3)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	I	I	358.710(b)(2)	
quinine						
internal analgesic	internal analgesic	analgesic	IIS	IIS	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antipyretic	IIS	IIS	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	310.545(a)(23)(i)	
quinine ascorbate						
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)	
quinine sulfate						
miscellaneous internal	leg muscle cramp	nocturnal leg muscle cramps	IIISE	IIISE	310.546	
racemethionine						

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Review Panel	Report				
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)
racedrine hydrochloride					
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	I	341.16(f)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	310.545(a)(6)(ii)(B)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIE	IIIE	310.545(a)(6)(ii)(B)
racedrine hydrochloride					
cough/cold	cough/cold (bronchodilator)	bronchodilator	n/a	n/a	341.16(g)
red petrolatum [see petrolatum, red]					
=====	=====	=====	=====	=====	=====
released carbon dioxide [see carbon dioxide, released]					
=====	=====	=====	=====	=====	=====
reosote					
=====	skin protectant	poison ivy/oak/sumac	n/a	IIISE	310.545(a)(18)(vi)(A)
dental	relief of oral discomfort	toothache relief	IIISE	IIISE	pending
resorcinol					
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending

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Ingredient						
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====	n/a	dandruff/seborrheic dermatitis/psoriasis	n/a	n/a	310.545(a)(7)	
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IISE	IISE	310.545(a)(22)(ii)	
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	keratolytic (external)	I	I	346.20(a)	
hemorrhoidal	anorectal	keratolytic (intrarectal)	IISE	IISE	346.20(a)	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	IISE	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	[56 FR 63567]	
miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
resorcinol monoacetate						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
rhubarb fluidextract						
laxative	antidiarrheal	antidiarrheal	IISE	IISE	310.545(a)(3)(ii)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	

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rhubarb, chinese						
	laxative	laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)
riboflavin						
	miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
rice polishings						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
rose petals, infusion of						
	ophthalmic	ophthalmic	astringent	IIIE	IIIE	310.545(a)(21)(iii)
rosin						
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
rosin cerate						
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
sabadilla alkaloids						
	miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
sabel, liposterolic extract of						
	miscellaneous internal	benign prostatic hypertrophy	benign prostatic hypertrophy	n/a	n/a	310.532(a)
saccharin						

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miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
sage oil						
miscellaneous external	skin protectant	astringent	n/a	IISE	310.545(a)(18)(ii)	
salicyl alcohol						
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	
salicylamide						
====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
internal analgesic	internal analgesic	analgesic adjuvant	IIISE	IIISE	pending	
internal analgesic	internal analgesic	analgesic	IIISE	IIISE	pending	
internal analgesic	internal analgesic	antipyretic adjuvant	IIISE	IIISE	pending	
internal analgesic	internal analgesic	antipyretic	IIISE	IIISE	pending	
internal analgesic	internal analgesic	antirheumatic adjuvant	IIISE	n/a	n/a	
internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	n/a	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	
miscellaneous internal	menstrual/diuretic	analgesic	IIISE	IIISE	pending	
sedative	nighttime sleep aid	sleep aid	IIE	IIE	[54 FR 6826]	
sedative	daytime sedative	sedative	IIE	IISE	310.519(a)	
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)	
salicylic acid						

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Ingredient						
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antimicrobial II	acne	acne	IIIE	I	333.310(c)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	
antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	I	I	358.710(a)(4)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)	
miscellaneous external	corn/callus remover	corn/callus remover	I	I	358.510(a)	
miscellaneous external	wart remover	wart remover	I	IISE	358.110(a)	
miscellaneous external	wart remover	wart remover	I	I	358.110(b)	
miscellaneous external	wart remover	wart remover	I	I	358.110(c)	
miscellaneous external	corn/callus remover	corn/callus remover	I	I	358.510 (b)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	I	I	358.710(b)(4)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	I	I	358.710(c)(2)	
salsalate						
internal analgesic	internal analgesic	analgesic	IIISE	IIISE	310.545(a)(23)(i)	

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
internal analgesic	internal analgesic	antipyretic	IIISE	IIISE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic	IIISE	not OTC	310.545(a)(23)(i)	
sanguinaria extract						
====	gingivitis/plaque	gingivitis/antiplaque	n/a	IIIE	pending	
sarsaparrilla						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
sassafras oil						
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
saw palmetto						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
scopolamine aminoxide hydrobromide						
sedative	nighttime sleep aid	sleep aid	IISE	IIS	[54 FR 6826]	
sedative	daytime sedative	sedative	IISE	IISE	310.519(a)	
scopolamine hydrobromide						
laxative	antidiarrheal	antidiarrheal	IIE	IIE	310.545(a)(3)(i)	
laxative	antiemetic	antiemetic	n/a	IIIE	[52 FR 15891]	
sedative	nighttime sleep aid	sleep aid	IISE	IIS	[54 FR 6826]	
sedative	daytime sedative	sedative	IISE	IISE	310.519(a)	
sea kelp [see kelp]						

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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	=====	=====	=====	=====	=====	=====
sea minerals						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
selenium sulfide						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	dandruff	I	I	358.710(a)(5)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	seborrheic dermatitis	I	I	358.710(b)(5)
selenium sulfide, micronized						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	dandruff	n/a	I	358.710(a)(6)
senecio aureus						
miscellaneous internal	menstrual/diuretic		dysmenorrhea	IISE	IISE	310.545(a)(24)(i)
senna						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(8)(ii)
senna fluidextract						
laxative	laxative		stimulant laxative	I	I/IIIS	pending
senna pod concentrate						
laxative	laxative		stimulant laxative	I	I/IIIS	pending
senna syrup						
laxative	laxative		stimulant laxative	I	I/IIIS	pending
sennosides a & b [see sennosides]						

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Review Panel	Report				
=====	=====	=====	=====	=====	=====
sennosides a and b					
laxative	laxative	stimulant laxative	I	I/IIIS	pending
sesame oil					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
sesame seed					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
shark liver oil					
=====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
=====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
=====	skin protectant	fever blister (topical)	n/a	I	pending
hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIIE	IIIE	310.545(a)(26)(x)
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(b)(3)
hemorrhoidal	anorectal	wound healing agent (external)	IIIE	IIIE	310.545(a)(26)(x)
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(b)(3)
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)

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Review Panel	Report				
miscellaneous external	skin protectant	protectant	I	I	pending
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending
topical analgesic	skin protectant	skin protectant	I	I	310.545(a)(18)(i)(B)
silicone					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
silver acetate					
miscellaneous internal	smoking deterrent	smoking deterrent	IIIE	IIIE	310.544(d)
silver nitrate					
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous internal	smoking deterrent	smoking deterrent	IISE	IISE	310.544(d)
silver protein, mild					
ophthalmic	ophthalmic	anti-infective	IIIE	IIIE	310.545(a)(21)(ii)
simethicone					
antacid	antacid	antacid	IIIE	IIIE	[39 FR 19873]
antacid	antiflatulent	antiflatulent	IIIE	I	332.10

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Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	[58 FR 54454]
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	IIIE	[58 FR 54454]
sodium					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
sodium 3, 4-dimethylphenyl-glyoxylate					
topical analgesic	sunscreen	sunscreen	IISE	IISE	[64 FR 27682]
sodium acetylsalicylate					
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
sodium aluminum chlorohydroxy lactate (aerosol)					
antiperspirant	antiperspirant	antiperspirant	IIISE	IIISE	310.545(a)(4)
sodium aluminum chlorohydroxy lactate (nonaerosol)					
antiperspirant	antiperspirant	antiperspirant	IIIE	IIIE	310.545(a)(4)
sodium aminobenzoate					
internal analgesic	internal analgesic	analgesic adjuvant	IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antipyretic adjuvant	IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antirheumatic adjuvant	IISE	n/a	310.545(a)(23)(i)
sodium benzoate					

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
sodium bicarbonate						
====	gingivitis/plaque	gingivitis/antiplaque	n/a	IIIE	pending	
antacid	antacid	antacid	I	I	331.11(k)(1)	
contraceptive/vaginal	vaginal	alters vaginal pH	IIIE	withdraw	n/a	
dental	anticaries	anticavity agent	IIE	IIE	[60 FR 52504]	
internal analgesic	internal analgesic	corrective	I	n/a	n/a	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	insect bite/sting	IISE	n/a	n/a	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	n/a	n/a	
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	I	pending	
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)	
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(8)(i)	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
oral cavity	oral health care	debriding agent	I	I	pending	

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
topical analgesic	skin protectant	skin protectant	I	I	347.10(o)	
sodium borate						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	astringent	IIISE	withdraw	n/a	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIE	IIE	310.545(a)(7)	
miscellaneous external	external analgesic	astringent	n/a	n/a	n/a	
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)	
oral cavity	oral health care	debriding agent	IISE	IISE	pending	
sodium borate monohydrate						
dental	oral mucosal injury	skin wound cleanser	IISE	IISE	pending	
sodium bromide						
sedative	nighttime sleep aid	sleep aid	IISE	IISE	[54 FR 6826]	
sedative	daytime sedative	sedative	IIS	IISE	310.519(a)	

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Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
sodium caprylate						
antimicrobial II	antifungal		antifungal	IIIE	IIIE	310.545(a)(22)(ii)
oral cavity	oral health care		antimicrobial	IIIE	IIIE	pending
sodium carbonate						
antacid	antacid		antacid	I	I	331.11(k)(1)
contraceptive/vaginal	vaginal		alters vaginal pH	IIISE	withdraw	n/a
internal analgesic	internal analgesic		corrective	I	n/a	n/a
sodium caseinate						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
sodium chloride						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
ophthalmic	ophthalmic		hypertonic agent	I	I	349.16
sodium citrate						
cough/cold	cough/cold (expectorant)		expectorant	IIIE	IIIE	310.545(a)(6)(iii)
dental	relief of oral discomfort		tooth desensitizer (in combination only)	IIIE	IIIE	pending
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)

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Review Panel	Report				
sodium citrate in solution					
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
sodium diacetate					
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
sodium dichromate					
oral cavity	oral health care	antimicrobial	IIS	IISE	pending
sodium dihydrogen phosphate [see sodium phosphate, monobasic]					
====	====	====	====	====	====
sodium fluoride					
dental	anticaries	anticavity dentifrice	I	I	355.10(a)(2)
dental	anticaries	anticavity dental rinse	I	I	355.10(a)(3)(iv)
dental	anticaries	anticavity dental rinse	I	I	355.10(a)(3)(v)
dental	anticaries	anticavity dentifrice	I	I	355.10(a)(1)
dental	anticaries	anticavity dental rinse	I	I	355.10(a)(3)(iii)
dental	relief of oral discomfort	tooth desensitizer (in combination only)	IISE	IISE	pending
dental	relief of oral discomfort	tooth desensitizer	IIIE	IIIE	pending
sodium lactate					

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Ingredient		Review Panel	Report	Drug Category	ANPR	PR	FR
		contraceptive/vaginal	vaginal	alters vaginal pH	IIIE	withdraw	n/a
sodium lauryl sulfate							
		contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	I	withdraw	n/a
sodium monofluorophosphate							
		dental	anticaries	anticavity dentifrice	I	I	355.10(b)(1)
		dental	anticaries	anticavity dental rinse	IIS	IIS	310.545(a)(2)(i)
		dental	relief of oral discomfort	tooth desensitizer	IIIE	IIIE	pending
		dental	anticaries	anticavity dentifrice	I	I	355.10(b)(2)
sodium nitrate							
		miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
sodium oleate							
		laxative	laxative	stimulant laxative	IIIE	IIIE	310.545(a)(12)(iv)(A)
sodium perborate							
		contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw	n/a
		contraceptive/vaginal	vaginal	astringent	IIISE	withdraw	n/a
		contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw	n/a
		contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
		oral cavity	oral health care	debriding agent	IIISE	IIISE	pending
sodium perborate monohydrate							

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
dental	oral health care	wound cleanser	IISE	I	pending	
sodium phosphate [see sodium phosphate, dibasic]						
=====	=====	=====	=====	=====	=====	
sodium phosphate, dibasic						
dental	anticaries	anticavity agent	IIE	IIE	310.545(a)(2)(ii)	
laxative	laxative	saline laxative	I	I	pending	
sodium phosphate, dibasic anhydrous reagent [see sodium phosphate, dibasic]						
=====	=====	=====	=====	=====	=====	
sodium phosphate, monobasic						
dental	anticaries	anticavity agent	IIE	IIE	310.545(a)(2)(ii)	
laxative	laxative	saline laxative	I	I	pending	
sodium picosulfate						
n/a	TEA	laxative	n/a			
sodium potassium tartrate						
antacid	antacid	antacid	I	I	331.11(j)(2) 331.11(k)(2)	
sodium potassium tartrate [see potassium sodium tartrate]						
=====	=====	=====	=====	=====	=====	
sodium propionate						
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	

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Ingredient						
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contraceptive/vaginal	vaginal	minor irritations	I	withdraw	n/a	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	IIISE	pending	
sodium salicylate						
contraceptive/vaginal	vaginal	minor irritations	IISE	withdraw	n/a	
internal analgesic	internal analgesic	analgesic	I	I	pending	
internal analgesic	internal analgesic	antipyretic	I	I	pending	
internal analgesic	internal analgesic	antirheumatic	I	not OTC	n/a	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIE	310.545(a)(7)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending	
miscellaneous internal	menstrual/diuretic	diuretic	IIIE	IIIE	310.545(a)(24)(i)	
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending	
sodium salicylate acid phenolate						
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)	
contraceptive/vaginal	vaginal	minor irritations	IISE	withdraw	n/a	
sodium sulfide						
miscellaneous external	ingrown toenail	ingrown toenail	n/a	I	538.310	

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Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
miscellaneous external	ingrown toenail	ingrown toenail	IIIE	IIIE	310.538(a) [removed 68 FR 24348]
sodium thiosulfate					
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)
sorbitan monostearate					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
sorbitan sesquioleate					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
sorbitol					
laxative	laxative	hyperosmotic laxative	I	I	pending
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
oral cavity	oral health care	oral health care nonantimicrobial	n/a	n/a	310.545(a)(14)
soyasterol					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a

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miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
soybean oil, hydrogenated					
miscellaneous internal	cholecystokinetic	cholecystokinetic	n/a	n/a	357.210(b)
soybean protein					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
soymeal					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
spermaceti					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
squill					
cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
squill extract					
cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
stannous fluoride					
====	antigingivitis	antigingivitis	I	=====	pending
dental	anticaries	anticavity dental gel	I	I	355.10(c)(2)
dental	anticaries	anticavity dentifrice	I	I	355.10(c)(1)
dental	anticaries	anticavity dental rinse	I	I	355.10(c)(3)

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Ingredient						
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dental	relief of oral discomfort	tooth desensitizer	IIIE	IIIE	pending	
stannous pyrophosphate and zinc citrate						
====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIIE	pending	
stearly alcohol						
====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)	
====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)	
====	skin protectant	Skin protectant	n/a	n/a	310.545(a)(18)(i)(B)	
stem bromelain						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
strawberry						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
strontium chloride						
dental	relief of oral discomfort	tooth desensitizer (in combination only)	IISE	IISE	pending	
dental	relief of oral discomfort	tooth desensitizer	IIIE	IIIE	pending	
strychnine						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
sucrose						

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Ingredient						
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miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
sucrose octaacetate						
miscellaneous external	nailbiting/thumbsucking	nailbiting/thumbsucking deterrent	IIIE	IIIE	310.536(a)	
sugars						
oral cavity	oral health care	oral health care nonantimicrobial	n/a	n/a	310.545(a)(14)	
sulfacetamide sodium						
miscellaneous external	hair growth/loss	hair grower	n/a	n/a	310.527(a)	
ophthalmic	ophthalmic	anti-infective	IIS	IIS	310.545(a)(21)(ii)	
sulfur						
====	external analgesic	poison ivy/oak/sumac	n/a	IIE	310.545(a)(10)(vii)	
====	skin protectant	wound healing agent	n/a	n/a	310.545(a)(18)(i)(A)	
antimicrobial II	acne	acne	I	I	333.310(d)	
antimicrobial II	acne	acne	I	I	333.310(e)	
miscellaneous external	boil treatment	boil treatment	n/a	IIISE	310.531(a)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	I	I	358.710(a)(7)	
miscellaneous external	skin protectant	diaper rash	defer	IISE	310.545(a)(18)(iii)	
miscellaneous external	skin protectant	fever blister (topical)	defer	IISE	310.545(a)(18)(iv)	
topical analgesic	skin protectant	skin protectant	IISE	IISE	310.545(a)(18)(i)(A)	

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Ingredient						
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sulfur (paraffinic hydrocarbons)						
miscellaneous external	hair growth/loss	hair grower	n/a	IIE	310.527(a)	
sulfur, precipitated						
hemorrhoidal	anorectal	keratolytic (external)	IIIE	IIIE	310.545(a)(26)(v)	
hemorrhoidal	anorectal	keratolytic (intrarectal)	IIE	IIE	310.545(a)(26)(v)	
sulfur, sublimed						
hemorrhoidal	anorectal	keratolytic (intrarectal)	IIE	IIE	310.545(a)(26)(v)	
hemorrhoidal	anorectal	keratolytic (external)	IIIE	IIIE	310.545(a)(26)(v)	
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)	
sulfurated oils of turpentine						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
sulisobenzone						
topical analgesic	sunscreen	sunscreen	I	I	352.10(o)	
sweet spirits of nitre						
miscellaneous external	sweet spirits of nitre	all indications	IISE	n/a	310.502(a)(12)	
syrup of pine tar [see pine tar syrup]						
=====	=====	=====	=====	=====	=====	
talc						

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Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
=====	antimicrobial	diaper rash	n/a	n/a	pending	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
talcum powder						
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a	
tannic acid						
=====	skin protectant	diaper rash	n/a	IISE	310.545(a)(18)(iii)	
=====	skin protectant	wound healing agent	n/a	n/a	310.545(a)(18)(i)	
antimicrobial II	antifungal	antifungal	IIE	IIE	310.545(a)(22)(ii)	
hemorrhoidal	anorectal	astringent (external)	IISE	IISE	310.545(a)(26)(iii)	
hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(iii)	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIISE	310.545(a)(10)(v)	
miscellaneous external	external analgesic	insect bite/sting	n/a	IIIE	pending	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIIE	310.545(a)(10)(vii)	
miscellaneous external	ingrown toenail	ingrown toenail	IIIE	IIIE	310.538(a)	

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miscellaneous external	ingrown toenail	astringent(external)	IIIE	IIIE	310.538(a)
miscellaneous external	skin protectant	fever blister (topical)	defer	IIISE	310.545(a)(18)(iv)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(8)(ii)
topical analgesic	skin protectant	skin protectant	IISE	IISE	310.545(a)(18)(i)(A)
tannic acid glycerite					
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
tar oil					
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
taraxacum officinale					
miscellaneous external	menstrual/diuretic	dysmenorrhea	IIE	IIE	310.545(a)(24)(i)
tartaric acid					
antacid	antacid	antacid	I	I	331.11(m)
contraceptive/vaginal	vaginal	alters vaginal pH	IIIE	withdraw	n/a
laxative	laxative	saline laxative	IIISE	IIISE	310.545(a)(12)(ii)
terpin hydrate					
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
terpin hydrate elixir					

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		cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
testosterone							
		miscellaneous internal	aphrodisiac	aphrodisiac	IIS	IIS	310.528(a)
tetracaine							
		=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
		hemorrhoidal	anorectal	anesthetic (external)	IIIE	I	346.10(h)
		hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]
		miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
		miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
		miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)
		miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
		miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
		oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)
		topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
tetracaine hydrochloride							
		=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
		antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)
		hemorrhoidal	anorectal	anesthetic (external)	IIIE	I	346.10(i)
		hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]

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miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending	
miscellaneous external	hair growth/loss	hair grower	IIE	IIE	310.527(a)	
oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
tetracycline hydrochloride						
antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.110(f)	
antimicrobial II	antibiotic	skin wound antibiotic	IIIE	defer	n/a	
antimicrobial II	antibiotic	skin wound protectant	I	defer	n/a	
tetrahydrozoline hydrochloride						
ophthalmic	ophthalmic	vasoconstrictor	I	I	349.18(d)	
thenyldiamine hydrochloride						
cough/cold	cough/cold (antihistamine)	antihistamine	IIIE	IIIE	310.545(a)(6)(i)(A)&(B)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	IIIE	[59 FR 43408]	
theobromine sodium salicylate						
miscellaneous internal	menstrual/diuretic	diuretic	IIIE	IIIE	310.545(a)(24)(i)	
theophylline						
miscellaneous internal	menstrual/diuretic	diuretic	IIIE	IIIE	310.545(a)(24)(i)	
theophylline (all combinations)						
cough/cold	cough/cold (bronchodilator)	bronchodilator	n/a	n/a	310.545(a)(6)(iv)(B)	

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Review Panel	Report				
theophylline anhydrous [see theophylline, anhydrous]					
=====	=====	=====	=====	=====	=====
theophylline anhydrous [see theophylline]					
=====	=====	=====	=====	=====	=====
theophylline calcium salicylate					
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
theophylline sodium glycinate					
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
theophylline, anhydrous					
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
thiamine					
miscellaneous internal	oral insect repellent	insect repellent	IIE	IIE	310.529(a)
thiamine hydrochloride					
miscellaneous external	hair growth/loss	hair grower	n/a	n/a	310.527(a)
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
sedative	nighttime sleep aid	sleep aid	IIE	IIE	[54 FR 6826]
sedative	daytime sedative	sedative	IIE	IISE	310.519(a)
thiamine mononitrate					

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miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
thimerosal					
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
miscellaneous external	mercury	first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
thiocyanoacetate					
====	pediculicide	pediculicide	n/a	n/a	310.545(a)(25)(i)
thonzylamine hydrochloride					
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(l)
threonine					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
thyme oil, white					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
thymol					
====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)
antimicrobial II	acne	acne	IIE	IIIE	310.545(a)(1)
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)

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cough/cold	cough/cold (antihistamine)	antitussive (topical/inhalant)	IIIE	IIIE	[52 FR 30055]
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (inhalant room spray)	IIIE	IIIE	310.545(a)(6)(ii)(A)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	IIIE	310.545(a)(6)(ii)(A)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIE	310.545(a)(6)(ii)(A)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIE	IIIE	310.545(a)(6)(ii)(A)
dental	relief of oral discomfort	toothache relief	IIIE	IIIE	pending
dental	relief of oral discomfort	oral mucosal analgesic	IIIE	IIIE	pending
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIE	310.545(a)(7)
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	external analgesic	fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending
oral cavity	oral health care	analgesic/anesthetic	IIIE	IIIE	310.545(a)(14)
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)
thymol iodide					
dental	relief of oral discomfort	oral mucosal analgesic	IIIE	IIIE	pending

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Review Panel	Report				
dental	relief of oral discomfort	toothache relief	IIIE	IIIE	pending
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending
tincture of impatiens bi-flora [see impatiens bi-flora tincture]					
=====	=====	=====	=====	=====	=====
tincture of iodine [see iodine tincture]					
=====	=====	=====	=====	=====	=====
titanium dioxide					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
topical analgesic	sunscreen	sunscreen	I	I	352.10(p)
tolindate					
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
tolnaftate					
antimicrobial II	antifungal	antifungal	I	I	333.210(e)
tolu					
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
tolu balsam					
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending

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oral cavity	oral health care	expectorant	IIIE	n/a	310.545(a)(6)(iii)	
tolu balsam tincture						
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)	
topical starch						
====	skin protectant	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(18)(vi)(A)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(9)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(9)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	astringent	IISE	IISE	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	IIISE	310.545(a)(18)(iv)	
topical analgesic	skin protectant	skin protectant	I	defer	347.10(q)	
triacetin						
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	
tribromsalan						
antimicrobial I	antimicrobial	antimicrobial	IIS	n/a	310.502(a)(5)	

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tricalcium phosphate						
antacid	antacid	antacid	n/a	n/a	331.11(i)(3)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
tricalcium phosphate [see calcium phosphate, tribasic]						
=====	=====	=====	=====	=====	=====	
triclocarban						
antimicrobial I	antimicrobial	skin antiseptic	n/a	IIIE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IISE	IIISE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IISE	IISE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IISE	IISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IISE	IISE	pending	
antimicrobial I	antimicrobial	skin protectant	IISE	IISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending	
triclosan						
antimicrobial I	antimicrobial	skin antiseptic	n/a	IIIE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IISE	IIISE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IISE	IIISE	pending	

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antimicrobial I	antimicrobial	skin wound cleanser	III SE	III SE	pending
antimicrobial I	antimicrobial	skin antiseptic	III SE	III SE	pending
antimicrobial I	antimicrobial	skin protectant	III SE	III SE	pending
antimicrobial I	antimicrobial	health care personnel handwash	II SE	III SE	pending
miscellaneous external	antimicrobial	diaper rash	defer	III SE	pending
miscellaneous external	boil treatment	boil treatment	n/a	n/a	310.531(a)
n/a	TEA	acne	n/a		
n/a	TEA	antigingivitis	n/a		
trillium					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
tripelennamine hydrochloride					
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	n/a	[57 FR 58373]
miscellaneous external	external analgesic	fever blister (topical)	defer	III E	310.545(a)(10)(v)
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
triple dye					
antimicrobial I	antimicrobial	skin antiseptic	n/a	III SE	pending
antimicrobial I	antimicrobial	antimicrobial soap	n/a	II SE	pending
antimicrobial I	antimicrobial	preoperative skin prep	n/a	II SE	pending

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antimicrobial I	antimicrobial	surgical hand scrub	n/a	IISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin protectant	n/a	IISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	n/a	IISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	n/a	IIISE	pending	
triprolidine hydrochloride						
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	I	341.12(m)	
triticum						
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
trolamine						
miscellaneous external	external analgesic	insect bite/sting	IIIE	IISE	pending	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	IIIE	310.545(a)(18)(iv)(A)	
miscellaneous external	skin protectant	insect bite/sting	IIIE	IIIE	310.545(a)(18)(v)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIIE	310.545(a)(18)(vi)(A)	
trolamine salicylate						
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	
miscellaneous external	external analgesic	insect bite/sting	n/a	IIIE	310.545(a)(10)(vi)	

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miscellaneous external	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	pending	
topical analgesic	sunscreen	sunscreen	I	I	352.10(q)	
tryptophan						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
turpentine oil						
cough/cold	cough/cold (antitussive)	antitussive (oral)	IISE	IISE	pending	
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	IIIE	IIIE	[52 FR 30055]	
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	IIIE	IIIE	310.545(a)(6)(iii)	
cough/cold	cough/cold (expectorant)	expectorant (oral)	IISE	IISE	310.545(a)(6)(iii)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	IISE	IISE	310.545(a)(6)(ii)(A)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	IIIE	310.545(a)(6)(ii)(A)	
topical analgesic	external analgesic	counterirritant	I	I	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)	
turpentine oil, rectified						

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hemorrhoidal	anorectal	counterirritant (intrarectal)	IISE	IISE	310.545(a)(26)(iv)	
hemorrhoidal	anorectal	counterirritant (external)	IISE	IISE	310.545(a)(26)(iv)	
turpentine, venice						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
tyrosine						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
undecoylilum chlorideiodine complex [see undecoylium chloride iodine complex]						
=====	=====	=====	=====	=====	=====	
undecoylium chlorideiodine complex						
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIE	IIIE	pending	
undecylenic acid						
antimicrobial II	antifungal	antifungal	I	I	333.210(f)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(i)	

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undecylenic acid monoethanolamine sulfosuccinate sodium						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIE	310.545(a)(7)	
urea						
miscellaneous external	hair growth/loss	hair grower	n/a	IIE	310.527(a)	
miscellaneous external	ingrown toenail	ingrown toenail	IISE	IISE	310.538(a)	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
uva ursi, extract						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
valine						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
vegetable						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
vegetable oil						
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)	
vitamin A						
contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a	
hemorrhoidal	anorectal	wound healing agent (external)	IIIE	IIIE	310.545(a)(26)(x)	
hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIIE	IIIE	310.545(a)(26)(x)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	

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miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending	
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
vitamin A acetate						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
vitamin A palmitate						
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
vitamin B						
miscellaneous external	hair growth/loss	hair grower	n/a	IIE	310.527(a)	
vitamin D [see cholecalciferol]						
=====	=====	=====	=====	=====	=====	
vitamin D2 [see ergocalciferol]						

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=====	=====		=====	=====	=====	=====
vitamin E						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	hair growth/loss		hair grower	IIE	n/a	310.527(a)
miscellaneous external	skin protectant		diaper rash	defer	withdraw	n/a
miscellaneous internal	leg muscle cramp		nocturnal leg muscle cramps	n/a	IIISE	310.546
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
sedative	stimulant		stimulant	IIE	IIE	[39 FR 6104]
vitamins						
miscellaneous external	hair growth/loss		hair grower	IISE	n/a	310.527(a)
miscellaneous internal	aphrodisiac		aphrodisiac	n/a	IISE	310.528(a)
vitromersal						
miscellaneous external	mercury		first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
miscellaneous external	mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)
water and additives						
=====	ophthalmic		emergency first aid eyewash	n/a	I	pending

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water, purified						
====		ophthalmic	eyewash	n/a	n/a	349.20
wax, candelilla						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
wax, carnauba						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
wax, white						
ophthalmic	ophthalmic		emollient	I	I	349.14(b)(6)
wax, yellow						
ophthalmic	ophthalmic		emollient	n/a	I	349.14(b)(7)
wheat germ						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
wheat germ glycerides						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
wheat germ oil						
miscellaneous external	hair growth/loss		hair grower	IIE	IIE	310.527(a)

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white ointment						
ophthalmic		ophthalmic	emollient	I	I	349.14(b)(8)
white petrolatum						
=====		skin protectant	skin protectant	n/a	n/a	347.10(r)
white pine						
cough/cold		cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
white pine extract, compound						
cough/cold		cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)
white pine syrup, compound						
cough/cold		cough/cold (expectorant)	expectorant	IIISE	IIIE	310.545(a)(6)(iii)
white thyme oil [see thyme oil, white]						
=====		=====	=====	=====	=====	=====
wintergreen oil [see methyl salicylate]						
=====		=====	=====	=====	=====	=====
witch hazel						
hemorrhoidal		anorectal	astringent (external)	I	I	346.18 (b)
hemorrhoidal		anorectal	astringent (intrarectal)	I	I	346.18 (b)
miscellaneous external		external analgesic	astringent	I	n/a	n/a
miscellaneous external		skin protectant	astringent	I	I	347.12(c)

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witch hazel water [see hamamelis water of xi]					
=====	=====	=====	=====	=====	=====
woodruff					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
wool alcohols [see lanolin alcohols]					
=====	=====	=====	=====	=====	=====
xanthan gum					
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)
xylometazoline hydrochloride					
cough/cold	cough/cold (nasal decongestant)	nasal decongestant	I	I	341.20(b)(10)
yeast					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
yeast cell derivative, live					
hemorrhoidal	anorectal	wound healing agent (external)	IIISE	IIISE	310.545(a)(26)(vii)
hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIISE	IIISE	310.545(a)(26)(vii)
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending

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	topical analgesic		skin protectant	wound healing agent	IIIE	IIIE	pending
yohimbine							
	miscellaneous internal		aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
yohimbine hydrochloride							
	miscellaneous internal		aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
yohimbinum							
	miscellaneous internal		aphrodisiac	aphrodisiac	n/a	n/a	310.528(a)
zinc acetate							
	====		skin protectant	diaper rash	n/a	n/a	310.545(a)(18)(iii)
	miscellaneous external		skin protectant	poison ivy/oak/sumac	defer	I	347.10(s)
	miscellaneous external		external analgesic	poison ivy/oak/sumac	defer	IISE	pending
	topical analgesic		skin protectant	wound healing agent	IIIE	IIIE	310.545(a)(18)(i)(A)
	topical analgesic		skin protectant	skin protectant	I	I	347.10(s)
zinc caprylate							
	antimicrobial II		antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)
zinc carbonate							
	====		skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)
	====		skin protectant	poison ivy/oak/sumac	n/a	I	347.10(t)

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topical analgesic	skin protectant	skin protectant	I	I	347.10(t)	
zinc chloride						
miscellaneous external	corn/callus remover	corn/callus remover	IIIE	IIIE	[55 FR 33261]	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
oral cavity	oral health care	astringent	I	I	pending	
zinc citrate						
====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIIE	pending	
zinc oxide						
====	n/a	sunscreen	n/a	I	352.10(r)	
====	skin protectant	poison ivy/oak/sumac	n/a	I	347.10(u)	
antimicrobial II	acne	acne	IIIE	IIIE	310.545(a)(1)	
hemorrhoidal	anorectal	astringent (external)	I	I	346.18 (c)	
hemorrhoidal	anorectal	astringent (intrarectal)	I	I	346.18 (c)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(b)(4)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(b)(4)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	

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miscellaneous external	external analgesic	astringent	IISE	IISE	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	diaper rash	defer	I	pending
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant	protectant	I	I	pending
topical analgesic	skin protectant	skin protectant	I	I	pending
zinc phenolsulfonate					
laxative	antidiarrheal	antidiarrheal	IIE	IIE	310.545(a)(3)(i)
laxative	antiemetic	antiemetic	IIIE	IIE	[52 FR 15891]
miscellaneous external	external analgesic	astringent	IISE	n/a	pending
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
zinc propionate					
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)
zinc pyrithione [see pyrithione zinc]					
=====	=====	=====	=====	=====	=====
zinc stearate					

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antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
zinc sulfate						
contraceptive/vaginal	vaginal	astringent	IIIE	withdraw	n/a	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIISE	310.545(a)(10)(v)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	fever blister (topical)	defer	IIIE	310.545(a)(18)(iv)	
miscellaneous internal	poison treatment	emetic	n/a	IISE	310.545(a)(16)	
ophthalmic	ophthalmic	astringent	I	I	349.10	
zinc sulfide						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
zinc undecylenate						
antimicrobial II	antifungal	antifungal	I	I	333.210(f)	

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zirconium oxide					
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous external	external analgesic	poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
zyloxin					
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	mercury	first aid antiseptic	IISE	n/a	310.545(a)(27)(i)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)