

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<b>dexpanthenol</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	IIE	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	IISE	IISE	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)

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	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)

**OTC Ingredient List**  
*Updated July 2003*

<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	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>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>					
antacid	antacid	antacid	n/a	n/a	331.11(a)(3)
internal analgesic	internal analgesic	corrective	I	n/a	n/a

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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)	IIIE	IIIE	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>						
	hemorrhoidal	anorectal	anesthetic (intrarectal)	IIISE	IIISE	310.545(a)(26)(vi)
	hemorrhoidal	anorectal	anesthetic (external)	IIIE	IIIE	310.545(a)(26)(vi)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<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)	
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)	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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>						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IISE	IISE	310.545(a)(8)(i)



**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<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)	
<b>elecampane</b>						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<b>elm bark</b>						
cough/cold	cough/cold (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]	
oral cavity	oral health care	demulcent	I	I	pending	
<b>endothemic hectorite [see hectorite]</b>						
=====	=====	=====	=====	=====	=====	
<b>ensulizole</b>						
topical analgesic	sunscreen	sunscreen	I	I	352.10(n)	
<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)	IIIE	IIIE	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>						
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)	

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	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)
	hemorrhoidal	anorectal	vasoconstrictor (intrarectal)	IIIE	IIIE	346.10(c)
<b>epinephrine hydrochloride (racemic) [see epinephrine hydrochloride]</b>						
	=====	=====	=====	=====	=====	=====

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<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>						
=====	=====	=====	=====	=====	=====	
<b>essential oils</b>						
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<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>							
	topical analgesic		sunscreen	sunscreen	I	I	310.545(a)(29)
<b>ethyl alcohol [see alcohol]</b>							
	=====		=====	=====	=====	=====	=====

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<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)(C)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIE	IIIE	310.545(a)(6)(ii)(C)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIE	310.545(a)(6)(ii)(C)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(6)(ii)(C) 310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending	
oral cavity	oral health care	analgesic/anesthetic	IIIE	IIIE	310.545(a)(14)	
<b>eucalyptol, menthol, methyl salicylate, and thymol</b>						
====	gingivitis/plaque	antiplaque/gingivitis	n/a	I	pending	
<b>eucalyptus oil</b>						
====	external analgesic	fever blister (topical)	n/a	IIIE	310.545(a)(10)(v)	
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 (antitussive)	antitussive (topical/inhalant)	IIIE	IIIE	[52 FR 30055]	
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 (mouthwash)	IIIE	IIIE	310.545(a)(6)(ii)(A)	
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	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	IISE	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	

**OTC Ingredient List**  
*Updated July 2003*

<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	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
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	poison ivy/oak/sumac	defer	IISE	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	IIISE	pending
miscellaneous external	external analgesic	astringent	IISE	n/a	pending
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)
<b>euphorbia pilulifera</b>					
cough/cold	cough/cold (bronchodilator)	bronchodilator	IIIE	IIIE	310.545(a)(6)(iv)(A)
<b>extract white pine compound [see white pine extract, compound]</b>					
=====	=====	=====	=====	=====	=====



**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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)
<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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<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</b> [see ergot, fluidextract]							
	=====		=====	=====	=====	=====	=====
<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>							
	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIE	IIE	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
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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<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>							
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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
	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
====	otic	swimmer's ear prevention	n/a	III E	310.545(a)(15)(ii)
<b>glycerin, anhydrous</b> [see glycerin]					
====	====	====	====	====	====
<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	II E	II E	310.545(a)(3)(i)
laxative	antiemetic	antiemetic	II E	II E	[52 FR 15891]
miscellaneous internal	benign prostatic hypertrophy	benign prostatic hypertrophy	II E	III SE	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	III E	310.545(a)(10)(vii)
miscellaneous external	external analgesic	fever blister (topical)	defer	III E	310.545(a)(10)(v)
topical analgesic	external analgesic	analgesic/anesthetic	III E	III E	pending
<b>glycyrrhiza</b>					
miscellaneous internal	aphrodisiac	aphrodisiac	II E	II SE	310.528(a)
miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	n/a	II SE	310.545(a)(24)(i)

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<b>golden seal</b>						
	miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
<b>golden seal</b> [see hydratis]						
	=====	=====	=====	=====	=====	=====
<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)
	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<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>					
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)



**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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	
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	IISE	310.545(a)(10)(v)	
topical analgesic	external analgesic	counterirritant	I	I	pending	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<b>histidine</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>homatropine methylbromide</b>						
laxative	antidiarrheal		antidiarrheal	IIISE	IIISE	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)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	menstrual/diuretic		smooth muscle relaxant	IIE	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	IISE	n/a	pending
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
<b>horehound</b>						
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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)
<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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel						
<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]
<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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<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>					
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>					
=====	=====	=====	=====	=====	=====

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<b>hydrogen fluoride</b>						
	dental	anticaries	anticavity dental rinse	n/a	IIISE	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	IIIE	IIIE	310.534(a)
	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)
	oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending
	oral cavity	oral health care	debriding agent	III	III	pending
<b>hydrogen peroxide and povidone iodine</b>						
	====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending
<b>hydrogen peroxide and sodium bicarbonate</b>						
	====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending
<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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<b>hydroxyethyl cellulose</b>					
ophthalmic	ophthalmic	demulcent	I	I	349.12(a)(2)
<b>hydroxyethylcellulose</b> [see hydroxyethyl cellulose]					
=====	=====	=====	=====	=====	=====
<b>hydroxypropyl methylcellulose</b> [see hypromellose]					
=====	=====	=====	=====	=====	=====
<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]
<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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
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
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



**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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>						
	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 [see clioquinol]</b>						
	=====	=====	=====	=====	=====	=====

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>	Review Panel	Report	Drug Category	ANPR	PR	FR
<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>						
	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
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
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)

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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)
<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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
====	skin protectant	diaper rash	n/a	n/a	pending	
hemorrhoidal	anorectal	counterirritant (external)	IIISE	n/a	n/a	
hemorrhoidal	anorectal	analgesic (external)	n/a	I	346.16(b)	
hemorrhoidal	anorectal	counterirritant (intrarectal)	IIISE	n/a	n/a	
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)	
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)	
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)	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
<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)	
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	IIIE	IIIE	310.527(a)	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
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
<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)



**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<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)
<b>l-desoxyephedrine [see desoxyephedrine, l-]</b>							
	=====		=====	=====	=====	=====	=====
<b>lead acetate</b>							
	miscellaneous external		external analgesic	poison ivy/oak/sumac	defer	IISE	
	miscellaneous external		skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii) 310.545(a)(18)(vi)(A)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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>						
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>Review Panel</b>	<b>Report</b>				
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)
<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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</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>							
	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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>						
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	

**OTC Ingredient List**  
*Updated July 2003*

<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 (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)
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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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>						
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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)	
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	



**OTC Ingredient List**  
*Updated July 2003*

<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	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)
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<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)
<b>mercuric chloride [see calomel]</b>					
=====	=====	=====	=====	=====	=====
<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)

**OTC Ingredient List**  
*Updated July 2003*

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
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 [see calomel]</b>					
=====	=====	=====	=====	=====	=====
<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)
=====	contraceptive (vaginal)	contraceptive	n/a	n/a	310.545(a)(28)
<b>mercury chloride [see mercuric chloride]</b>					
=====	=====	=====	=====	=====	=====
<b>mercury oleate</b>					
miscellaneous external	mercury	first aid antiseptic	n/a	IISE	310.545(a)(27)(i)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
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>						
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	IIE	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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
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	IIE	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)
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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)
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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)	
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	

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
ophthalmic	ophthalmic	demulcent	I	I	349.12(a)(4)	
<b>methylen 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</b> [see cellulose, microporous]						
=====	=====	=====	=====	=====	=====	
<b>milk solids, dried</b>						
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	



**OTC Ingredient List**  
*Updated July 2003*

<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	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>					
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)

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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>						
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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)
<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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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>						
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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>						
Review Panel	Report		Drug Category	ANPR	PR	FR
<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>						
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)

**OTC Ingredient List**  
*Updated July 2003*

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
<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>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]	=====	=====	=====	=====	=====	=====
<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)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
Review Panel	Report				
<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)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
<b>oxybenzone</b>					
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

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>		<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
		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]							
		=====	=====	=====	=====	=====	=====
<b>oxytetracycline hydrochloride</b>							
		antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.120 [combos]
		antimicrobial II	antibiotic	skin wound antibiotic	IIIE	defer	n/a
		antimicrobial II	antibiotic	skin wound protectant	I	defer	n/a



**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>	Review Panel	Report	Drug Category	ANPR	PR	FR
<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