

**OTC Ingredient List**  
*Updated August 2006*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>danthron</b>						
laxative	laxative	stimulant laxative	I	IIS	310.545(a)(12)(iv)(B)	
<b>d-calcium pantothenate</b> [see calcium pantothenate]						
=====	=====	=====	=====	=====	=====	
<b>dehydrocholic acid</b>						
laxative	laxative	stimulant 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)	
<b>denatonium benzoate</b>						
miscellaneous external	nailbiting/thumbsucking	nailbiting/thumbsucking deterrent	IIIE	IIIE	310.536(a)	
<b>dequalinium chloride</b>						
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
<b>desoxyephedrine, l-</b> [see levomethamphetamine]						
=====	=====	=====	=====	=====	=====	
<b>dexbromopheniramine maleate</b>						
cough/cold	cough/cold (antihistamine)	antihistamine	IIISE	I	341.12(d)	
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	I	341.12(f)	
<b>dexchlorpheniramine maleate</b>						
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	I	341.12(e)	

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Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>dexpantenol</b>						
====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
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	external analgesic	insect bite/sting	n/a	IIIE	pending	
miscellaneous external	hair growth/loss	hair grower	n/a	IIIE	310.527(a)	
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending	
<b>dextran 70</b>						
ophthalmic	ophthalmic	demulcent	I	I	349.12(b)	
<b>dextromethorphan</b>						
cough/cold	cold/cough (antitussive)	antitussive	I	I	341.14(a)(3)	
<b>dextromethorphan hydrobromide</b>						
cough/cold	cough/cold (antitussive)	antitussive	n/a	n/a	341.14(a)(4)	
<b>dextrose</b>						
miscellaneous internal	weight control	anorectic	IIISE	IIISE	310.545(a)(20)	
<b>diastase</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>diastase malt</b>						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	

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Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>dibenzothiophene</b>						
antimicrobial II	acne	acne	IIS	IIS	310.545(a)(1)	
<b>dibucaine</b>						
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIISE	IIISE	[55 FR 1779]	
hemorrhoidal	anorectal	anesthetic (external)	IIS	I	346.10(d)	
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	
<b>dibucaine hydrochloride</b>						
=====	external analgesic	fever blister (topical)	n/a	I	pending	
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
hemorrhoidal	anorectal	anesthetic (external)	IIS	I	346.10(c)	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIISE	IIISE	[55 FR 1779]	
oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)	

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
<b>dicalcium phosphate dihydrate</b> [see calcium phosphate, dibasic]						
=====	gingivitis/plaque	gingivitis/antiplaque	n/a	IIIE	pending	
<b>dichlorodiphenyl trichloroethane</b> [see chlorophenothane]						
=====	=====	=====	=====	=====	=====	
<b>dichlorophen</b>						
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)	
<b>diethanolamine methoxycinnamate</b>						
topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)	
<b>diethanolamine p-methoxy-cinnamate</b> [see diethanolamine methoxycinnamate]						
=====	=====	=====	=====	=====	=====	
<b>diethylhexyl butamido triazone (Uvasorb HEB)</b>						
n/a	TEA	sunscreen	n/a			
<b>digalloyltriolate</b>						
topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)	
<b>dihydroxyaluminum aminoacetate</b>						
antacid	antacid	antacid	I	I	331.11(a)(3)	
<b>dihydroxyaluminum aminoacetic acid</b>						

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Review Panel	Report	Drug Category	ANPR	PR	FR	
antacid	antacid	antacid	n/a	n/a	331.11(a)(3)	
internal analgesic	internal analgesic	corrective	I	n/a	n/a	
<b>dihydroxyaluminum sodium carbonate</b>						
antacid	antacid	antacid	I	I	331.11(a)(5)	
internal analgesic	internal analgesic	corrective	I	n/a	n/a	
miscellaneous internal	digestive aid	digestive aid (ippuad)	III E	III E	310.545(a)(8)(i)	
<b>dimenhydrinate</b>						
laxative	antiemetic	antiemetic	I	I	336.10(b)	
<b>dimethicone</b>						
====	skin protectant	diaper rash	n/a	I	pending	
====	skin protectant	fever blister (topical)	n/a	I	pending	
topical analgesic	skin protectant	skin protectant	I	I	347.10(g)	
<b>dimethisoquin hydrochloride</b>						
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
====	external analgesic	fever blister (topical)	n/a	I	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
<b>dioxybenzone</b>						
topical analgesic	sunscreen	sunscreen	I	I	352.10(e)	
<b>diperodon</b>						

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Review Panel	Report	Drug Category	ANPR	PR	FR	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIISE	IIISE	310.545(a)(26)(vi)	
hemorrhoidal	anorectal	anesthetic (external)	IIE	IIIE	310.545(a)(26)(vi)	
<b>diperodon hydrochloride</b>						
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	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)(10)(vii)(A)	
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]	
<b>diphenhydramine citrate</b>						
cough/cold	cough/cold (antitussive)	antitussive	n/a	n/a	341.14(a)(5)	
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	n/a	341.12(f)	
sedative	nighttime sleep aid	sleep aid	n/a	n/a	338.10(b)	
<b>diphenhydramine hydrochloride</b>						
====	external analgesic	fever blister (topical)	n/a	I	pending	
cough/cold	cough/cold (antitussive)	antitussive	I	IIIE	341.14(a)(6)	
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(g)	
laxative	antiemetic	antiemetic	IIIE	IIIE	336.10(c)	

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<b>Review Panel</b>	<b>Report</b>				
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
sedative	daytime sedative	sedative	IISE	IISE	310.519(a)
sedative	nighttime sleep aid	sleep aid	IIISE	IIISE	336.10(a)
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>diphenhydramine monocitrate</b> [see diphenhydramine citrate]					
=====	=====	=====	=====	=====	=====
<b>dipropylene glycol salicylate</b>					
topical analgesic	sunscreen	sunscreen	IIISE	IIISE	[64 FR 27682]
<b>dl-methionine</b> [see racemethionine]					
=====	=====	=====	=====	=====	=====
<b>docusate calcium</b>					
laxative	laxative	stool softener	I	I	pending
<b>docusate potassium</b>					
laxative	laxative	stool softener	I	I	pending
<b>docusate sodium</b>					
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	I	withdraw	n/a
laxative	laxative	stool softener	I	I	pending
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)

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Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
<b>dodecaethylene glycol monolaurate</b>						
contraceptive/vaginal	contraceptive (vaginal)	contraceptive	IIIE	withdraw	310.545(a)(28)	
<b>dodecaethyleneglycol monolaurate</b> [see dodecaethylene glycol monolaurate]						
=====	=====	=====	=====	=====	=====	
<b>dog grass</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>dog grass extract</b>						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
<b>domiphen bromide</b>						
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
<b>don qual</b>						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
<b>doxylamine succinate</b>						
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(h)	
sedative	daytime sedative	sedative	IISE	IISE	310.519(a)	
sedative	nighttime sleep aid	sleep aid	IIISE	IIISE	[54 FR 6826]	
<b>duodenal substance</b>						



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miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IISE	IISE	310.545(a)(8)(i)	
<b>dyclonine hydrochloride</b>						
=====	external analgesic	fever blister (topical)	n/a	I	pending	
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
hemorrhoidal	anorectal	anesthetic (external)	IIIE	I	346.10(e)	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]	
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
<b>e. coli vaccines</b>						
hemorrhoidal	anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)	
hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)	
<b>edetate disodium</b>						
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
dental	relief of oral discomfort	tooth desensitizer (in combination only)	IISE	IISE	pending	
<b>edetate sodium</b>						
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
<b>elaterin resin</b>						
laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)	

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<b>elecampane</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>elm bark</b>						
cough/cold	cough/cold (antitussive)	antitussive	III E	III E	[52 FR 30054]	
oral cavity	oral health care	demulcent	I	I	pending	
<b>endothemic hectorite</b> [see hectorite]						
=====	=====	=====	=====	=====	=====	
<b>ensulizole</b>						
topical analgesic	sunscreen	sunscreen	I	I	352.10(n)	
<b>enzacamene</b>						
n/a	TEA	sunscreen	n/a			
<b>ephedrine</b>						
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	I	341.16(a)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(1)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	III E	III E	310.545(a)(6)(ii)(B)	
<b>ephedrine (any ingredient)</b>						
=====	menstrual/diuretic	menstrual	n/a	n/a	310.545(a)(24)(ii)	
=====	internal analgesic	analgesic	n/a	n/a	310.545(a)(23)(ii)	
<b>ephedrine hydrochloride</b>						

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cough/cold	cough/cold (bronchodilator)	bronchodilator	I	I	341.16(b)	
miscellaneous external	MALE GENITAL DESENSITIZER	male genital desensitizer	IISE	IISE	310.545(a)(10)(iii)	
ophthalmic	ophthalmic	vasoconstrictor	I	I	349.18(a)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIE	IIIE	310.545(a)(6)(ii)(B)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(3)	
<b>ephedrine sulfate</b>						
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	I	341.16(c)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(4)	
hemorrhoidal	anorectal	vasoconstrictor (intrarectal)	I	I	346.12(a)	
hemorrhoidal	anorectal	vasoconstrictor (external)	I	I	346.10(a)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIE	IIIE	310.545(a)(6)(ii)(B)	
<b>epinephrine</b>						
cough/cold	cough/cold (bronchodilator)	bronchodilator (inhalation)	I	I	341.16(d)	
hemorrhoidal	anorectal	vasoconstrictor (external)	IIISE	I	346.10(b)	
hemorrhoidal	anorectal	vasoconstrictor (intrarectal)	IIISE	IIISE	346.10(b)	
<b>epinephrine bitartrate</b>						
cough/cold	cough/cold (bronchodilator)	bronchodilator (inhalation)	I	I	341.16(e)	
<b>epinephrine hydrochloride</b>						
hemorrhoidal	anorectal	vasoconstrictor (external)	I	I	346.10(c)	

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hemorrhoidal	anorectal	vasoconstrictor (intrarectal)	IIE	IIE	346.10(c)	
<b>epinephrine hydrochloride (racemic) [see epinephrine hydrochloride]</b>						
====	====	====	====	====	====	
<b>epinephrine undecylenate</b>						
hemorrhoidal	anorectal	vasoconstrictor (external)	IIISE	IIISE	310.545(a)(26)(ix)	
hemorrhoidal	anorectal	vasoconstrictor (intrarectal)	IIE	IIE	310.545(a)(26)(ix)	
<b>ergocalciferol</b>						
contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	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	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
<b>ergot fluidextract</b>						
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
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)(18)(v)(A)	
<b>escalol 506 [see padimate a]</b>						

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	=====	=====	=====	=====	=====	=====
<b>essential oils</b>						
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)	
<b>estradiol</b>						
miscellaneous external	hair growth/loss	hair grower	IIE	IIE	310.527(a)	
<b>estrogens</b>						
miscellaneous external	hormone	hormone	IIE	IIE	310.530(a)	
miscellaneous internal	aphrodisiac	aphrodisiac	IIS	IIS	310.528(a)	
<b>estrone</b>						
antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)	
<b>ether</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>ethohexadiol</b>						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIE	IIIE	310.545(a)(7)	
<b>ethoxylated alkyl alcohol</b>						
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)(18)(v)	
<b>ethyl 4-(bis (hydroxypropyl)) aminobenzoate</b>						

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topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)	
<b>ethyl alcohol</b> [see alcohol]						
=====	=====	=====	=====	=====	=====	
<b>ethyl nitrate</b>						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
<b>ethylhexyl p-methoxycinnamate</b> [see white pine extract, compound]						
=====	=====	=====	=====	=====	=====	
<b>ethylmorphine hydrochloride</b>						
cough/cold	cough/cold (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]	
<b>eucalyptol</b>						
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	IIIE	IIIE	[52 FR 30055]	
cough/cold	cough/cold (antitussive)	antitussive (mouthwash)	IIIE	IIIE	[52 FR 30055]	
cough/cold	cough/cold (antitussive)	antitussive (lozenge)	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 (topical/inhalant)	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)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIE	310.545(a)(6)(ii)(A)	

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	antigingivitis/antiplaque	antigingivitis/antiplaque	I			
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	III E	III E	310.545(a)(7)	
miscellaneous external	external analgesic	diaper rash	defer	II SE	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
oral cavity	oral health care	antimicrobial	III E	III E	pending	
oral cavity	oral health care	analgesic/anesthetic	III E	III E	310.545(a)(14)	
<b>eucalyptol, menthol, methyl salicylate, and thymol</b>						
=====	gingivitis/plaque	antiplaque/gingivitis	I	=====	pending	
<b>eucalyptus oil</b>						
=====	external analgesic	fever blister (topical)	n/a	III E	310.545(a)(10)(v)	
cough/cold	cough/cold (antitussive)	antitussive (mouthwash)	III E	III E	[52 FR 30055]	
cough/cold	cough/cold (antitussive)	antitussive (lozenge)	III E	III E	[52 FR 30054]	
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	III E	III E	[52 FR 30055]	
cough/cold	cough/cold (expectorant)	expectorant (lozenge)	III E	III E	310.545(a)(6)(iii)	
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	III E	III E	310.545(a)(6)(iii)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	III E	III E	310.545(a)(6)(ii)(A)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (inhalant room spray)	III E	III E	[59 FR 43408]	

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cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIE	310.545(a)(6)(ii)(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	astringent	IIESE	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIESE	310.545(a)(10)(vii)	
miscellaneous external	hair growth/loss	hair grower	IIESE	n/a	310.527(a)	
miscellaneous external	skin protectant	astringent	IIESE	IIESE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIESE	310.545(a)(18)(vi)	
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)	
topical analgesic	external analgesic	counterirritant	IIIE	IIIE	310.545(a)(10)(ii)	
<b>eugenol</b>						
====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
dental	relief of oral discomfort	toothache relief	I	IIIESE	pending	
miscellaneous external	external analgesic	astringent	IIESE	n/a	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	
miscellaneous external	skin protectant	astringent	IIESE	IIESE	310.545(a)(18)(ii)	
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)	



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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>euphorbia pilulifera</b>					
cough/cold	cough/cold (bronchodilator)	bronchodilator	IIIE	IIIE	310.545(a)(6)(iv)(A)
<b>extract white pine compound</b> [see white pine extract, compound]					
=====	=====	=====	=====	=====	=====
<b>fatty acids</b>					
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
<b>fennel acid</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>ferric ammonium citrate</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>ferric chloride</b>					
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)(18)(v)(A)
miscellaneous external	skin protectant	poison ivy/oak/sumac	IISE	IISE	310.545(a)(18)(vi)(A)
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
oral cavity	oral health care	antimicrobial	IISE	IISE	pending
<b>ferric pyrophosphate</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<b>ferric subsulfate</b>						
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
<b>ferrous fumarate</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>ferrous gluconate</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>ferrous sulfate</b>						
	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)
<b>flax seed</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>fluid extract ergot [see ergot, fluidextract]</b>						
	=====	=====	=====	=====	=====	=====
<b>fluorosalan</b>						
	antimicrobial I	antimicrobial	antimicrobial	IIS	IIS	pending
<b>folic acid</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>formaldehyde solution</b>						

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<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
	dental		relief of oral discomfort	tooth desensitizer	IIIE	IIIE	pending
<b>formic acid</b>							
	miscellaneous external		pediculicide	pediculicide	n/a	n/a	310.545(a)(25)(i)
<b>frangula</b>							
	laxative		laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)
<b>fructose</b>							
	miscellaneous internal		overindulgence in alcohol/food	minimize inebriation	IIIE	IIIE	[48 FR 32873]
	miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>galega</b>							
	miscellaneous internal		digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>gamboge</b>							
	laxative		laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
<b>garlic, dehydrated</b>							
	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)
<b>gastric mucin</b>							
	antacid		antacid	antacid	IIIE	IIIE	[39 FR 19873]
<b>gelatin</b>							
	oral cavity		oral health care	demulcent	I	I	pending

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
ophthalmic	ophthalmic	demulcent	I	I	349.12(c)	
<b>gentian violet</b>						
miscellaneous internal	anthelmintic	anthelmintic	I	IIS	[51 FR 27758]	
oral cavity	oral health care	antimicrobial	IIIE	IIE	pending	
<b>gentiana lutea (gentian)</b>						
miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)	
<b>ginger</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>ginger, ground</b> [see ginger, jamaica]						
=====	=====	=====	=====	=====	=====	
<b>ginger, jamaica</b>						
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)	
<b>ginseng</b>						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
sedative	stimulant	stimulant	IIE	IIE	[39 FR 6104]	
<b>ginseng, korean</b>						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
<b>glutamic acid</b>						

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	benign prostatic hypertrophy	benign prostatic hypertrophy	IIE	IIISE	310.532(a)	
<b>glutamic acid hydrochloride</b>						
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)	
<b>glycerin</b>						
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(3)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(3)	
laxative	laxative	hyperosmotic laxative	I	I	pending	
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	DEF	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	IIISE	310.545(a)(18)(iii)	
miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)	
oral cavity	oral health care	demulcent	I	I	pending	

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
ophthalmic	ophthalmic	demulcent	I	I	349.12(d)(1)	
topical analgesic	otic	ear wax softening agent	I	IIIE	[51 FR 28660]	
topical analgesic	skin protectant	skin protectant	I	I	347.10(h)	
<b>glycerin, anhydrous</b>						
=====	otic	drying water/water clogged ears	n/a	IIIE	310.545(a)(15)(ii)	
=====	otic	swimmer's ear prevention	n/a	IIIE	310.545(a)(15)(ii)	
<b>glycerin, anhydrous [see glycerin]</b>						
=====	=====	=====	=====	=====	=====	
<b>glyceryl aminobenzoate</b>						
topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)	
<b>glycine</b>						
antacid	antacid	antacid	I	I	331.11(f)	
internal analgesic	internal analgesic	corrective	I	n/a	pending	
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(i)	
laxative	antiemetic	antiemetic	IIIE	IIIE	[52 FR 15891]	
miscellaneous internal	benign prostatic hypertrophy	benign prostatic hypertrophy	IIIE	IIISE	310.532(a)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>glycol salicylate</b>						
=====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>Review Panel</b>	<b>Report</b>				
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	pending
<b>glycyrrhiza</b>					
miscellaneous internal	aphrodisiac	aphrodisiac	IIE	IISE	310.528(a)
miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
<b>golden seal</b>					
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
<b>golden seal [see hydratis]</b>					
=====	=====	=====	=====	=====	=====
<b>gotu kola</b>					
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
<b>gramicidin</b>					
antimicrobial II	antibiotic	first aid antibiotic	n/a	IIISE	[52 FR 47322]
antimicrobial II	antibiotic	skin wound protectant	IIS	defer	[52 FR 47322]
antimicrobial II	antibiotic	skin wound antibiotic	IIISE	defer	[52 FR 47322]
<b>guaifenesin</b>					
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	341.18
<b>guar gum</b>					
laxative	laxative	bulk laxative	IIIE	IIIE	310.545(a)(12)(i)

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
<b>haloprogin</b>						
antimicrobial II	antifungal	anticandidal	I	n/a	n/a	
antimicrobial II	antifungal	antifungal	I	I	333.210(b)	
<b>hamamelis water of xi</b> [see witch hazel]						
=====	=====	=====	=====	=====	=====	
<b>hard fat</b>						
=====	skin protectant	skin protectant	n/a	n/a	347.10(i)	
hemorrhoidal	anorectal	protectant (external)	n/a	n/a	346.14(4)	
hemorrhoidal	anorectal	protectant (intrarectal)	n/a	n/a	346.14(4)	
<b>hectorite</b>						
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)	n/a	n/a	310.545(a)(18)(ii)	
<b>hemicellulase</b>						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(8)(i)	
miscellaneous internal	exocrine pancreatic insufficiency	exocrine pancreatic insufficiency	IIE	IIE	310.543(a)	
<b>hexachlorophene</b>						



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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antimicrobial I	antimicrobial	antimicrobial	IIS	n/a	[37 FR 20163]	
contraceptive/vaginal	vaginal	minor irritations	IISE	withdraw	n/a	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	IISE	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	skin protectant	diaper rash	defer	n/a	pending	
<b>hexylresorcinol</b>						
====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IIE	pending	
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	I	I	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIIE	IIIE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIIE	IIIE	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)
<b>histamine dihydrochloride</b>					
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
topical analgesic	external analgesic	counterirritant	I	I	pending
<b>histidine</b>					
miscellaneous internal	weight control	anorectic	IIIE	IIIE	310.545(a)(20)
<b>homatropine methylbromide</b>					
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)
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)
miscellaneous internal	menstrual/diuretic	smooth muscle relaxant	IIIE	IIIE	310.545(a)(24)(i)
<b>homosalate</b>					
miscellaneous external	external analgesic	fever blister (topical)	defer	defer	pending
topical analgesic	n/a	sunscreen	n/a	I	352.10(f)
<b>honey</b>					
miscellaneous external	external analgesic	astringent	IIIE	n/a	pending
miscellaneous external	skin protectant	astringent	IIIE	IIIE	310.545(a)(18)(ii)
<b>horehound</b>					

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
cough/cold	cough/cold (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]	
oral cavity	oral health care	expectorant	IIIE	IIIE	310.545(a)(6)(iii)	
<b>hormone constituents</b>						
miscellaneous external	hair growth/loss	hair grower	IISE	IIE	310.527(a)	
<b>horsetail</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>huckleberry</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>hyascyamine sulfate</b>						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
<b>hydrangea, powdered extract (extract of hydrangea)</b>						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
<b>hydrastis</b>						
hemorrhoidal	anorectal	counterirritant (intrarectal)	IISE	IISE	310.545(a)(26)(iv)	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(iv)	
hemorrhoidal	anorectal	counterirritant (external)	IISE	IISE	310.545(a)(26)(iv)	
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>hydrastis canadensis (golden seal)</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>hydrastis fluid extract</b>					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>hydrate magnesium aluminate activated sulfate</b>					
antacid	antacid	antacid	n/a	n/a	331.11(g)(1)
<b>hydriodic acid syrup</b>					
cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
<b>hydrochloric acid</b>					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>hydrochloric acid diluted</b> [see hydrochloric acid, diluted]					
=====	=====	=====	=====	=====	=====
<b>hydrochloric acid, diluted</b>					
miscellaneous internal	stomach acidifier	stomach acidifier	IIE	IIE	310.540(a)
<b>hydrocodone bitartrate</b>					
cough/cold	cough/cold (antitussive)	antitussive	IIS	IIS	[52 FR 30054]

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>hydrocortisone</b>						
antimicrobial II	antifungal	anti-inflammatory	I combo	n/a	n/a	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIISE	defer	n/a	
topical analgesic	external analgesic	antipruritic	I	I	pending	
<b>hydrocortisone (0.25-5%)</b>						
miscellaneous external	external analgesic	dandruff/seborrheic dermatitis/psoriasis	n/a	I	pending	
<b>hydrocortisone (0.5-1%)</b>						
miscellaneous external	external analgesic	dandruff	n/a	IIISE	pending	
<b>hydrocortisone acetate</b>						
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
antimicrobial II	antifungal	anti-inflammatory (dissent)	I combo	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	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIISE	defer	n/a	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
topical analgesic	external analgesic	antipruritic	I	I	pending	
<b>hydrocortisone acetate (0.25-5.0%)</b>						

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<b>Review Panel</b>	<b>Report</b>				
miscellaneous external	external analgesic	dandruff/seborrheic dermatitis/psoriasis	n/a	I	pending
<b>hydrocortisone acetate (0.25%-0.5%)</b>					
miscellaneous external	external analgesic	dandruff/seborrheic dermatitis /psoriasis	n/a	I	pending
<b>hydrocortisone alcohol [see hydrocortisone]</b>					
=====	=====	=====	=====	=====	=====
<b>hydrogen fluoride</b>					
dental	anticaries	anticavity dental rinse	n/a	III SE	310.545(a)(2)(i)
<b>hydrogen peroxide</b>					
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending
dental	oral mucosal injury	wound cleanser	I	I	pending
dental	oral mucosal injury	wound healing agent	III E	III E	310.534(a)
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	II SE	310.545(a)(10)(vii)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	II SE	310.545(a)(18)(vi)(A)
oral cavity	oral health care	antimicrobial	III E	III E	pending
oral cavity	oral health care	debriding agent	III	III	pending
<b>hydrogen peroxide and povidone iodine</b>					
=====	gingivitis/plaque	antiplaque/gingivitis	n/a	III SE	pending
<b>hydrogen peroxide and sodium bicarbonate</b>					
=====	gingivitis/plaque	antiplaque/gingivitis	n/a	III SE	pending

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc chloride</b>					
====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending
<b>hydroquinone</b>					
miscellaneous external	skin bleach	skin bleaching	I	I	pending
<b>hydroxyethyl cellulose</b>					
ophthalmic	ophthalmic	demulcent	I	I	349.12(a)(2)
<b>hydroxyethylcellulose [see hydroxyethyl cellulose]</b>					
====	====	====	====	====	====
<b>hydroxypropyl methylcellulose [see hypromellose]</b>					
====	====	====	====	====	====
<b>hyoscyamine sulfate</b>					
laxative	antidiarrheal	antidiarrheal	IIISE	IIISE	310.545(a)(3)
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>hypromellose</b>					
ophthalmic	ophthalmic	demulcent	I	I	349.12(a)(3)
<b>ibuprofen</b>					
====	internal analgesic	analgesic	n/a	I	[67 FR 54139]
====	internal analgesic	antipyretic	n/a	I	[67 FR 54139]

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>ichthammol</b>					
miscellaneous external	boil treatment	boil treatment	IISE	IIISE	310.531(a)
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
<b>impatiens biflora tincture</b>					
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
<b>infusion of rose petal</b> [see rose petal, infusion of]					
=====	=====	=====	=====	=====	=====
<b>inositol</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>iodine</b>					
miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending
<b>iodine complex/phosphate ester of alkylaryloxy polyethylene</b>					
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending
antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending



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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin preparation	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
<b>iodine tincture</b>						
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	preoperative skin prep	I	I	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIS	IIS	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	
antimicrobial I	antimicrobial	skin wound protectant	IISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIS	IIIS	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIS	IIIS	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IISE	IISE	pending	
<b>iodine topical solution</b>						
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
<b>iodized lime</b>						
cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)	
<b>iodoantipyrine</b>						

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
internal analgesic	internal analgesic	analgesic	IISE	IISE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antipyretic	IISE	IISE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	310.545(a)(23)(i)	
<b>iodochlorhydroxyquin</b> [see clioquinol]						
=====	=====	=====	=====	=====	=====	
<b>ipecac</b>						
cough/cold	cough/cold (expectorant)	expectorant	IIE	IIE	310.545(a)(6)(iii)	
<b>ipecac fluidextract</b>						
cough/cold	cough/cold (expectorant)	expectorant	IIE	IIE	310.545(a)(6)(iii)	
miscellaneous internal	poison treatment	emetic	n/a	IIS	310.545(a)(16)	
<b>ipecac syrup</b>						
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)	
miscellaneous internal	emetic	emetic	I	I	pending	
miscellaneous internal	poison treatment	emetic	n/a	I	pending	
<b>ipecac tincture</b>						
miscellaneous internal	poison treatment	emetic	n/a	IIS	310.545(a)(16)	
<b>ipomea</b>						
laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)	
<b>iron ox bile</b>						

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>iron oxide</b>					
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	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)
<b>isobornyl thiocynoacetate</b>					
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
<b>isobutamben</b>					
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
<b>isobutyl p-aminobenzoate [see isobutaben]</b>					
====	====	====	====	====	====
<b>isoleucine</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>isopropyl alcohol</b>					
miscellaneous external	alcohols (topical)	antiseptic	I	I	pending
miscellaneous external	mercury	first aid antiseptic	n/a	I	pending

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>Review Panel</b>	<b>Report</b>				
miscellaneous external	external analgesic	astringent	IISE	n/a	pending
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
<b>isopropyl palmitate</b>					
=====	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)
<b>jalap</b>					
laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
<b>johns wort</b>					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>jojoba oil</b>					
miscellaneous external	hair growth/loss	hair grower	n/a	IIE	310.527(a)
<b>juniper</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>juniper oil (oil of juniper)</b>					
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>juniper tar</b>						
=====	antifungal	diaper rash	n/a	n/a	310.545(a)(22)(i)	
=====	antimicrobial	diaper rash	n/a	n/a	pending	
=====	external analgesic	diaper rash	n/a	IISE	310.545(a)(10)(iv)	
=====	external analgesic	fever blister (topical)	n/a	I	pending	
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
=====	skin protectant	diaper rash	n/a	n/a	pending	
hemorrhoidal	anorectal	counterirritant (external)	IISE	n/a	n/a	
hemorrhoidal	anorectal	analgesic (external)	n/a	I	346.16(b)	
hemorrhoidal	anorectal	counterirritant (intrarectal)	IISE	n/a	n/a	
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)	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
<b>juniper, extract</b>						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
<b>kaolin</b>						
=====	skin protectant	poison ivy/oak/sumac	n/a	I	347.10(j)	
antacid	antacid	antacid	IIIE	IIIE	[39 FR 19873]	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(5)	

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(5)	
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	347.10(b)	
miscellaneous external	skin protectant	diaper rash	n/a	I	pending	
topical analgesic	skin protectant	skin protectant	I	I	347.10(j)	
<b>kaolin, colloidal</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>karaya [see karaya gum]</b>						
=====	=====	=====	=====	=====	=====	
<b>karaya gum</b>						
laxative	laxative	bulk laxative	I	I	pending	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
<b>kelp</b>						
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
<b>knotgrass</b>						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
<b>lactic acid</b>						
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIIE	withdraw	n/a	
contraceptive/vaginal	vaginal	alters vaginal pH	IIIE	withdraw	n/a	

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	wart remover	wart remover	IIIE	IIIE	[55 FR 33254]	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>lactobacillus acidophilus</b>						
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(i)	
miscellaneous internal	fever blister (oral)	fever blister/oral	IIIE	IIIE	310.537(a)	
<b>lactobacillus bulgaricus</b>						
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(i)	
miscellaneous internal	fever blister (oral)	fever blister/oral	IIIE	IIIE	310.537(a)	
<b>lactose</b>						
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)	
<b>lanolin</b>						
====	skin protectant	skin protectant	n/a	n/a	347.10(k)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(6)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(6)	
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)	

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	hair growth/loss	hair grower	IIE	IIE	310.527(a)
miscellaneous external	skin protectant	diaper rash	defer	I	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
<b>lanolin (in combination)</b>					
ophthalmic	ophthalmic	emollient	I	I	349.14(a)(2)
<b>lanolin alcohol</b> [see lanolin alcohols]					
=====	=====	=====	=====	=====	=====
<b>lanolin alcohols</b>					
hemorrhoidal	anorectal	protectant (external)	I	IIISE	310.545(a)(26)(viii)
hemorrhoidal	anorectal	protectant (intrarectal)	I	IIISE	310.545(a)(26)(viii)
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
<b>lanolin anhydrous</b> [see lanolin, anhydrous]					
=====	=====	=====	=====	=====	=====
<b>lanolin nonionic derivatives</b>					
ophthalmic	ophthalmic	emollient	I	I	349.14



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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>lanolin, anhydrous (in combination)</b>						
ophthalmic	ophthalmic	emollient	I	I	349.14(a)(1)	
<b>lappa extract</b>						
hemorrhoidal	anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)	
hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)	
<b>laureth 10s</b>						
contraceptive/vaginal	contraceptive (vaginal)	contraceptive	IIIE	withdraw	310.545(a)(28)	
<b>lauric diethanolamide</b>						
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)	
<b>lauryl isoquinolinium bromide</b>						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIE	IIIE	310.545(a)(7)	
<b>lavender compound, tincture of</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
<b>lavender oil</b>						
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	
<b>lawsone with dihydroxyacetone</b>						
topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)	

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>l-desoxyephedrine</b> [see desoxyephedrine, l-]					
=====	=====	=====	=====	=====	=====
<b>lead acetate</b>					
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)
<b>lecithin</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>lemon oil (terpeneless)</b>					
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
<b>leptandra extract</b>					
hemorrhoidal	anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)
hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)
<b>leucine</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>levmetamfetamine</b>					
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant))	IIIE	I	341.20(b)(1)
<b>levomethamphetamine</b> [see desoxyephedrine, l-]					
=====	=====	=====	=====	=====	=====
<b>licorice</b>					

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
<b>licorice root extract</b>					
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
<b>lidocaine</b>					
hemorrhoidal	anorectal	anesthetic (external)	IIIE	I	346.10(f)
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
miscellaneous external	male genital desensitizer	male genital desensitizer	I	I	348.10(a)(2)
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>lidocaine hydrochloride</b>					
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>linden</b>					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>lipase</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>live yeast cell derivative</b>					
=====	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)
topical analgesic	skin protectant	skin protectant	IIIE	IIIE	310.545(a)(18)(i)(B)
<b>liver concentrate</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>lobeline</b>					
miscellaneous internal	smoking deterrent	smoking deterrent	IIIE	IIIE	310.544(d)
<b>lysine</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>lysine aspirin</b>					
internal analgesic	internal analgesic	analgesic	n/a	IISE	310.545(a)(23)(i)
<b>lysine hydrochloride</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	fever blister (oral)	fever blister/oral	IIIE	IIIE	310.537(a)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>magaldrate</b>					

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	antacid		antacid	antacid	I	I	331.11(g)(2)
<b>magnesium</b>							
	miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>magnesium aluminum silicate</b>							
	antimicrobial II		acne	acne	IIE	IIE	310.545(a)(1)
	antacid		antacid	antacid	I	I	331.11(g)(3) 331.11(k)(2)(1)
<b>magnesium aluminumsilicate</b> [see magnesium aluminum silicate]							
	=====		=====	=====	=====	=====	=====
<b>magnesium carbonate</b>							
	antacid		antacid	antacid	I	I	331.11(g)(4)
	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		skin protectant	diaper rash	defer	n/a	pending
	miscellaneous internal		overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
<b>magnesium citrate</b>							
	laxative		laxative	saline laxative (oral solution)	I	I	pending
<b>magnesium glycinate</b>							

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antacid	antacid	antacid	I	I	331.11(g)(5)	
<b>magnesium hydroxide</b>						
antacid	antacid	antacid	I	I	331.11(g)(6)	
internal analgesic	internal analgesic	corrective	I	n/a	pending	
laxative	laxative	saline laxative	I	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)	
<b>magnesium oxide</b>						
antacid	antacid	antacid	I	I	331.11(g)(7)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
<b>magnesium salicylate</b>						
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 internal	menstrual/diuretic	analgesic	I	I	pending	
<b>magnesium sulfate</b>						
antimicrobial II	acne	acne	IIIE	IIIE	310.545(a)(1)	
laxative	laxative	saline laxative	I	I	pending	
miscellaneous external	boil treatment	boil treatment	IISE	IIIE	310.531(a)	

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<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
		miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>magnesium trisilicate</b>							
		antacid	antacid	antacid	I	I	331.11(g)(8)
		miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	IIIE	331.11(k)(3)(1) 310.545(a)(8)(i)
		miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
<b>malt</b>							
		miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>malt soup extract</b>							
		laxative	laxative	bulk laxative	I	I	pending
<b>maltodextrin</b>							
		miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>mandrake</b>							
		miscellaneous internal	aphrodisiac	aphrodisiac	n/a	n/a	310.528(a)
<b>manganese citrate</b>							
		miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>mannitol</b>							
		miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
		miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>meclizine hydrochloride</b>							

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
laxative	antiemetic	antiemetic	I	I	336.10(d)	
<b>menfegol</b>						
contraceptive/vaginal	contraceptive (vaginal)	contraceptive (dissent)	I	withdraw	n/a	
<b>menthol</b>						
antimicrobial II	antifungal	antifungal	IIE	IIE	310.545(a)(22)(ii)	
cough/cold	cough/cold (antitussive)	antitussive (mouthwash)	IIIE	IIIE	[52 FR 30055]	
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	IIIE	I	341.14(b)(2)	
cough/cold	cough/cold (antitussive)	antitussive (lozenge)	IIIE	I	341.14(b)(2)	
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	IIIE	IIIE	310.545(a)(6)(iii)	
cough/cold	cough/cold (expectorant)	expectorant (lozenge)	IIIE	IIIE	310.545(a)(6)(iii)	
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)	
dental	relief of oral discomfort	toothache relief	IIS	IIS	pending	
hemorrhoidal	anorectal	analgesic (external)	n/a	I	346.16(c)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)	
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	pending	
miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)	



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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>Review Panel</b>	<b>Report</b>				
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	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	defer	pending
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)
miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
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	I	I	pending
topical analgesic	external analgesic	counterirritant	I	I	pending
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>menthol (0.1 to 1.0%)</b>					
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
<b>menthol (1.25 to 16%)</b>					
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
hemorrhoidal	anorectal	counterirritant (intrarectal)	IIE	IIE	310.545(a)(26)(iv)

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
hemorrhoidal	anorectal	counterirritant (external)	I	IIE	310.545(a)(26)(iv)
<b>menthyl anthranilate</b> [see meradimate]					
=====	=====	=====	=====	=====	=====
<b>meradimate</b>					
topical analgesic	sunscreen	sunscreen	I	I	352.10(h)
<b>meralein sodium</b>					
oral cavity	oral health care	antimicrobial	IISE	IISE	pending
<b>merbromin</b>					
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)
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
<b>merbromin (mercurochrome)</b>					
miscellaneous external	mercury	first aid antiseptic	n/a	IIIE	310.545(a)(27)(i)
<b>mercufenol chloride</b>					
miscellaneous external	mercury	first aid antiseptic	n/a	IIIE	310.545(a)(27)(i)
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
miscellaneous external	antimicrobial	first aid antiseptic	n/a	IIS	310.545(a)(27)(i)
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)

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Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
<b>mercuric chloride</b> [see calomel]					
=====	=====	=====	=====	=====	=====
<b>mercuric oxide, yellow</b>					
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)
ophthalmic	ophthalmic	anti-infective	IIISE	IISE	310.545(a)(21)(ii)
<b>mercuric salicylate</b>					
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)
<b>mercuric sulfide, red</b>					
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)
<b>mercurous chloride</b> [see calomel]					
=====	=====	=====	=====	=====	=====
<b>mercury</b>					
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)
<b>mercury (any ingredient)</b>					
=====	antimicrobial	diaper rash	defer	n/a	310.545(a)(27)(ii)

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Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
====	contraceptive (vaginal)	contraceptive	n/a	n/a	310.545(a)(28)
<b>mercury chloride</b> [see mercuric chloride]					
====	====	====	====	====	====
<b>mercury oleate</b>					
miscellaneous external	mercury	first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	310.545(a)(7)
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
<b>mercury, ammoniated</b>					
miscellaneous external	antimicrobial	first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
miscellaneous external	skin bleach	skin bleaching	IISE	IISE	310.545(a)(17)
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
<b>metaproterenol sulfate</b>					
cough/cold	cough/cold (bronchodilator)	bronchodilator	n/a	III	310.545(a)(6)(iv)(A)
<b>methapyrilene</b>					
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
<b>methapyrilene fumarate</b>					

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<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>Review Panel</b>	<b>Report</b>				
cough/cold	cough/cold (antihistamine)	antihistamine	I	IIS	310.545(a)(6)(i)(A)&(B)
internal analgesic	internal analgesic	analgesic adjuvant	IIIE	IIS	310.545(a)(23)(i)
internal analgesic	internal analgesic	antihistamine	IIIE	n/a	310.545(a)(6)(A)
internal analgesic	internal analgesic	antipyretic adjuvant	IIIE	IIS	310.545(a)(23)(i)
internal analgesic	internal analgesic	antirheumatic adjuvant	IIIE	IIS	310.545(a)(23)(i)
sedative	daytime sedative	sedative	IIISE	IISE	310.519(a)
sedative	nighttime sleep aid	sleep aid	IIISE	IIS	[54 FR 6826]
<b>methapyrilene hydrochloride</b>					
====	external analgesic	poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)
cough/cold	cough/cold (antihistamine)	antihistamine	I	IIS	310.545(a)(6)(i)(A)&(B)
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)
sedative	nighttime sleep aid	sleep aid	IIISE	IIS	[54 FR 6826]
sedative	daytime sedative	sedative	IIISE	IIS	310.519(a)
topical analgesic	external analgesic	analgesic/anesthetic	I	IIS	310.545(a)(10)(i)
<b>methenamine</b>					
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>methionine</b>					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
<b>methoxyphenamine hydrochloride</b>						
cough/cold	cough/cold (bronchodilator)	bronchodilator	I	IIE	310.545(a)(6)(iv)(A)	
<b>methoxypolyoxyethylene glycol 550 laurate</b>						
contraceptive/vaginal	contraceptive (vaginal)	contraceptive	IIIE	IIIE	310.545(a)(28)	
<b>methyl nicotinate</b>						
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	
topical analgesic	external analgesic	counterirritant	I	I	pending	
<b>methyl salicylate</b>						
dental	relief of oral discomfort	toothache relief	IISE	IISE	pending	
dental	relief of oral discomfort	oral mucosal analgesic	IISE	IISE	pending	
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	astringent	n/a	n/a	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)	

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]	
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	counterirritant	I	I	pending	
<b>methylbenzethonium chloride</b>						
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	I	I	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIE	IIIE	pending	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	IIISE	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	cradle cap	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]	
<b>methylcellulose</b>						
antacid	antacid	antacid	IIIE	IIIE	[39 FR 19873]	
laxative	laxative	bulk laxative	I	I	pending	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
ophthalmic	ophthalmic	demulcent	I	I	349.12(a)(4)	
<b>methylene blue</b>						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
<b>methylparaben</b>						
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
<b>methyltestosterone</b>						
miscellaneous internal	aphrodisiac	aphrodisiac	IIS	IIS	310.528(a)	
<b>miconazole nitrate</b>						
antimicrobial II	antifungal	anticandidal	I	n/a	n/a	
antimicrobial II	antifungal	antifungal	I	I	333.210(c)	
<b>microporous cellulose [see cellulose, microporous]</b>						
=====	=====	=====	=====	=====	=====	
<b>milk solids, dried</b>						



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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antacid	antacid	antacid	I	I	331.11(h)	
<b>mineral oil</b>						
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(7)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(7)	
laxative	laxative	lubricant laxative	I	I	pending	
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	n/a	pending	
ophthalmic	ophthalmic	emollient	I	I	349.14(b)(2)	
<b>mineral oil, emulsified</b> [see mineral oil]						
====	====	====	====	====	====	
<b>mineral oil, light</b>						
ophthalmic	ophthalmic	emollient	I	I	349.14(b)(1)	
<b>minerals</b>						
miscellaneous internal	aphrodisiac	aphrodisiac	n/a	IISE	310.528(a)	
<b>mono-and di-glycerides</b>						

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		miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>mullein</b>							
	hemorrhoidal		anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)
	hemorrhoidal		anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)
<b>mustard oil</b> [see allyl isothiocyanate]							
	=====		=====	=====	=====	=====	=====
<b>mycozyme</b>							
	miscellaneous internal		digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>myrrh</b>							
	dental		relief of oral discomfort	oral mucosal protectant	IIISE	IIISE	pending
<b>myrrh tincture</b>							
	oral cavity		oral health care	antimicrobial	IISE	IISE	310.545(a)(14)
	oral cavity		oral health care	astringent	IISE	IISE	pending
<b>myrrh tincture of</b> [see myrrh tincture]							
	=====		=====	=====	=====	=====	=====
<b>myrrh, fluid extract of</b>							
	miscellaneous internal		digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>naphazoline hydrochloride</b>							

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<b>Review Panel</b>	<b>Report</b>				
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant))	I	I	341.20(b)(6)
ophthalmic	ophthalmic	vasoconstrictor	I	I	349.18(b)
<b>natural estrogenic hormone</b>					
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)
<b>neomycin sulfate</b>					
antimicrobial II	antibiotic	skin wound protectant	IIIS	defer	n/a
<b>neomycin sulfate (cream)</b>					
antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.110(e)
<b>neomycin sulfate (ointment)</b>					
antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.110(d)
<b>nettle</b>					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>niacinamide</b>					
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	daytime sedative	sedative	IIE	IISE	310.519(a)
<b>nickel-pectin</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)

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Review Panel	Report				
<b>nitromersol</b>					
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)
oral cavity	oral health care	antimicrobial	IISE	IISE	pending
<b>nonoxynol 9</b>					
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	I	withdraw	n/a
contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a
contraceptive/vaginal	contraceptive (vaginal)	contraceptive	I	withdraw	n/a
<b>nonylphenoxypoly (ethyleneoxy) ethanol iodine</b>					
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending
antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending
antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending
<b>noscapine</b>					
cough/cold	cough/cold (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]
<b>noscapine hydrochloride</b>					

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		cough/cold	cough/cold (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]
<b>nucleic acids</b>							
		miscellaneous external	hair growth/loss	hair grower	n/a	n/a	310.527(a)
<b>nutmeg oil (oil of nutmeg)</b>							
		miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>nux vomica</b>							
		miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
<b>nux vomica extract</b>							
		miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>nystatin</b>							
		antimicrobial II	antifungal	anticandidia	I	IIISE	310.545(a)(22)(iv)
<b>obtundia surgical dressing</b>							
		miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	pending
		miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	pending
<b>octinoxate</b>							
		topical analgesic	sunscreen	sunscreen	I	I	352.10(j)
<b>octisalate</b>							
		topical analgesic	sunscreen	sunscreen	I	I	352.10(k)
<b>octocrylene</b>							

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<b>Review Panel</b>	<b>Report</b>				
topical analgesic	sunscreen	sunscreen	I	I	352.10(i)
<b>octoxynol 9</b>					
contraceptive/vaginal	vaginal	minor irritations	IIIE		withdraw 310.545(a)(28)(ii)
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	I		withdraw 310.545(a)(28)(ii)
contraceptive/vaginal	contraceptive (vaginal)	contraceptive	I		withdraw 310.545(a)(28)(ii)
<b>octyl salicylate</b> [see octisalate]					
=====	=====	=====	=====	=====	=====
<b>octyldodecanol</b>					
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
<b>octylmethoxycinnamate</b> [see octinoxate]					
=====	=====	=====	=====	=====	=====
<b>octyl triazone</b>					
n/a	TEA	sunscreen	n/a		
<b>oil of erigeron</b>					
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>olive oil</b>					
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
<b>opium powder</b> [see opium, powdered]					

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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	=====	=====	=====	=====	=====	=====
<b>opium tincture</b>						
laxative		antidiarrheal	antidiarrheal	I	IIISE	310.545(a)(3)(i)
<b>opium, tincture of</b> [see opium tincture]						
	=====	=====	=====	=====	=====	=====
<b>opium, powdered</b>						
laxative		antidiarrheal	antidiarrheal	I	IIISE	310.545(a)(3)(i)
<b>organic vegetables</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>orthophosphoric acid</b>						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>orthophosphoric acid</b> [see phosphoric acid]						
	=====	=====	=====	=====	=====	=====
<b>ox bile</b>						
laxative	laxative		stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)
<b>ox bile extract</b>						
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)
<b>oxybenzone</b>						

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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
topical analgesic	sunscreen	sunscreen	I	I	352.10(l)	
<b>oxymetazoline hydrochloride</b>						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(7)	
<b>oxyquinoline</b>						
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	IIISE	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	
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
<b>oxyquinoline citrate</b>						
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
<b>oxyquinoline sulfate</b>						
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
<b>oxyquinoline sulfate</b> [see oxyquinoline]						



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<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
=====	=====	=====	=====	=====	=====	=====
<b>oxytetracycline hydrochloride</b>						
antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.120 [compos]	
antimicrobial II	antibiotic	skin wound antibiotic	IIIE	defer	n/a	
antimicrobial II	antibiotic	skin wound protectant	I	defer	n/a	
<b>ozokerite</b>						
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a	