

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
2-ethylhexyl salicylate [see octyl salicylate]						
=====	=====	=====	=====	=====	=====	
2-ethylhexyl-4-phenylbenzophenone-2-carboxylic acid						
topical analgesic	sunscreen	sunscreen	IISE	IISE	pending	
5-(3,3-dimethyl-2-norbornylidene)3-pentene-2-one [see bornelone]						
=====	=====	=====	=====	=====	=====	
8-hydroxyquinoline [see oxyquinoline]						
=====	=====	=====	=====	=====	=====	
acetaminophen						
internal analgesic	internal analgesic	analgesic	I	I	pending	
internal analgesic	internal analgesic	antipyretic	I	I	pending	
internal analgesic	internal analgesic	antirheumatic	IIE	not OTC	n/a	
miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending	
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending	
sedative	nighttime sleep aid	sleep aid	IIE	IIE	[54 FR 6826]	
sedative	daytime sedative	sedative	IISE	IISE	310.519(a)	
acetanilid [see acetanilide]						
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OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
acetanilide						
internal analgesic	internal analgesic	analgesic	IIS	IIS	pending	
internal analgesic	internal analgesic	antipyretic	IIS	IIS	pending	
internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	n/a	
acetic acid						
====	otic	swimmer's ear prevention	n/a	IIIE	310.545(15)(i)	
contraceptive/vaginal	vaginal	alters vaginal pH	IIIE	withdraw	n/a	
miscellaneous external	wart remover	wart remover	IIISE	IIISE	[55 FR 33254]	
acetic acid, glacial						
miscellaneous external	wart remover	wart remover	IIIE	IIISE	[55 FR 33254]	
miscellaneous external	corn/callus remover	corn/callus remover	IIIE	IIISE	[55 FR 33261]	
acetone						
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(18)(ii)	
acidulated phosphate fluoride (sod fluoride/sod phos /phos acid)						
dental	anticaries	anticavity dental rinse	I	I	355.10(a)(2)(ii)	
acidulated phosphate fluoride (sodium fluoride/hydrogen fluoride)						
dental	anticaries	anticavity dental rinse	IIS	IIS	355.10(a)(2)(ii)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
acidulated phosphate fluoride (sodium fluoride/sodium phos dibasic/ phos acid)						
dental	anticaries	anticavity dental rinse	I	I	355.10(a)(3)(ii)	
agar						
laxative	laxative	bulk laxative	IIIE	IIIE	310.545(12)(i)	
alanine						
miscellaneous internal	benign prostatic hypertrophy	benign prostatic hypertrophy	IIE	IIISE	310.532(a)	
alcloxa						
antimicrobial II	acne	acne	IIE	IIE	310.545(1)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(22)(ii)	
hemorrhoidal	anorectal	keratolytic (external)	I	I	346.20(a)	
hemorrhoidal	anorectal	keratolytic (intrarectal)	I	I	346.20(a)	
alcohol						
miscellaneous external	alcohols (topical)	antiseptic	I	defer	n/a	
miscellaneous external	mercury	first aid antiseptic	n/a	I	pending	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	defer	n/a	
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)	
miscellaneous external	skin protectant	fever blister (topical)	IISE	IISE	pending	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
miscellaneous internal	menstrual/diuretic	analgesic adjuvant	n/a	IISE	310.545(a)(24)(i)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
oral cavity	oral health care	antimicrobial	IIIE	IIISE	pending	
alcohol, 14 percent [see alcohol]						
=====	=====	=====	=====	=====	=====	
alcohol, ethoxylated alkyl						
=====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(A)	
aldioxa						
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending	
alfalfa						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
alfalfa leaves						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
alginic acid						
antacid	antacid	antacid	IIIE	IIIE	[39 FR 19873]	
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
alkaloids of sabadilla [see sabadilla alkaloids]						
=====	=====	=====	=====	=====	=====	
alkyl arylsulfonate						
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIIE	withdraw	n/a	
alkyl dimethyl amine oxide and alkyl dimethyl glycine						
=====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending	
alkyl isoquinolinium bromide						
antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIE	IIIE	310.545(a)(7)	
alkyldimethyl benzylammonium chloride [see benzalkonium chloride]						
=====	=====	=====	=====	=====	=====	
allantoin						
contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a	
dental	oral mucosal injury	wound healing agent	IIIE	IIIE	310.534(a)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIE	pending	
miscellaneous external	hair growth/loss	hair grower	IIE	n/a	310.527(a)	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIE	pending	
miscellaneous external	corn/callus remover	corn/callus remover	IIE	IIE	[55 FR 33261]	
topical analgesic	skin protectant	skin protectant	I	I	347.10(a)	
topical analgesic	skin protectant	wound healing agent	IIIE	IIIE	310.545(a)(18)(i)(A)	
allantoin (with aminobenzoic acid)						
topical analgesic	sunscreen	sunscreen	IIIE	IIIE	[64 FR 27682]	
allyl isothiocyanate						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIE	IIE	310.545(a)(6)(ii)(A)	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIE	310.545(a)(10)(v)	
topical analgesic	external analgesic	counterirritant	I	I	pending	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
almadrade sulfate						
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	n/a	310.545(a)(8)(ii)	
aloe						
=====	skin protectant	diaper rash	n/a	withdraw	n/a	
contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a	
laxative	laxative	stimulant laxative	I	I/IIIS	310.545(a)(12)(iv)(C)	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
aloe extract						
=====	laxative	stimulant laxative	n/a	n/a	310.545(a)(12)(iv)(C)	
aloe flower extract						
=====	laxative	stimulant laxative	n/a	n/a	310.545(a)(12)(iv)(C)	
aloe vera [see aloe]						
=====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIIE	pending	
aloe vera stabilized [see aloe]						
=====	=====	=====	=====	=====	=====	
aloes [see aloe]						
=====	=====	=====	=====	=====	=====	
aloin						
laxative	laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)	

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
alum (powdered alum) [see alum, ammonium/alum, potassium]					
=====	=====	=====	=====	=====	=====
alum [see alum, ammonium/alum, potassium]					
=====	=====	=====	=====	=====	=====
alum ammonium [see alum, ammonium]					
=====	=====	=====	=====	=====	=====
alum, ammonium					
contraceptive/vaginal	vaginal	astringent	IIIE	withdraw	n/a
miscellaneous external	external analgesic	astringent	IISE	n/a	pending
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
oral cavity	astringent	astringent	I	defer	n/a
oral cavity	oral health care	astringent	I	I	pending
alum, potassium					
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)
antiperspirant	antiperspirant	antiperspirant	IIISE	IIISE	310.545(a)(4)
contraceptive/vaginal	vaginal	astringent	IIIE	withdraw	n/a
miscellaneous external	external analgesic	astringent	IISE	n/a	pending
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(18)(ii)
oral cavity	oral health care	astringent	I	I	pending

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
aluminum acetate						
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	I	I	347.12(a)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		astringent	I	I	347.10(a)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	pending
aluminum aspirin [see aspirin, aluminum]						
=====	=====		=====	=====	=====	=====
aluminum bromohydrate						
antiperspirant	antiperspirant		antiperspirant	IISE	IISE	310.545(a)(4)
aluminum carbonate (gel) [see aluminum hydroxide]						
=====	=====		=====	=====	=====	=====
aluminum carbonate gel (basic)						
antacid	antacid		antacid	I	I	331.11(a)(1)
aluminum carbonate gel [see basic aluminum carbonate gel]						
=====	=====		=====	=====	=====	=====
aluminum chlorhydroxy complex						
miscellaneous external	external analgesic		astringent	IISE	n/a	pending

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
aluminum chloride (aerosol) (15% or less aqueous solution)					
antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.545(a)(4)
aluminum chloride (alcoholic solutions)					
antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.545(a)(4)
aluminum chloride (nonaerosol) (15% or less aqueous solution)					
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(a)
aluminum chloride hexahydrate					
miscellaneous external	external analgesic	astringent	n/a	IIIE	pending
aluminum chlorohydrate (aerosol)					
antiperspirant	antiperspirant	antiperspirant	IIS	I	350.10(b)
aluminum chlorohydrate (nonaerosol)					
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(b)
aluminum chlorohydrate					
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)
aluminum chlorohydrate polyethylene glycol (aerosol)					
antiperspirant	antiperspirant	antiperspirant	IIS	I	350.10(c)
aluminum chlorohydrate polyethylene glycol (nonaerosol)					
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(c)

OTC Ingredient List
Updated August 2006

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum chlorohydrax polyethylene glycol complex [see name with “complex”]	=====	=====	=====	=====	=====	=====
aluminum chlorohydrax polyplene glycol (aerosol)	antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(d)
aluminum chlorohydrax polyplene glycol (nonaerosol)	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(d)
aluminum dichlorohydrate	antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(e)
aluminum dichlorohydrate (nonaerosol)	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(e)
aluminum dichlorohydrax polyethylene glycol (aerosol)	antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(f)
aluminum dichlorohydrax polyethylene glycol (nonaerosol)	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(f)
aluminum dichlorohydrax polyethylene glycol complex [see name with “complex”]	=====	=====	=====	=====	=====	=====
aluminum dichlorohydrax propylene glycol (aerosol)	antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(g)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
aluminum dichlorohydrate propylene glycol (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(g)	
aluminum dichlorohydrate propylene glycol complex [see name with “complex”]						
=====	=====	=====	=====	=====	=====	
aluminum dihydroxy allantoinate [see aldioxa]						
=====	=====	=====	=====	=====	=====	
aluminum hydroxide						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	acne	IIE	IIE	310.545(a)(1)	
antacid	antacid	antacid	I	I	331.11(a)(2)	
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(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	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	n/a	310.545(a)(8)(ii)	
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending	
topical analgesic	skin protectant	skin protectant	I	I	347.10(b)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
aluminum hydroxide (gel) [see aluminum hydroxide gel]						
=====	=====		=====	=====	=====	=====
aluminum hydroxide gel						
=====	skin protectant		poison ivy/oak/sumac	n/a	I	347.10(b)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(1)
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(1)
internal analgesic	internal analgesic		corrective	I	n/a	n/a
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending
topical analgesic	skin protectant		skin protectant	I	I	347.10(b)
aluminum hydroxide sucrose powder hydrated						
antacid	antacid		antacid	I	I	331.11(a)(2)
aluminum hydroxide-hexitol, stabilized polymer						
antacid	antacid		antacid	I	I	331.11(a)(2)
aluminum hydroxide-magnesium carbonate, co-dried gel						
antacid	antacid		antacid	I	I	331.11(a)(2)
aluminum hydroxide-magnesium trisilicate, co-dried gel						
antacid	antacid		antacid	I	I	331.11(a)(2)
aluminum phosphate (gel) [see aluminum phosphate gel]						
=====	=====		=====	=====	=====	=====

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
aluminum phosphate gel						
antacid	antacid	antacid	I	I	331.11(i)(1)	
miscellaneous internal	hypophosphatemia/hyperphosphatemia	hypophosphatemia	IIS	IIS	310.541(a)	
aluminum phosphate gel (when used as part of antacid combination)						
antacid	antacid	antacid	I	I	331.11(a)(4)	
aluminum sesquichlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(h)	
aluminum sesquichlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(h)	
aluminum sesquichlorohydrate propylene glycol (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(j)	
aluminum sesquichlorohydrate propylene glycol complex [see name without “complex”]						
=====	=====	=====	=====	=====	=====	
aluminum sesquichlorohydrate polyethylene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(i)	
aluminum sesquichlorohydrate polyethylene glycol (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(i)	
aluminum sulfate						
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antiperspirant	antiperspirant	antiperspirant	IIISE	IIISE	310.545(a)(4)	
miscellaneous external	external analgesic	astringent	IIIE	n/a	Pending	
miscellaneous external	skin protectant	astringent	IIIE	I	347.12(b)	
aluminum sulfate, buffered (aerosol)						
antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.545(a)(4)(ii)	
aluminum sulfate, buffered (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	310.545(a)(4)(ii)	
aluminum zirconium octachlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)	
aluminum zirconium octachlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(k)	
aluminum zirconium octachlorohydrate glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)	
aluminum zirconium octachlorohydrate glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	I	I	350.10(1)	
aluminum zirconium octachlorohydrate glycine complex [see name without “complex”]						
=====	=====	=====	=====	=====	=====	
aluminum zirconium pentachlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant	IIS	IIS	350.10(m)	

OTC Ingredient List
Updated August 2006

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum zirconium pentachlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(m)
aluminum zirconium pentachlorohydrate glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium pentachlorohydrate glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(m)
aluminum zirconium pentachlorohydrate glycine complex [see name without “complex”]						
=====	=====	=====	=====	=====	=====	=====
aluminum zirconium tetrachlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium tetrachlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(o)
aluminum zirconium tetrachlorohydrate glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium tetrachlorohydrate glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(p)
aluminum zirconium tetrachlorohydrate glycine complex [see name without “complex”]						
=====	=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated August 2006

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum zirconium trichlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium trichlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(q)
aluminum zirconium trichlorohydrate glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium trichlorohydrate glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(r)
aluminum zirconium trichlorohydrate glycine complex [see name without “complex”]						
=====	=====	=====	=====	=====	=====	=====
aluminum sesquichlorohydrate propylene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant	antiperspirant	IIIS	I	350.10(r)
aminacrine hydrochloride						
miscellaneous external	boil treatment	boil treatment	boil treatment	IISE	IISE	310.531(a)
amiloxate						
n/a	TEA		sunscreen	n/a		
amino acids						
miscellaneous external	hair growth/loss	hair grower	hair grower	IISE	IIE	310.527(a)
aminoacetic acid [see glycine]						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
=====	=====		=====	=====	=====	=====
aminoacridine hydrochloride [see aminacrine hydrochloride]						
=====	=====		=====	=====	=====	=====
aminobenzoic acid						
internal analgesic	internal analgesic		analgesic adjuvant	IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic adjuvant	IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic adjuvant	IISE	n/a	310.545(a)(23)(i)
miscellaneous external	hair growth/loss		hair grower	n/a	IIE	310.527(a)
aminobenzoic acid (PABA)						
topical analgesic	sunscreen		sunscreen	I	I	352.10(b)
aminophylline						
cough/cold	cough/cold (bronchodilator)		bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
ammonia						
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	pending
ammonia solution, strong						
miscellaneous external	external analgesic		insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant		insect bite/sting	IISE	IISE	310.545(a)(18)(v)
topical analgesic	external analgesic		counterirritant	I	I	pending

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
topical analgesic	external analgesic	fever blister (topical)	n/a	IISE	310.545(a)(10)(v)	
ammonium alum [see alum, ammonium]						
=====	=====	=====	=====	=====	=====	
ammonium bromide						
sedative	daytime sedative	sedative	IISE	IISE	310.519(a)	
sedative	nighttime sleep aid	sleep aid	IISE	IISE	[54 FR 6826]	
ammonium carbonate						
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
ammonium chloride						
cough/cold	cough/cold (expectorant)	expectorant	IIIE	IIIE	310.545(a)(6)(iii)	
miscellaneous internal	menstrual/diuretic	diuretic	I	I	pending	
oral cavity	oral health care	expectorant	IIIE	IIIE	310.545(a)(6)(iii)	
sedative	stimulant	stimulant	IIE	IIE	[39 FR 6104]	
ammonium hydroxide						
miscellaneous external	external analgesic	insect bite/sting	IIIE	IIIE	310.545(a)(18)(v)(A)	
miscellaneous external	skin protectant	insect bite/sting	IIIE	IIISE	310.545(a)(18)(v)(A)	
amyl dimethyl-p-aminobenzoate [see padimate A]						
=====	=====	=====	=====	=====	=====	

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
amyl para-dimethylaminobenzoate [see padimate A]					
=====	=====	=====	=====	=====	=====
amylase					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(8)(ii)
amyltricresols, secondary					
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending
amylum [see starch]					
=====	=====	=====	=====	=====	=====
amyltricresol, secondary [see amyltricresols, secondary]					
=====	=====	=====	=====	=====	=====
anion and cation exchange resins buffered					
miscellaneous external	external analgesic	poison ivy/oak/sumac	IIIE	IIIE	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac	IIIE	IIIE	310.545(a)(10)(vii)(A)
anise					
miscellaneous internal	aphrodisiac	aphrodisiac	n/a	n/a	310.528(a)
anise oil					
miscellaneous internal	weight control	anorectic	IIISE	IIISE	310.545(a)(20)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
anise seed						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
antimony potassium tartrate						
cough/cold	cough/cold (expectorant)		expectorant	IISE	IISE	310.545(a)(6)(iii)
antipyrine						
internal analgesic	internal analgesic		analgesic	IIISE	IIISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic	IIISE	IIISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic	IIISE	not OTC	310.545(a)(23)(i)
oral cavity	oral health care		analgesic/anesthetic	IISE	IISE	310.545(a)(14)
ophthalmic	ophthalmic		analgesic/anesthetic	IIS	IIS	310.545(a)(21)(i)
topical analgesic	otic		analgesic/anesthetic	IISE	IISE	[51 FR 28660]
aqua ammonia [see ammonium solution, strong]						
=====	=====		=====	=====	=====	=====
aqueous coconut oil soap [see coconut oil soap, aqueous]						
=====	=====		=====	=====	=====	=====
arginine						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
aromatic oils						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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	pending	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
aromatic powder						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
aromatics						
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
asafetida						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
asclepias tuberosa						
miscellaneous internal	menstrual/diuretic	dysmenorrhea	IISE	IISE	310.545(a)(24)(i)	
ascorbic acid						
miscellaneous external	hair growth/loss	hair grower	IIIE	IIIE	310.527(a)	
miscellaneous external	wart remover	wart remover	IIIE	IIIE	[55 FR 33254]	
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
asparagus						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
aspergillus oryzae enzymes (except lactase enzyme from aspergillus oryzae)						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
aspirin						
=====	external analgesic	fever blister (topical)	n/a	IIIE	310.545(a)(10)(v)	
=====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
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	
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending	
oral cavity	oral health care	analgesic/anesthetic	I	IIIE	pending	
sedative	daytime sedative	sedative	IIIE	IISE	310.519(a)	
sedative	nighttime sleep aid	sleep aid	IIIE	IIIE	[54 FR 6826]	
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)	
aspirin, aluminum						
internal analgesic	internal analgesic	analgesic	n/a	IISE	310.545(a)(23)(i)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
internal analgesic	internal analgesic	antipyretic	IIIE	IIIE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic	IIIE	not OTC	310.545(a)(23)(i)	
aspirin, calcium						
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	
atropine						
=====	menstrual/diuretic	menstrual	n/a	n/a	310.545(a)(24)(ii)	
=====	internal analgesic	analgesic	n/a	n/a	310.545(a)(23)(ii)	
hemorrhoidal	anorectal	anticholinergic (external)	IISE	IISE	310.545(a)(26)(i)	
hemorrhoidal	anorectal	anticholinergic (intrarectal)	IISE	IISE	310.545(a)(26)(i)	
atropine sulfate						
cough/cold	cough/cold (anticholinergic)	anticholinergic	IIIE	IIIE	310.533(a)	
laxative	antidiarrheal	antidiarrheal	IIISE	IIISE	310.545(a)(3)(i)	
attapulgate, activated						
laxative	antidiarrheal	antidiarrheal	IIIE	I	310.545(a)(3)(ii)	
avobenzone						
=====	n/a	sunscreen	n/a	1	352.10(a)	

OTC Ingredient List
Updated August 2006

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bacillus acidophilus						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
bacitracin						
	antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.110(a)
	antimicrobial II	antibiotic	skin wound antibiotic	IIIE	defer	n/a
bacitracin zinc						
	antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.110(b)
balsam peru [see peruvian balsam]						
	=====	=====	=====	=====	=====	=====
balsam peru oil [see peruvian balsam oil]						
	=====	=====	=====	=====	=====	=====
barosma						
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
basic aluminum carbonate gel						
	miscellaneous internal	hypophosphatemia/hyperphosphatemia	hyperphosphatemia	IIS	IIS	310.541(a)
basic fuchsin						
	antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
bean						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
bearberry						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
bearberry (extract of uva ursi)						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
bearberry fluidextract (extract of bearberry)						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
beeswax						
=====	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)	
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	pending	
miscellaneous external	skin protectant	diaper rash	defer	n/a	310.545(a)(18)(i)(B)	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
belladonna alkaloids						
cough/cold	cough/cold (bronchodilator)	bronchodilator (inhalation)	IISE	IISE	310.545(a)(6)(iv)(A)	
cough/cold	cough/cold (anticholinergic)	anticholinergic	IIIE	IIIE	310.533(a)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
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)	
belladonna alkaloids (inhalation) atropa belladonna/datura stramonium						
cough/cold	cough/cold (anticholinergic)	anticholinergic	IISE	IISE	310.533(a)	
belladonna extract						
hemorrhoidal	anorectal	anticholinergic (intrarectal)	IISE	IISE	310.545(a)(26)(i)	
hemorrhoidal	anorectal	anticholinergic (external)	IISE	IISE	310.545(a)(26)(i)	
belladonna leaves, powdered extract						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
bemotrizinol						
n/a	TEA	sunscreen	n/a			
benzalkonium chloride						
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	I	I	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
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	dandruff	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending	
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
benzethonium chloride						
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	I	I	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIE	IIIE	pending	
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(i)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/cradle cap	IIIE	IIIE	310.545(a)(7)	
miscellaneous external	external analgesic	astringent	IISE	n/a	310.545(a)(18)(ii)	
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	diaper rash	defer	n/a	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)(A)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
benzocaine						
antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)	
contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a	
dental	relief of oral discomfort	oral mucosal analgesic	I	I	pending	
dental	relief of oral discomfort	toothache relief	IIIE	IIIE	pending	
hemorrhoidal	anorectal	anesthetic (intra-rectal)	IIIE	IIIE	[55 FR 1779]	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
hemorrhoidal	anorectal	anesthetic (external)	I	I	346.10(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	boil treatment	boil treatment	IISE	IIISE	310.531(a)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	[56 FR 63567]	
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	fever blister (topical)	defer	I	pending	
miscellaneous external	external analgesic	insect bite/sting	n/a	IIIE	pending	
miscellaneous external	male genital desensitizer	male genital desensitizer	I	I	348.10(a)(1)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending	
miscellaneous external	external analgesic	poison/ivy/oak/sumac	defer	IIIE	IISE (0.5-1.25%)	
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)	
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	DEF	pending	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	n/a	310.545(a)(10)(vii)	
miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]	
miscellaneous internal	weight control	anorectic	I	IISE	pending	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
topical analgesic	otic	analgesic/anesthetic	IISE	IISE	[51 FR 28660]	
topical analgesic	external analgesic	poison ivy/oak/sumac	IIIE	n/a	310.545(a)(10)(vii)	
benzoic acid						
antimicrobial II	acne	acne	IIIE	IIIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a	
miscellaneous external	hair growth/loss	hair grower	IIIE	IIIE	310.527(a)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending	
benzoin tincture, compound						
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	IIIE	IIIE	310.545(a)(6)(iii)	
dental	relief of oral discomfort	oral mucosal protectant	I	I	pending	
benzoin, tincture						
cough/cold	cough/cold (expectorant)	expectorant	n/a	n/a	310.545(a)(6)(iii)	
benzonatate						
cough/cold	cough/cold (antitussive)	antitussive	n/a	I	310.533(a)	
benzoxiquine						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
benzoyl peroxide						
antimicrobial II	acne	acne	I	I	pending	
benzyl alcohol						
dental	relief of oral discomfort	toothache relief	IIISE	IIISE	pending	
dental	relief of oral discomfort	oral mucosal analgesic	IIISE	I	pending	
hemorrhoidal	anorectal	anesthetic (external)	IIIE	I	346.10(b)	
hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]	
miscellaneous external	alcohols (topical)	antiseptic	IIE	defer	n/a	
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending	
miscellaneous external	male genital desensitizer	male genital desensitizer	IISE	IISE	310.545(a)(10)(iii)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending	
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)(A)	
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
benzyl benzoate						
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)	
betaine hydrochloride						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
miscellaneous internal	stomach acidifier	stomach acidifier	IIE	IIE	310.540(a)	
bicarbonate						
antacid	antacid	antacid	n/a	n/a	331.11(b)	
bicarbonate of soda [see sodium bicarbonate]						
=====	=====	=====	=====	=====	=====	
bile salts/acids						
laxative	laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)	
biotin						
miscellaneous external	hair growth/loss	hair grower	n/a	IISE	310.527(a)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
bisacodyl						
laxative	laxative	stimulant laxative	I	I/IIIS	pending	
bismuth aluminate						
antacid	antacid	antacid	I	I	331.11(c)(1)	
bismuth carbonate						
antacid	antacid	antacid	I	I	331.11(c)(2)	
bismuth oxide						

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
hemorrhoidal	anorectal	protectant (external)	IIIE	IIIE	310.545(a)(26)(viii)
hemorrhoidal	anorectal	protectant (intrarectal)	IIIE	IIIE	310.545(a)(26)(viii)
bismuth sodium tartrate					
miscellaneous external	external analgesic	fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	skin protectant	fever blister (topical)	defer	defer	pending
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IISE	IISE	310.545(a)(8)(i)
bismuth subcarbonate					
antacid	antacid	antacid	I	I	331.11(c)(3)
hemorrhoidal	anorectal	protectant (intrarectal)	IIIE	IIIE	310.545(a)(26)(viii)
hemorrhoidal	anorectal	protectant (external)	IIIE	IIIE	310.545(a)(26)(viii)
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
bismuth subgallate					
antacid	antacid	antacid	I	I	331.11(c)(4)
hemorrhoidal	anorectal	protectant (external)	IIIE	IIIE	310.545(a)(26)(viii)
hemorrhoidal	anorectal	protectant (intrarectal)	IIIE	IIIE	310.545(a)(26)(viii)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	deodorants for internal use	internal deodorant	IIIE	I	357.810(a)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
bismuth subnitrate						
=====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)	
=====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)	
=====	skin protectant	fever blister (topical)	n/a	IISE	310.545(a)(10)(iv)	
=====	skin protectant	poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)(A)	
antacid	antacid	antacid	I	I	331.11(c)(5)	
hemorrhoidal	anorectal	protectant (external)	IIS	IIS	310.545(a)(26)(viii)	
laxative	antidiarrheal	antidiarrheal	IIISE	IIISE	pending	
miscellaneous external	anorectal	protectant (intrarectal)	IIS	IIS	310.545(a)(26)(viii)	
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	skin protectant	diaper rash	defer	IISE	pending	
topical analgesic	skin protectant	skin protectant	IISE	IISE	pending	

bismuth subsalicylate

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	335.10(a)	
laxative	antiemetic	antiemetic	IIIE	IIIE	defer (overindulgence)	
miscellaneous internal	overindulgence in alcohol/food	upset stomach	I	I	pending	
bisotrizole						
n/a	TEA	sunscreen	n/a			
bithionol						
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)	
black radish powder						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
blessed thistle (cnicus benedictus)						
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)	
bone marrow, red						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
borax [see sodium borate]						
=====	=====	=====	=====	=====	=====	
boric acid						
=====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
=====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)	
=====	skin protectant	fever blister (topical)	n/a	IISE	310.545(a)(18)(iv)	
=====	skin protectant	poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)(A)	
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	
contraceptive/vaginal	vaginal	astringent	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	IISE	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis	IISE	IISE	310.545(a)(7)	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	IIS	pending	
oral cavity	oral health care	antimicrobial	IISE	IISE	pending	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
ophthalmic	ophthalmic	anti-infective	IIIE	IIE	310.545(a)(21)(ii)	
topical analgesic	skin protectant	skin protectant	IISE	IISE	310.545(a)(18)(i)(B)	
bornelone						
topical analgesic	sunscreen	sunscreen	IIIE	IIIE	[64 FR 27682]	
bornyl acetate						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical)	IIIE	IIIE	310.545(a)(6)(ii)(B)	
boroglycerin						
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	astringent	IIISE	withdraw	n/a	
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw	n/a	
hemorrhoidal	anorectal	antiseptic (external)	IIESE	IIESE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (intrarectal)	IIESE	IIESE	310.545(a)(26)(ii)	
oral cavity	oral health care	antimicrobial	IIESE	IIESE	pending	
boroglycerin glycerite [see boroglycerin]						
=====	=====	=====	=====	=====	=====	
bran						
laxative	laxative	bulk laxative	I	I	pending	

OTC Ingredient List
Updated August 2006

Ingredient		Report	Drug Category	ANPR	PR	FR
Review Panel						
bran, dietary [see bran]						
=====		=====	=====	=====	=====	=====
bran, tablets [see bran]						
=====		=====	=====	=====	=====	=====
brompheniramine maleate						
cough/cold		cough/cold (antihistamine)	antihistamine	I	I	341.12(a)
buchu						
miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
buchu powdered extract (extract of buchu)						
miscellaneous internal		menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
buchu, extract						
miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
buckthorn						
miscellaneous internal		digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
buffered mixture anion/cation exchange resin [see anion/cation exchange resins]						
=====		=====	=====	=====	=====	=====
butacaine sulfate						
dental		relief of oral discomfort	oral mucosal analgesic	I	I	pending

OTC Ingredient List
Updated August 2006

Ingredient					
Review Panel	Report	Drug Category	ANPR	PR	FR
dental	relief of oral discomfort	toothache relief	III SE	III SE	pending
butamben picrate					
=====	external analgesic	fever blister (topical)	n/a	I	pending
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
butylated hydroxyanisole					
=====	external analgesic	fever blister (topical)	n/a	n/a	pending
=====	skin protectant	fever blister (topical)	n/a	n/a	pending
caffeine					
cough/cold	cough/cold (miscellaneous)	corrective	III E	III E	pending
internal analgesic	internal analgesic	analgesic adjuvant	III E	III E	pending
internal analgesic	internal analgesic	antipyretic adjuvant	III E	III E	pending
internal analgesic	internal analgesic	antirheumatic adjuvant	III E	n/a	pending
miscellaneous internal	menstrual/diuretic	analgesic adjuvant	III E	III E	pending
miscellaneous internal	menstrual/diuretic	diuretic	I	I	pending
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
miscellaneous internal	weight control	anorectic	II SE	II SE	310.545(a)(20)
sedative	stimulant	stimulant	I	I	340.10
calamine					

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
hemorrhoidal	anorectal	astringent (external)	I	I	346.18(a)	
hemorrhoidal	anorectal	astringent (intrarectal)	I	I	346.18(a)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(b)(1)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(b)(1)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)	
miscellaneous external	skin protectant	skin protectant	I	I	347.10(c)	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	I	347.10(c)	
topical analgesic	skin protectant	skin protectant	I	I	347.10(c)	
calamine (in combination only)						
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(b)(1)	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(b)(1)	
calcium						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
calcium acetate					
=====	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	external analgesic	astringent	IISE	n/a	pending
calcium carbaspirin [see carbaspirin calcium]					
=====	=====	=====	=====	=====	=====
calcium carbonate					
antacid	antacid	antacid	I	I	331.11(d)
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
calcium carbonate, precipitated					
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
calcium casinate					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
calcium gluconate					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)

OTC Ingredient List
Updated August 2006

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
calcium hydroxide						
	laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(ii)
calcium iodide, anhydrous						
	cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
calcium lactate						
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
calcium pantothenate						
	laxative	laxative	stimulant laxative	IIIE	IIIE	310.545(a)(12)(iv)(A)
	miscellaneous external	wart remover	wart remover	IIIE	IIIE	[55 FR 33254]
	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)
calcium phosphate						
	antacid	antacid	antacid	I	I	331.11(d)
calcium phosphate, dibasic						
	dental	anticaries	anticavity agent	IIIE	n/a	[60 FR 52504]
	internal analgesic	internal analgesic	corrective	I	n/a	n/a
calcium phosphate, tribasic						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antacid	antacid	antacid	I	I	331.11(d)	
calcium polysulfide						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
calcium propionate						
contraceptive/vaginal	vaginal	minor irritations	I	withdraw	n/a	
calcium salicylate						
internal analgesic	internal analgesic	analgesic	n/a	IIE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antirheumatic	n/a	not OTC	310.545(a)(23)(i)	
calcium salt (mono or dibasic)						
antacid	antacid	antacid	n/a	n/a	331.11(i)(2)	
calcium silicate						
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
calcium sucrose phosphate						
dental	anticaries	anticavity agent	IIE	n/a	310.545(a)(2)(ii)	
calcium thiosulfate						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
calcium undecylenate						
antimicrobial II	antifungal	antifungal	I	I	333.210(f)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	IIISE	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIISE	IIISE	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	
calomel						
laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)	
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)	
calomel (mercurous chloride)						
miscellaneous external	antimicrobial	first aid antiseptic	n/a	IIIE	310.545(a)(27)(i)	
calomel [see mercuric chloride]						
=====	=====	=====	=====	=====	=====	
camphor						
antimicrobial II	acne	acne	IIIE	IIIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(ii)	
cough/cold	cold/cough (antitussive)	antitussive (topical/inhalant)	IIIE	I	341.14(b)(1)	
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)	

OTC Ingredient List
Updated August 2006

Ingredient					
Review Panel	Report	Drug Category	ANPR	PR	FR
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	IIIE	[59 FR 43408]
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIE	310.545(a)(6)(ii)(A)
dental	relief of oral discomfort	oral mucosal analgesic	IIE	IIE	pending
hemorrhoidal	anorectal	analgesic (external)	n/a	I	346.16(a)
miscellaneous external	antifungal	diaper rash	defer	IIE	310.545(a)(22)(ii)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	boil treatment	boil treatment	IIE	IIIE	310.531(a)
miscellaneous external	external analgesic	diaper rash	defer	IIE	310.545(a)(10)(iv)
miscellaneous external	external analgesic	insect bite/sting	IIE	I	pending
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
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	IIE	IIE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIE	310.545(a)(10)(vii)(A)
miscellaneous external	wart remover	wart remover	IIE	IIE	[55 FR 33254]
miscellaneous external	external analgesic	external analgesic (less than 2.5%)	I	I	pending
miscellaneous external	external analgesic	external analgesic (greater than 2.5%)	IIE	IIE	pending
oral cavity	oral health care	antimicrobial	IIE	IIE	pending
oral cavity	oral health care	analgesic/anesthetic	IIE	IIE	310.545(a)(14)

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
topical analgesic	external analgesic	counterirritant	I	I	pending
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
topical analgesic	external analgesic	external analgesic	I	I	pending
topical analgesic	sunscreen	sunscreen	IISE	IISE	[64 FR 27682]
topical analgesic	external analgesic	antipyretic	n/a	I	pending
camphor (>3 - 11 %)					
miscellaneous external	external analgesic	fever blister (topical)	defer	IISE	310.545(a)(10)(v)
camphor (0.1-3*%)					
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
camphor (greater than 3% to 11%)					
hemorrhoidal	anorectal	counterirritant (intrarectal)	IISE	IISE	310.545(a)(26)(iv)
hemorrhoidal	anorectal	counterirritant (external)	IISE	IISE	310.545(a)(26)(iv)
camphor gum					
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
camphorated metacresol					
=====	external analgesic	fever blister (topical)	n/a	I	pending
=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(iv)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	MALE GENITAL DESENSITIZER	male genital desensitizer	n/a	IISE	310.545(a)(10)(iii)	
topical analgesic	external analgesic	analgesic/anesthetic	IIISE	I	pending	
camphorated oil						
miscellaneous external	camphorated oil	counterirritant	IIS	n/a	310.502(a)(4)	
candelillia wax [see wax, candelilla]						
=====	=====	=====	=====	=====	=====	
candididin						
antimicrobial II	antifungal	anticandidial	IISE	IISE	310.545(a)(22)(ii)	
cantharides						
miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)	
capsaicin						
miscellaneous external	external analgesic	fever blister (topical)	defer	IISE	310.545(a)(10)(v)	
topical analgesic	external analgesic	counterirritant	I	I	pending	
capsicum						
dental	relief of oral discomfort	counterirritant (external)	IIIE	IIIE	pending	
dental	relief of oral discomfort	toothache relief	IISE	IISE	pending	
miscellaneous external	external analgesic	fever blister (topical)	defer	IISE	310.545(a)(10)(v)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(8)(ii)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
topical analgesic	external analgesic	counterirritant	I	I	pending	
capsicum oleoresin						
miscellaneous external	external analgesic	fever blister (topical)	defer	IIE	310.545(a)(10)(v)	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IIE	310.545(a)(24)(i)	
topical analgesic	external analgesic	counterirritant	I	I	pending	
capsicum, fluid extract of						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
captan						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIE	IIIE	310.545(a)(7)	
caramiphen edisylate						
cough/cold	cold/cough (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]	
carbamide peroxide						
miscellaneous external	external analgesic	fever blister (topical)	defer	defer	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	defer	pending	
oral cavity	oral health care	debriding agent	III	III	pending	
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending	
carbamide peroxide (in anhydrous glycerin)						
dental	oral mucosal injury	wound cleanser	I	I	pending	
dental	oral mucosal injury	wound healing agent	IIIE	IIIE	310.534(a)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
carbamide peroxide 6.5% (in anhydrous glycerin)						
topical analgesic	otic	ear wax softening agent	I	I	344.10	
carbaspirin calcium						
internal analgesic	internal analgesic	antipyretic	I	I	pending	
internal analgesic	internal analgesic	analgesic	I	I	pending	
internal analgesic	internal analgesic	antirheumatic	I	not OTC	n/a	
miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending	
carbetapentane citrate						
cough/cold	cold/cough (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]	
carbon						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
carbon dioxide, released						
laxative	laxative	laxative	I	I	pending	
carboxymethylcellulose						
antacid	antacid	antacid	IIIE	IIIE	[39 FR 19874]	
carboxymethylcellulose sodium						
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(i)	
laxative	laxative	bulk laxative	I	I	pending	
miscellaneous internal	weight control	anorectic	IIIE	IIIE	310.545(a)(20)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
ophthalmic	ophthalmic	demulcent	I	I	349.12(a)(1)	
carnauba wax [see wax, carnauba]						
=====	=====	=====	=====	=====	=====	
carrageenan						
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
carrageenan (degraded) [see carrageenan, degraded]						
=====	=====	=====	=====	=====	=====	
carrageenan (native) [see carrageenan, native]						
=====	=====	=====	=====	=====	=====	
carrageenan, degraded						
laxative	laxative	bulk laxative	IIS	IIS	310.545(a)(12)(i)	
carrageenan, native						
laxative	laxative	bulk laxative	IIIE	IIIE	310.545(a)(12)(i)	
casanthranol						
laxative	laxative	stimulant laxative	I	I/IIIS	pending	
cascara fluidextract aromatic [see cascara fluidextract, aromatic]						
=====	=====	=====	=====	=====	=====	
cascara fluidextract, aromatic						
laxative	laxative	stimulant laxative	I	I/IIIS	310.545(a)(12)(iv)(C)	

OTC Ingredient List
Updated August 2006

Ingredient		Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous internal		menstrual/diuretic	diuretic	n/a	I/ISE	310.545(a)(24)(i)
cascara sagrada							
	laxative		laxative	stimulant laxative	I	I/IIIS	310.545(a)(12)(iv)(C)
cascara sagrada bark [see cascara sagrada]							
	=====		=====	=====	=====	=====	=====
cascara sagrada extract							
	miscellaneous internal		digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
cascarasagrada extract							
	laxative		laxative	stimulant laxative	I	I/IIIS	310.545(a)(12)(iv)(C)
cascarasagrada fluid extract							
	laxative		laxative	stimulant laxative	I	I/IIIS	310.545(a)(12)(iv)(C)
casein							
	miscellaneous external		antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external		antimicrobial	diaper rash	defer	n/a	n/a
	miscellaneous external		external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external		skin protectant	diaper rash	defer	withdraw	n/a
castor oil							
	laxative		laxative	stimulant laxative	I	I	pending
	miscellaneous external		external analgesic	fever blister (topical)	defer	n/a	n/a

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]	
catechu, tincture						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
catnip						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
cedar leaf oil						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical)	IIIE	IIIE	310.545(a)(6)(ii)(B)	
cellulase						
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)	
cellulose						
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	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	n/a	
cellulose, microporous						
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	

OTC Ingredient List
Updated August 2006

Ingredient						
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	IIISE	pending	
cetalkonium chloride						
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)(vii)(A)	
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending	
cetyl alcohol						
=====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)	
=====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)	
=====	skin protectant	skin protectant	n/a	n/a	310.545(a)(18)(i)(B)	
miscellaneous external	external analgesic	fever blister (topical)	n/a	n/a	n/a	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
cetylpyridinium chloride						
=====	antigingivitis/antiplaque	antigingivitis/antiplaque	I	=====	pending	
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
chamomile flowers						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
charcoal, activated						

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
antacid	antacid	antacid	IIIE	IIIE	[39 FR 19873]	
laxative	antidiarrheal	antidiarrheal	IIIE	IIIE	310.545(a)(3)(ii)	
miscellaneous internal	deodorants for internal use	internal deodorant	IIIE	IIIE	[55 FR 19864]	
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(8)(iii)	
miscellaneous internal	overindulgence in alcohol/food	minimize hangover symptoms	IIIE	IIIE	[48 FR 32873]	
miscellaneous internal	poison treatment	poison absorbent	n/a	I	pending	
miscellaneous internal	acute toxic ingestion	poison treatment	I	I	pending	
charcoal, wood						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(18)(ii)	
chlorthalidone hydrochloride						
cough/cold	cold/cough (antitussive)	antitussive	n/a	I	341.14(a)(1)	
chloral hydrate						
====	external analgesic	fever blister (topical)	n/a	IIIE	310.545(a)(10)(v)	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIIE	310.545(a)(10)(vii)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIIE	310.545(a)(10)(vii)(A)	
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)	
topical analgesic	external analgesic	counterirritant	n/a	n/a	310.545(a)(10)(ii)	
chlorcyclizine hydrochloride						
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	I	341.12(b)	

OTC Ingredient List
Updated August 2006

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
chlorhydroxyquinoline [see cloxyquin]					
=====	=====	=====	=====	=====	=====
chlorobutanol					
=====	external analgesic	fever blister (topical)	n/a	IIIE	310.545(a)(10)(v)
=====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)
miscellaneous external	alcohols (topical)	antiseptic	IIE	defer	n/a
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
topical analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)
chloroform					
cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
chlorophenothane					
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
chlorophyll [see chlorophyllin copper complex]					
=====	=====	=====	=====	=====	=====
chlorophyllin					
dental	relief of oral discomfort	oral mucosal analgesic	n/a	IIISE	pending
chlorophyllin copper complex					
dental	oral mucosal injury	wound healing agent	IIIE	IIIE	310.534(a)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous internal	deodorants for internal use	internal deodorant	IIIE	I	357.810(b)	
oral cavity	oral health care	antimicrobial	IIIE	IIIE	pending	
chlorophyllins, water-soluble [see chlorophyllin copper complex]						
=====	=====	=====	=====	=====	=====	
chlorothymol						
antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)	
chloroxlyneol						
antimicrobial I	antimicrobial	first aid antiseptic	n/a	IIIE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIE	IIIE	pending	
antimicrobial II	acne	acne	IIIE	IIIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IIIE	IIIE	310.545(a)(22)(iv)	
miscellaneous external	antifungal	diaper rash	defer	IIIE	310.545(a)(22)(i)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	antimicrobial	diaper rash	defer	IIISE	pending	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis	IIISE	IIISE	310.545(a)(7)	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	ingrown toenail	ingrown toenail	IISE	IISE	310.538(a)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
chlorpheniramine maleate						
cough/cold	cough/cold (antihistamine)	antihistamine	I	I	341.12(c)	
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)(10)(vii)(A)	
chlorprophenpyridamine maleate						
miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)	
chlortetracycline hydrochloride						
antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.110(c)	
antimicrobial II	antibiotic	skin wound antibiotic	IIE	defer	n/a	
antimicrobial II	antibiotic	skin wound protectant	I	defer	n/a	
chloxyquin						
antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)	
cholecalciferol						
hemorrhoidal	anorectal	wound healing agent (external)	IIIE	IIIE	310.545(a)(26)(x)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIIE	IIIE	310.545(a)(26)(x)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
cholesterol						
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
choline						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
choline salicylate						
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	
chondrus						
miscellaneous internal	weight control	anorectic	IIIE	IISE	310.545(a)(20)	
cimicifuga racemosa						
miscellaneous internal	menstrual/diuretic	dysmenorrhea	IISE	IISE	310.545(a)(24)(i)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
cinnamedrine hydrochloride						
miscellaneous internal	menstrual/diuretic	smooth muscle relaxant	IIIE	IIIE	pending	
cinnamon oil						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
cinnamon tincture						
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
cinoxate						
topical analgesic	sunscreen	sunscreen	I	I	352.10(c)	
citric acid						
contraceptive/vaginal	vaginal	alters vaginal pH	IIIE	withdraw	n/a	
dental	relief of oral discomfort	tooth desensitizer (in combination only)	IIIE	IIIE	pending	
internal analgesic	internal analgesic	corrective	I	n/a	n/a	
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIE	n/a	310.545(a)(18)(ii)	
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIE	n/a	310.545(a)(18)(ii)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
citric acid/salt						
antacid	antacid	antacid	I	I	331.11(e)	
citrus pectin						

OTC Ingredient List
Updated August 2006

Ingredient					
Review Panel	Report	Drug Category	ANPR	PR	FR
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
climbazole					
n/a	TEA	dandruff	n/a		
clioquinol					
antimicrobial II	antifungal	antifungal	I	I	333.210(a)
cloflucarban					
antimicrobial I	antimicrobial	skin antiseptic	n/a	IISE	pending
antimicrobial I	antimicrobial	skin wound protectant	IISE	IISE	pending
antimicrobial I	antimicrobial	first aid antiseptic	IISE	IISE	pending
antimicrobial I	antimicrobial	antimicrobial soap	IIIS	IIIS	pending
antimicrobial I	antimicrobial	skin wound cleanser	IISE	IIISE	pending
antimicrobial I	antimicrobial	preoperative skin prep	IISE	IISE	pending
antimicrobial I	antimicrobial	surgical hand scrub	IISE	IISE	pending
antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending
clotrimazole					
n/a	n/a	antifungal	n/a	I	[67 FR 5942]
clove					
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
clove oil					

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
cloves, ground [see clove]						
=====	=====	=====	=====	=====	=====	
cnicus benedictus						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
coal tar						
antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IISE	IISE	310.545(a)(22)(ii)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	I	I	358.710(c)(1)	
coal tar (shampoo)						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	I	I	358.710(a)(1)	
coal tar (non shampoo)						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	IIIE	I	358.710(b)(1)	
cocoa butter						
=====	skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)	
=====	skin protectant	fever blister (topical)	n/a	I	pending	
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(2)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(2)	
topical analgesic	skin protectant	skin protectant	I	I	347.10(d)	
cocoa butter substitutes [see hard fat]						
=====	=====	=====	=====	=====	=====	
coconut oil soap, aqueous						
miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)	
cod liver oil						
=====	skin protectant	skin protectant	n/a	n/a	347.10(e)	
cough/cold	cold/cough (antitussive)	antitussive	IIIE	IIIE	[52 FR 30054]	
hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIISE	IIISE	310.545(a)(26)(x)	
hemorrhoidal	anorectal	wound healing agent (external)	IIISE	IIISE	310.545(a)(26)(x)	
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	I	pending	
cod liver oil (in combination only)						
hemorrhoidal	anorectal	protectant (external)	I	I	346.14(b)(2)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(b)(2)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
codeine						
=====	menstrual/diuretic	menstrual	n/a	n/a	310.545(a)(24)(i)	
cough/cold	cold/cough (antitussive)	antitussive	I	I	341.14(a)(2)(i)	
internal analgesic	internal analgesic	analgesic	IISE	IISE	310.545(a)(23)(i)	
internal analgesic	internal analgesic	antipyretic	IISE	IISE	310.545(a)(23)(i)	
miscellaneous internal	menstrual/diuretic	analgesic	IIS	IISE	310.545(a)(24)(i)	
codeine phosphate						
cough/cold	cold/cough (antitussive)	antitussive	I	I	341.14(a)(2)(ii)	
internal analgesic	internal analgesic	analgesic	IISE	n/a	310.545(a)(23)(i)	
codeine sulfate						
cough/cold	cold/cough (antitussive)	antitussive	I	I	341.14(a)(2)(iii)	
internal analgesic	internal analgesic	analgesic	IISE	n/a	310.545(a)(23)(i)	
codeine, alkaloid [see codeine]						
=====	=====	=====	=====	=====	=====	
collinsonia extract						
hemorrhoidal	anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)	
hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)	
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	

OTC Ingredient List
Updated August 2006

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
colloidal oatmeal						
	=====	skin protectant	skin protectant	n/a	n/a	347.10(f)
	=====	skin protectant	poison ivy/oak/sumac	n/a	I	347.10(f)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIE	IIE	310.545(a)(7)
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
	miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending
colocynth						
	laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
compound white pine syrup [see white pine syrup, compound]						
	=====	=====	=====	=====	=====	=====
copper						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
copper gluconate						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
copper oleate						
	miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
copper undecylenate						
	antimicrobial II	antifungal	antifungal	I	I	333.210(f)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
coriander						
miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)	
coriander, ground [see coriander]						
=====	=====	=====	=====	=====	=====	
corn oil						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
corn oil, aqueous emulsion						
miscellaneous internal	cholecystokinetic	cholecystokinetic	I	I	357.210(a)	
corn silk						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
corn silk, potassium extract						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
corn starch [see starch, corn]						
=====	=====	=====	=====	=====	=====	
corn syrup						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
couch grass						
miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report		Drug Category	ANPR	PR	FR
creosote						
dental	relief of oral discomfort		toothache relief	IIIE	IIIE	pending
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)(A)
creosote, beechwood						
=====	skin protectant		poison ivy/oak/sumac	n/a	IISE	310.545(a)(18)(vi)
cough/cold	cold/cough (antitussive)		antitussive	IIIE	IIIE	[52 FR 30054]
cough/cold	cough/cold (expectorant)		expectorant	IIIE	IIIE	310.545(a)(6)(iii)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (oral)	IIIE	IIIE	310.545(a)(6)(ii)(A)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical)	IIIE	IIIE	310.545(a)(6)(ii)(B)
dental	relief of oral discomfort		toothache relief	IIISE	IIISE	pending
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
cresol						
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(iv)
dental	relief of oral discomfort		toothache relief	IIISE	IIISE	pending
miscellaneous external	external analgesic		astringent	IISE	n/a	pending
miscellaneous external	astringent		antiseptic	IIE	defer	n/a
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
oral cavity	oral health care		antimicrobial	IIS	IISE	pending
oral cavity	oral health care		analgesic/anesthetic	IISE	IISE	310.545(a)(14)

OTC Ingredient List
Updated August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
oral cavity	relief of oral discomfort	oral mucosal analgesic	IIISE	IIISE	pending	
cresol saponated						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	310.545(a)(7)	
cupric sulfate						
miscellaneous external	external analgesic	astringent	IISE	n/a	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
cyanocobalamin (vitamin B12)						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	
cyclizine hydrochloride						
laxative	antiemetic	antiemetic	I	I	336.10(a)	
cyclomethycaine sulfate						
=====	external analgesic	fever blister (topical)	n/a	IIIE	310.545(a)(10)(v)	
=====	external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)	
internal analgesic	external analgesic	analgesic/anesthetic	IIIE	IIIE	310.545(a)(10)(i)	
cysteine hydrochloride						
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 August 2006

Ingredient						
Review Panel	Report	Drug Category	ANPR	PR	FR	
miscellaneous external	skin protectant	diaper rash	defer	IISE	310.545(a)(18)(iii)	
cystine						
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)	