

## Milestone Status of OTC Drug Review Documents

*Updated June 13, 2003*

DRUG CATEGORY	Advance Notice of Proposed Rulemaking (with Panel Report)	Notice of Proposed Rulemaking/ Tenative Final Monograph	Final Rule/ Final Monograph
<b>Acne</b>	3/23/82	1/15/85 8/7/91	8/16/91
<b>Alcohol</b>		10/21/93	3/13/95
exempt IPECAC max. conc. limits		5/10/96	11/18/96
<b>Anorectal</b>	5/27/80	8/15/88	8/3/90
310.545 listing (LYCD)			9/2/93
witch hazel name change			6/3/94
<b>Antacid</b>	4/5/73	11/12/73	6/4/74
in vitro test		5/27/80	8/31/82
statement of identity/upset stomach		9/21/79	8/31/82
exemption/accidental overdose		4/13/84	8/1/86
combo/antacid & analgesic		11/16/88	
relief of upset stomach/overindulgence		12/24/91	
drug interaction precaution		7/30/86	8/26/93
USP testing procedures		9/23/93	2/8/96
sodium bicarbonate warning		2/2/94	
<b>Anthelmintic</b>	9/9/80	8/24/82	8/1/86
<b>Antibiotics (First Aid)</b>	4/1/77	7/9/82	12/11/87
technical			5/25/88
anesthetics in aerosols		8/18/89	3/15/90
revised standards for BA/PO aerosols		5/11/90	10/3/90
anesthetics		6/8/90	12/5/90
allergy warning		2/14/96	11/15/96
<b>Anticaries</b>	3/28/80	9/30/85 6/15/88	10/6/95 10/6/95
partial delay of effective date			10/7/96
partial stay of regulation; enforcement policy			12/16/96
<b>Antidiarrheal</b>	3/21/75	4/30/86 4/17/03	4/17/03
amend to add traveler's diarrhea			
<b>Antiemetic</b>	3/21/75	7/13/79 8/26/93 8/29/97	4/30/87 4/11/94 12/6/02
diphenhydramine labeling			

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<b>Antiflatulent</b>	4/5/73	11/12/73	6/4/74
exemption/accidental overdose		4/13/84	8/1/86
statement of identity		1/29/88	3/5/96
<b>Antifungal</b>	3/23/82	12/12/89	9/23/93
diaper rash*	9/7/82	6/20/90	12/18/92
nails and scalp	3/23/82	12/12/89	9/2/93
amend indications		7/22/99	8/29/00
clotrimazole		5/29/01	2/8/02
<b>Antimicrobials: Alcohols (Topical)</b>	5/21/82	7/22/91	not applicable
<b>Antimicrobials: Antiseptics (Health Care)</b>	9/13/74	1/6/78	
		6/17/94	
<b>Antimicrobials: Diaper Rash*</b>	9/7/82	6/20/90	
<b>Antimicrobials: Mercurials</b>	1/5/82	7/22/91	4/22/98
<b>Antiperspirant</b>	10/10/78	8/20/82	6/9/03
<b>Antiseptics (First aid)</b>	9/13/74	1/6/78	
		7/22/91	
<b>Aphrodisiac</b>	10/1/82	1/15/85	7/7/89
<b>Benign Prostatic Hypertrophy</b>	10/1/82	2/20/87	2/27/90
<b>Boil Treatment</b>	6/29/82	1/26/88	11/15/93
<b>Camphorated Oil</b>	9/26/80	not applicable	9/21/82
<b>Category II/III Ingredients (Phase I)</b>	not applicable	5/16/90	11/7/90
			1/30/92
<b>Category II/III Ingredients (Phase II)</b>	not applicable	8/25/92	5/10/93
<b>Category II/III Ingredients (Certain Additional)</b>		not applicable	4/22/98
			8/24/98
			5/9/02
			5/9/02
<b>Cholecystokinetic</b>	2/12/80	8/24/82	6/10/83
soybean oil		8/15/88	2/28/89
<b>Cold/Cough: Anticholinergic</b>	9/9/76	7/9/82	11/8/85
<b>Cold/Cough: Antihistamine</b>	9/9/76	1/15/85	12/9/92
		8/24/87	12/9/92
amend to FR doxylamine			1/28/94
amend to FR diphenhydramine			4/9/96
diphenhydramine labeling		8/29/97	
reopening of admin. record (colds)		8/25/00	12/6/02

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<b>Cold/Cough: Antitussive</b>	9/9/76	10/19/83	8/12/87
exempt menthol lozenges from overdose warning		7/6/89	7/6/90
amend to use the term lozenge		10/2/89	6/3/90
MAOI drug interact. warn. dextromethorphan		6/19/92	10/20/93
include diphenhydramine		12/9/92	4/9/96
diphenhydramine labeling		8/29/97	12/6/02
flammability warning		7/20/98	8/1/00
<b>Cold/Cough: Bronchodilator</b>	9/9/76	10/26/82	10/2/86
MAOI drug interaction warning		6/19/92	10/20/93
remove ephedrine from market		7/27/95	
remove pressurized aerosol epinephrine		3/9/95	5/20/96
<b>Cold/Cough Combinations</b>	9/9/76	8/12/88	12/23/02
diphenhydramine combinations		11/14/88	
theophylline combinations		2/23/95	4/9/96
bronchodilator combinations			7/27/95
			9/27/01
<b>Cold/Cough: Expectorant</b>	9/9/76	7/9/82	2/28/89
updating/tech. changes			6/30/92
310.545 listing			9/14/92
<b>Cold/Cough: Nasal Decongestant</b>	9/9/76	1/15/85	8/23/94
levmetamfetamine (formerly l-desoxyephedrine)			3/8/96
			7/30/98
<b>Corn/Callus Remover</b>	1/5/82	2/20/87	8/14/90
<b>Dandruff/Seborrhea/Psoriasis</b>	12/3/82	7/30/86	12/4/91
micronized selenium sulfide		4/5/93	1/28/94
<b>Daytime Sedative</b>	12/8/75	6/13/78	6/22/79
<b>Deodorants (Internal)</b>	1/5/82	6/17/85	5/11/90
<b>Digestive Aids</b>	1/5/82	1/19/88	10/21/93
<b>Eligibility Criteria (Additional Conditions)</b>	10/3/96	12/20/99	1/23/02
<b>Exocrine Pancreatic Insufficiency</b>	12/21/79	11/8/85	4/24/95
		7/15/91	4/24/95
<b>External Analgesic</b>	12/4/79	2/8/83	
hydrocortisone 1% amend. TFM		2/27/90	
diphenhydramine labeling		8/29/97	12/6/02
diaper rash	9/7/82	6/20/90	12/18/92
fever blister/cold sore (ext.)**	9/7/82	1/31/90	
insect bites/stings & poison ivy/oak/sumac	9/7/82	10/3/89	
male genital desensitizers	9/7/82	10/2/85	6/19/92
<b>Fever Blister/Cold Sore (Internal)</b>	1/5/82	6/17/85	6/30/92

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<b>Hair Grower/Loss</b>	11/7/80	1/15/85	7/7/89
<b>Hexachlorophene</b>	1/7/72	not applicable	9/27/72
<b>Hormone (Topical)</b>	1/5/82	10/2/89	9/9/93
<b>Hypo/Hyperphosphatemia</b>	12/9/80	1/15/85	5/11/90
<b>Ingrown Toenail Relief</b>	10/17/80	9/3/82 10/4/02	9/9/93 5/7/03
<b>Insect Repellents (Internal)</b>	1/5/82	6/10/83	6/17/85
<b>Internal Analgesic</b>	7/8/77	11/16/88	
overindulgence		12/24/91	
ibuprofen and labeling		8/21/02	
consumer warning (professional uses of ASA)		10/20/93	
professional labeling of aspirin products		6/13/96	10/23/98
technical amend.			9/14/99
leg muscle cramps	10/1/82	11/8/85	8/22/94
malaria		4/19/95	3/20/98
sodium bicarbonate warning		2/2/94	
<b>Labeling Regulations</b>			
sodium labeling		4/25/91	4/22/96
partial delay of effective date			4/24/97
reye syndrome warning for other salicylates		10/20/93	4/17/03
calcium, magnesium, and potassium		4/22/96	
alcohol warning		11/14/97	10/23/98
alcohol warning; compliance date			3/17/99
<b>Labeling Requirements</b>		2/27/97	3/17/99
correction			4/15/99
technical amendment			1/3/00
partial extension of compliance dates			6/20/00
guidance for industry: column format		12/1/99	12/19/00
guidance for industry: exemptions & deferrals		12/19/00	
guidance for industry: ANDA labeling		2/22/01	10/18/02
partial delay of compliance dates			4/5/02
guidance for industry: drug products containing ensulizole, hypromellose, meradimate, octinoxate, and octisalate- labeling enforcement			6/3/03

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<b>Laxative</b>	3/21/75	1/15/85	
bulk (amend to PR)		10/1/86	
docusate salts (amend to PR)		9/2/93	
sodium phosphates package size		3/31/94	5/21/98
danthron and phenolphthalein		9/2/97	1/29/99
sodium phosphates labeling		5/21/98	12/9/98
			(withdrawn)
stimulant laxatives		6/19/98	
rectal sodium phosphates labeling stay			12/7/98
<b>Menstrual Products</b>	12/7/82	11/16/88	
<b>Nailbiting/Thumbsucking Deterrent</b>	10/17/80	9/3/82	9/2/93
<b>Nighttime Sleep Aid</b>	12/8/75	6/13/78	2/14/89
diphenhydramine labeling		8/29/97	12/6/02
<b>Standardize Diphenhydramine Warnings</b>		8/26/93	4/11/94
diphenhydramine labeling		8/29/97	12/6/02
<b>Ophthalmic</b>	5/6/80	6/28/83	3/4/88
ophthalmic/antiinfective			12/18/92
add/revise warnings		2/23/98	6/21/00
technical amendment (eyewashes)			2/19/03
emergency first aid use		2/19/03	
technical amendment (name change)			6/3/03
<b>Oral Health Care</b>			
antiseptic	5/25/82	2/9/94	
non/antimicrobial	5/25/82	1/27/88	
		(1 <sup>st</sup> segment)	
plaque/gingivitis	5/29/03		
<b>Oral Discomfort (Relief)</b>	5/25/82	9/24/91	
		(2 <sup>nd</sup> segment)	
amend. menthol lozenge		5/13/92	
<b>Oral Mucosal Injury</b>	11/2/79	7/26/83	
<b>Oral Wound Healing</b>	11/2/79	7/26/83	7/18/86
<b>Otic (Earwax Removal)</b>	12/16/77	7/9/82	8/8/86
<b>Otic (Swimmer's Ear)</b>	12/16/77	7/30/86	2/15/95
partial stay/water/clogged ear claim			8/16/95
water/clogged ears/lift partial stay		8/17/99	8/10/00
<b>Overindulgence Remedies</b>	10/1/82	12/24/91	
reye syndrome warning		5/5/93	
remedies/prevents inebriation	10/1/82	not applicable	7/19/83

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<b>Pediculicides</b>	6/29/82	4/3/89	12/14/93
technical amendment			8/13/98
revise labeling		5/10/02	
<b>Poison Treatment</b>			
emetic drug products	3/21/75	9/5/78	
acute toxic ingestion treatment/emetic	1/5/82 <sup>†</sup>	1/15/85 <sup>†</sup>	
<b>Salicylanilides (TBS)</b>	9/13/74	not applicable	10/30/75
<b>Silver</b>		10/15/96	8/17/99
<b>Skin Bleaching</b>	11/3/78	9/3/82	
<b>Skin Protectant</b>	8/4/78	2/15/83	6/4/03
astringents**	9/7/82	4/3/89	10/21/93
revise labeling		6/13/03	6/13/03
insect bites/stings & poison ivy/oak/sumac	9/7/82	10/3/89	6/4/03
diaper rash*	9/7/82	6/20/90	
fever blister/cold sore**	9/7/82	1/31/90	
<b>Smoking Deterrent</b>	1/5/82	7/3/85	6/1/93
<b>Stimulant</b>	12/8/75	6/13/78	2/29/88
hangover claim		12/24/91	
<b>Stomach Acidifier</b>	10/19/79	1/15/85	8/17/88
<b>Sunscreen</b>	8/25/78	5/12/93	5/21/99
include only USP ingredients		6/8/94	5/21/99
include avobenzone		9/16/96	5/21/99
include zinc oxide		10/30/97	5/21/99
extend effective date			6/8/00
partial stay			12/31/01
names amendment			6/20/02
<b>Sweet Spirits of Nitre</b>	2/22/80	not applicable	6/27/80
<b>Vaginal Contraceptive</b>	12/12/80	2/3/95	
required labeling		1/16/03	
<b>Vaginal Drug Products</b>	10/13/83	not applicable	2/3/94 (withdrawn)
<b>Vaginal (Yeast Infections)</b>	7/16/98		
<b>Vitamin/Mineral</b>	3/16/79	not applicable	11/27/81 (withdrawn)
<b>Wart Remover</b>	10/3/80	9/3/82	8/14/90
		3/27/87	8/14/90
		1/28/94	11/23/94

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<b>Weight Control</b>	2/26/82	10/30/90	
certain ingredients			8/8/91
water soluble gums		10/30/90	8/26/93
PPA labeling		2/14/96	
<b>Zirconium (Aerosol)</b>	6/5/75	not applicable	8/16/77

\* see Antifungal, Antimicrobial, External Analgesic, and Skin Protectant

\*\* see External Analgesic and Skin Protectant

† separate publications that include Emetic and Acute Toxic Ingestion