yourhealth AT HAND book

Guide to OTC Active Ingredients in the United States

Supplement to *Pharmacy Today*

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Regulatory Background and Glossary

Regulatory Routes for the Marketing of Over-the-Counter (OTC) Drug Products in the United States

OTC drug products can be marketed under the authority of an approved product-specific new drug application (NDA), abbreviated NDA (ANDA), or under an OTC drug monograph. Unlike NDAs which are based on drug products, monographs specify the active ingredients that can be contained within OTC drug products. In addition to specifying the active ingredients, the OTC monographs contain information regarding the permitted concentrations of active ingredients, dosage limits, indications, and other requirements for legal marketing under monograph status. In order to be eligible for an OTC drug monograph, it is FDA's policy (with limited exceptions) that an active ingredient had to be marketed as an OTC medicine at the inception of the OTC Drug Review on May 11, 1972, later extended to December 4, 1975, or before. OTC drug products are marketed under a final monograph (FM), which is a regulation, or a tentative final monograph (TFM), which represents FDA's current position on the requirements for safe and effective labeling, formulation, and marketing of a product. In addition, it is FDA's practice (with limited exceptions) to permit the continued marketing of active ingredients or certain combinations during the pendency of an FM or TFM on condition that these ingredients were commercially marketed within OTC products prior to December 4, 1975, and that such products do not constitute a hazard to health. This document focuses on permitted OTC active ingredients. Users of this document are invited to consult the pertinent *Federal Register* notices and NDAs about permitted concentrations of active ingredients, dosage limits, indications, and other requirements for legal marketing under monograph status.

Product Categories

The *Your Health at Hand Book* follows FDA's classification of active ingredients and their allocation to product categories. However, since active ingredients listed in the product category "Dermal Antifungals," for example, can have an anti-dandruff indication without being mentioned in the product category of "Dandruff Drug Products," we used the FDA's product category organization rather than cross-referencing all possible indications.

Active Ingredients

The tables provide the names of the active moieties of ingredients which are used in OTC drug products in the United States under one of the following regulatory status:

1. New drug application (NDA). The date of the first NDA OTC approval of the ingredient, ingredient combination, extended release form, or new indication is provided. However, the tables do not contain subsequent approvals of generic versions; other strengths, concentrations, formulations, or uses in subpopulations (e.g. children); or salts, esters, or other derivatives of the active ingredient.

2. Category I ingredients (generally recognized as safe and effective for the claimed therapeutic indication) contained in a tentative final monograph (TFM) or a final monograph (FM). The date of issuance of the monograph is provided in brackets.

3. Category III ingredients (insufficient data available to permit final classification) contained in marketed products. Such ingredients are referred to as "FM pending."

Only where it was deemed as essential for the understanding of the active ingredient information, the tables include the names of salts, esters, or other derivatives of the active moieties.

Brand Examples

Sources used for identifying brand examples were the *PDR for Nonprescription Drugs, Dietary Supplements, and Herbs* (21 edition, 2010) and the web page of the largest Internet retailer in the United States, drugstore.com (accessed August 2010). The purpose of providing brand examples is to reflect the use of active ingredients rather than providing an inclusive list of all brands on the market. These brand examples are not listed in any particular order.

Date of NDA OTC Approval

The *Orange Book* and various other FDA sources were used to identify and verify the information concerning NDA approval dates.

Glossary of abbreviations:

ANPR =	Advance notice of proposed rulemaking
ER =	Extended release
FM =	Final monograph
NDA =	New drug application
NPR =	Notice of proposed rulemaking
TFM =	Tentative final monograph

A. Internal (Oral) Analgesics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Internal Analgesics	OTC Monograph Single Ingredients	TFM (Nov. 16, 1988)	aspirin	BAYER ASPIRIN, ECOTRIN, BUFFERIN
			acetaminophen	TYLENOL
			carbaspirin	
			salicylate and its salts (choline, magnesium, or sodium)	DOAN'S, PERCOGESIC MAXIMUM STRENGTH magnesium salicylate
	OTC Monograph Combinations	TFM (Nov. 16, 1988)	acetaminophen with other analgesics	GOODY'S BODY PAIN acetaminophen/aspirin
			acetaminophen with antacids	
			aspirin with antacids	ALKA SELTZER EXTRA STRENGTH aspirin/citric acid/sodium bicarbonate
			combinations with cough and cold ingredients	See *B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products*
			combinations with diuretics	*see L. Menstrual Products*
		Proposed TFM amendment (Dec. 24, 1991)	any analgesic with caffeine	EXCEDRIN EXTRA STRENGTH, ANACIN HEADACHE, VANQUISH acetaminophen/aspirin/caffeine
	NDA	prior Jan. 1, 1982	acetaminophen suppositories	FEVERALL
		May 18, 1984	ibuprofen	ADVIL, MOTRIN
		June 8, 1984	acetaminophen ER	TYLENOL ARTHRITIS PAIN
		Sept. 19, 1989	ibuprofen/pseudoephedrine	ADVIL COLD & SINUS
		Jan. 11, 1994	naproxen	ALEVE
		Oct. 6, 1995	ketoprofen	
		Jan. 14, 1998	aspirin/acetaminophen/caffeine for migraine	EXCEDRIN MIGRAINE
		Nov. 29, 1999	naproxen/pseudoephedrine	ALEVE-D SINUS & COLD
		Feb. 25, 2000	ibuprofen for migraine	MOTRIN MIGRAINE, ADVIL MIGRAINE
		Oct. 18, 2001	aspirin for migraine	BAYER ASPIRIN MIGRAINE
		Dec. 19, 2002	ibuprofen/pseudoephedrine/ chlorpheniramine	ADVIL ALLERGY SINUS

B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Oral Antitussives	OTC Monograph Single Ingredients	FM (Aug. 12, 1987)	chlophedianol	
			codeine	
			dextromethorphan	ROBITUSSIN DM, SUCRETS DM, HOLD DM, VICKS DAYQUIL
		FM (June 3, 1994)	diphenhydramine	
	NDA	Oct. 8, 1982	dextromethorphan (ER)	DELSYM ER
		April 29, 2004	dextromethorphan/guaifenesin (ER)	MUCINEX DM ER
Oral Nasal Decongestants	OTC Monograph Single Ingredients	FM (Aug. 23, 1994)	pseudoephedrine	SUDAFED
			phenylephrine	SUDAFED PE
	NDA	Sept. 13, 1982	pseudoephedrine (ER12 hours)	SUDAFED 12 HOURS
		Dec. 15, 1992	pseudoephedrine (ER 24 hours)	
Oral First-Generation Antihistamines	OTC Monograph Single Ingredients	FM (Dec. 9, 1992)	brompheniramine, chlorcyclizine, chlorpheniramine, dexbrompheniramine, dexchlorpheniramine, diphenhydramine, phenindamine, pheniramine, pyrilamine, thonzylamine, triprolidine	BENADRYL ALLERGY diphenhydramine
				CHLOR-TRIMETON chlorpheniramine
		FM (Jan. 28, 1994)	doxylamine	
	NDA	prior Jan. 1, 1982	chlorpheniramine (ER)	CHLOR-TRIMETON 12 HOURS
		prior Jan. 1, 1982	chlorpheniramine/pseudoephedrine (ER)	
		Sept. 13, 1982	dexbrompheniramine/pseudoephedrine (ER)	DRIXORAL
		May 22, 1987	dexbrompheniramine/ pseudoephedrine/acetaminophen ER	DRIXORAL PLUS
		Aug. 21, 1992	clemastine	TAVIST
		March 1, 2001	clemastine/pseudoephedrine/ acetaminophen	TAVIST ALLERGY SINUS HEADACHE
Oral Second-Generation Antihistamines	NDA	Nov. 27, 2002	loratadine	CLARITIN, ALAVERT
		Nov. 27, 2002	loratadine/pseudoephedrine (ER)	CLARITIN D 24 HOURS
		Nov. 16, 2007	cetirizine	ZYRTEC
		Nov. 9, 2007	cetirizine/pseudoephedrine	ZYRTEC D
Oral Expectorants	OTC Monograph Single Ingredients	FM (Feb. 28, 1989)	guaifenesin	MUCINEX, LITTLE COLDS MUCUS RELIEF
	NDA	July 12, 2002	guaifenesin (ER)	MUCINEX ER
		June 22, 2004	guaifenesin/pseudoephedrine (ER)	MUCINEX D ER

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B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products
continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Oral Cough and Cold Active Ingredients Combinations	OTC Monograph Combinations	FM (Dec. 23, 2002)	combinations of antitussive, decongestant, antihistamine, expectorant, analgesic, and oral demulcent active ingredients	TRIAMINIC DAYTIME phenylephrine/dextromethorphan
				DIMETAPP NIGHTTIME phenylephrine/diphenhydramine
				TYLENOL COUGH DAYTIME phenylephrine/ dextromethorphan/ acetaminophen
				VICKS NYQUIL VITAMIN C, CORICIDIN HBP NIGHTTIME doxylamine/ dextromethorphan/ acetaminophen
				THERAFLU COLD & COUGH pheniramine/phenylephrine/ dextromethorphan
				BUCKLEY'S CHEST CONGESTION guaifenesin/menthol
Bronchodilators	OTC Monograph Single Ingredients	FM (Oct. 2, 1986)	ephedrine, racephedrine	
			epinephrine, racepinephrine	PRIMATENE MIST
	OTC Monograph Oral Combinations	FM pending	ephedrine/guaifenesin	PRIMATENE TABLETS, BRONKAID
Topical Antitussives	OTC Monograph Single Ingredients	FM (Aug. 12, 1987)	camphor	VICKS VAPOSTEAM
			menthol	FISHERMAN'S FRIEND
	OTC Monograph Combinations	FM (Dec. 23, 2002)	camphor/menthol	
			camphor/menthol/eucalyptus oil	VICKS VAPORUB, MENTHOLATUM CHEST RUB
Topical Nasal Decongestants	OTC Monograph Single Ingredients	FM (Aug. 23, 1994)	ephedrine	
			naphazoline	
			oxymetazoline	AFRIN, VICKS SINEX, SUDAFED OM, NOSTRILLA, ZICAM SINUS RELIEF
			phenylephrine	NEO-SYNEPHRINE, LITTLE NOSES DECONGESTANT, 4-WAY
			propylhexedrine	BENZEDREX
			xylometazoline	
Topical Nasal Allergy Symptom Controllers	NDA	Jan. 6, 1997	cromolyn sodium	NASALCROM

C. Nighttime Sleep Aids

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Nighttime Sleep-Aids	OTC Monograph Single Ingredients	FM (Feb. 14, 1989)	diphenhydramine	UNISOM, SOMINEX, COMPOZ
	OTC Monograph Combinations	FM pending	aspirin/diphenhydramine	BAYER ASPIRIN PM
			acetaminophen/diphenhydramine	TYLENOL PM
	NDA	Oct. 18, 1978	doxylamine	UNISOM
			ibuprofen/diphenhydramine	ADVIL PM

D. Stimulants (Caffeine)

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Stimulants	OTC Monograph Single Ingredients	FM (Feb. 29, 1988)	caffeine	NODOZ, VIVARIN

E. Gastrointestinals

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Acid reducers - Antacids	OTC Monograph Single Ingredients	FM (June 4, 1974)	aluminum-based antacids, bicarbonate-based antacids, bismuth-based antacids, calcium (carbonate or phosphate), citrate ion as citric acid or salt, glycine, magnesium-based antacids, milk solids dried, phosphate-based antacids, potassium-based antacids, sodium-based antacids, silicates, tartaric acid or its salts	PEPTO-BISMOL ORIGINAL bismuth subsalicylate
				TUMS, PEPTO-BISMOL CHILDREN'S calcium carbonate
				PHILLIPS ORIGINAL magnesium hydroxide
	OTC Monograph Combinations	FM (June 4, 1974)	combinations of antacids	ALKA SELTZER ANTACID RELIEF citric acid/sodium bicarbonate/ potassium bicarbonate
				MYLANTA aluminum hydroxide / magnesium hydroxide
				ROLAIDS calcium carbonate/magnesium hydroxide
				GAVISCON aluminum hydroxide/magnesium carbonate
			combinations with any nonantacid laxative	
			combinations with analgesics	See *A. Internal Analgesics*
			combinations with anti-flatulents	MAALOX CHILDREN'S calcium carbonate /simethicone
				MAALOX, GELUSIL aluminum hydroxide/magnesium hydroxide/simethicone
Acid reducers - H_2- Antagonists	NDA	April 28, 1995	famotidine	PEPCID
		June 19, 1995	cimetidine	TAGAMET
		Dec. 19, 1995	ranitidine	ZANTAC
		May 9, 1996	nizatidine	
		Oct. 17, 2000	famotidine/calcium carbonate/ magnesium hydroxide	PEPCID COMPLETE
Acid reducers - Proton Pump Inhibitors	NDA	June 20, 2003	omeprazole	PRILOSEC OTC
		May 18, 2009	lansoprazole	PREVACID
		Dec. 1, 2009	omeprazole/sodium bicarbonate	ZEGERID OTC
Antiflatulents	OTC Monograph Single Ingredients	FM (April 6, 1974)	simethicone	GAS-EX, LITTLE TUMMY'S GAS
	OTC Monograph Combinations	FM (April 6, 1974)	combinations with antacids	see above Antacids - combinations with antiflatulents

E. Gastrointestinals
continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antidiarrheals	OTC Monograph Single Ingredients	FM (April 17, 2003)	bismuth subsalicylate	
			kaolin	
	NDA	March 3, 1988	loperamide	IMODIUM
		June 26, 1997	loperamide/simethicone	IMODIUM MULTI-SYMPTOM RELIEF
Bulk-Forming Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	polycarbophil	FIBERCON, EQUALACTIN
			psyllium ingredients	METAMUCIL
			bran	
			cellulose	CITRUCEL methylcellulose
			karaya	
			malt soup extract	
Hyperosmotic Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	glycerin	FLEET LIQUID GLYCERIN
			sorbitol	
	NDA	October 6, 2006	polyethylene glycol 3350	MIRALAX
Lubricants	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	mineral oil	FLEET MINERAL OIL ENEMA
Saline Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	magnesium hydroxide	
			sodium phosphate, sodium biphosphate	FLEET PEDIA-LAX ENEMA
			magnesium citrate, magnesium sulfate	
Stimulant Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	bisacodyl	DULCOLAX, ALOPHEN, FLEET STIMULANT LAXATIVE, CORRECTOL
			sennosides	SENOKOT, EX-LAX, FLETCHER'S LAXATIVE
			castor oil	
			dehydrocholic acid	
Stool Softeners	OTC Monograph Single Ingredients	TFM (Sept. 2, 2003)	docusate	COLACE, PHILLIPS STOOL SOFTENER
Carbon Dioxide-Releasing Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	carbon dioxide released from combined sodium biphosphate anhydrous, sodium acid pyrophosphate and sodium bicarbonate	
			carbon dioxide released from combined sodium bicarbonate and potassium bitartrate	
Laxative Active Ingredients Combinations	OTC Monograph Combinations	TFM (Jan. 15, 1985)	combinations of laxatives	
				PERI-COLACE sennosides/docusate

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E. Gastrointestinals
continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antiemetics	OTC Monograph Single Ingredients	FM (April 30, 1987)	cyclizine	BONINE FOR CHILDREN, MAREZINE
			dimenhydrinate	DRAMAMINE ORIGINAL, TRIPTONE
			diphenhydramine	
			meclizine	BONINE, ANTIVERT
Anthelmintics	OTC Monograph Single Ingredients	FM (Aug. 1, 1986)	pyrantel pamoate	PIN-X, PRONTO
Poison Treatment	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	ipecac syrup	
			activated charcoal	CHARCOCAPS

F. Analgesics, Anesthetics, Counterirritants, & Antipruritics (External Analgesics)

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Amine and Caine'-Type Ingredients (Local Anesthetics)	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	benzocaine, butamben picrate, dibucaine, dimethisoquin, dyclonine, lidocaine, pramoxine, tetracaine	SOLARCAINE lidocaine
				SCALPICIN WIPES pramoxine
				ORAJEL COLD SORE dyclonine
Alcohols and Ketones	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	benzyl alcohol, camphor, camphorated metacresol, juniper tar, menthol, phenol, phenolate sodium, resorcinol	
Antihistamines	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	diphenhydramine	
			tripelennamine	
Hydrocortisone Preparations	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	hydrocortisone	CORTIZONE, CORTAID, ITCH-X HYDROCORTIFOAM
Irritants That Produce Redness	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	allyl isothiocyanate, ammonia, methyl salicylate, turpentine oil	AFTER BITE ammonia
		FM pending	trolamine salicylate	ASPERCREME, MOBISYL
Irritants That Produce Cooling Sensation	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	camphor	BLUE STAR
			menthol	ICY HOT, ABSORBINE, BENGAY, STOPAIN
Irritants That Produce Vasodilation	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	histamine dihydrochloride	
			methyl nicotinate	
Irritants That Don't Produce Redness	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	capsaicin	CAPZASIN, ZOSTRIX

F. Analgesics, Anesthetics, Counterirritants, & Antipruritics (External Analgesics)

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
External Analgesics Combinations	OTC Monograph Combinations	TFM (Feb. 8, 1983)	combinations of external analgesic active ingredients, combinations with skin protectant and topical antimicrobial active ingredients	BENADRYL GEL diphenhydramine/zinc acetate
				BACTINE lidocaine/benzalkonium chloride
				IVAREST POISON IVY diphenhydramine/calamine/benzyl alcohol
				LANACANE benzocaine/benzethonium chloride
				VAGISIL ANTI-ITCH benzocaine/resorcinol
				THERAGESIC, MENTHOLATUM DEEP HEATING benzocaine/resorcinol
				SATOGESIC methyl salicylate/camphor/menthol
				BOROLEUM camphor/menthol/white petrolatum
	NDA	Feb. 20, 2008	methyl salicylate/menthol	SALONPAS PATCH

G. Skin Treatment Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Skin Protectants	OTC Monograph Single Ingredients	FM (June 4, 2003)	allantoin, aluminum hydroxide gel, calamine, cocoa butter, cod liver oil, colloidal oatmeal, dimethicone, glycerin, hard fat, kaolin, lanolin, mineral oil, petrolatum, sodium bicarbonate, topical starch, white petrolatum, zinc acetate, zinc carbonate, zinc oxide	AVEENO BABY dimethicone
				JOHNSON'S BABY, BALMEX DIAPER RASH zinc oxide
				DESITIN MULTI-PURPOSE white petrolatum
Skin Protectants Astringents	OTC Monograph Single Ingredients	FM (June 4, 2003)	aluminum acetate, aluminum sulfate, witch hazel	
Skin Protectants Combinations	OTC Monograph Combinations	FM (June 4, 2003)	combinations with external analgesic, first aid antiseptic, and sunscreen active ingredients	GOLD BOND MEDICATED BODY LOTION zinc oxide/menthol
				BLISTEX MEDICATED LIP BALM dimethicone/oxybenzone/padimate
				PALMER'S MEDICATED LIP BUTTER petrolatum/camphor/menthol
				CHAPSTICK MEDICATED LIP BALM petrolatum/camphor/menthol/phenol
				SOFTLIPS LIP PROTECTANT dimethicone/octinoxate/oxybenzone/ octisalate
		FM (March 6, 2009)	aluminum sulfate tetradecahydrate combined with calcium acetate monohydrate in powder or tablet form to provide an aluminum acetate solution	
Cold Sore Treatment Combinations	OTC Monograph Combinations	NPR (Jan. 1, 1990)	combinations of skin protectant with external analgesic active ingredients	ANBESOL COLD SORE allantoin/camphor/benzocaine/white petrolatum
				CARMEX menthol/camphor/alum/salicylic acid/ phenol
	NDA	July 25, 2000	docosanol	ABREVA
Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products	OTC Monograph Single Ingredients	FM (Dec. 4, 1991)	coal tar	NEUTROGENA T/GEL ORIGINAL, PSORIASIN
			pyrithione zinc	HEAD & SHOULDERS, ZINCON
			salicylic acid	DENOREX, DERMAREST PSORIASIS
			selenium sulfide	SELSUN
			sulfur	
	OTC Monograph Combinations	FM (Dec. 4, 1991)	salicylic acid/sulfur	ALA SEB
		FM (March 6, 2007)	coal tar/menthol	

G. Skin Treatment Products

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Acne Products	OTC Monograph Single Ingredients	FM (Aug. 16, 1991)	resorcinol	
			salicylic acid	CLEARASIL, CLEAN & CLEAR, PANOXYL, OXY, STRIDEX, PHISODERM
			sulfur	
		FM (March 4, 2010)	benzoyl peroxide	CLEARASIL, CLEAN & CLEAR, PANOXYL, OXY
	OTC Monograph Combinations	FM (Aug. 16, 1991)	resorcinol/sulfur	ACNOMEL
Corn, Callus, and Wart Removers	OTC Monograph Single Ingredients	FM (Aug. 14, 1990)	salicylic acid	DR.SCHOLL'S, WART-OFF, COMPOUND W
Poison Ivy, Oak & Sumac Rash Prevention	NDA	Aug. 26, 1997	bentoquatam	IVY BLOCK
Antiperspirants	OTC Monograph Single Ingredients	FM (Jun. 9, 2003)	aluminum chlorohydrate, aluminum chlorohydrex, aluminum zirconium, and derivatives thereof	SPEED STICK, GILLETTE, AXE
Skin Bleaching Products	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	hydroquinone	PALMER'S, AMBI
Dermal Antifungals	OTC Monograph Single Ingredients	FM (Sept. 23, 1993)	clioquinol	
			haloprogin	
			miconazole	DESENEX, CRUEX
			povidone-iodine	
			tolnaftate	TINACTIN, TING, ODOR-EATERS, DR.SCHOLL'S
			undecylenic acid and its salts (calcium, copper, and zinc)	
		FM (Feb. 8, 2002)	clotrimazole	MYCELEX
	NDA	Oct. 10, 1997	ketoconazole	NIZORAL
		March 9, 1999	terbinafine	LAMISIL
		Dec. 7, 2001	butenafine	LOTRIMIN ULTRA
Pediculicides	OTC Monograph Combinations	FM (Dec. 14, 1993)	pyrethrum extract/piperonyl butoxide	RID, PRONTO
	NDA	May 2, 1990	permethrin	PERMETHRIN, NIX

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G. Skin Treatment Products

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Sunscreens	OTC Monograph Single Ingredients	FM (May 21, 1999)	aminobenzoic acid (PABA), avobenzone, cinoxate, dioxybenzone, homosalate, menthyl anthranilate (meradimate), octocrylene, octyl methoxy-cinnamate (octinoxate), octyl salicylate (octisalate), oxybenzone, padimate O, phenylbenzimidazole sulfonic acid (ensulozide), sulisobenzone, titanium dioxide, trolamine salicylate, zinc oxide	
	OTC Monograph Combinations	FM (May 21, 1999)	combinations of sunscreen active ingredients	BAIN SOLEIL, COPPERTONE, BULL FROG, NEUTROGENA
	NDA	July 21, 2006	ecamsule/avobenzone/octocrylene	ANTHELIOS SX

H. Hair Loss Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Hair Grower	NDA	Feb. 9, 1996	minoxidil	ROGAINE

I. Topical Antiseptics and Antibiotics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Healthcare Antiseptics (applied topically to the skin to prevent infection or cross contamination)	OTC Monograph Single Ingredients	TFM (June 17, 1994)	Handwash products: alcohol, povidone-iodine	PURELL alcohol
			Patient preoperative skin preparations: alcohol, iodine tincture, isopropyl alcohol, povidone-iodine	
			Surgical hand scrubs: alcohol, povidone-iodine	
		FM pending	triclosan (handwash, patient preoperative preparation)	PALMOLIVE ULTRA, DIAL
			triclocarban (all uses)	CUTICURA
	NDA	Sept. 17, 1976	chlorhexidine gluconate	HIBICLENS, BETASEPT
		Nov. 29, 1985	povidone-iodine (sponge)	E-Z SCRUB 201
First Aid Antiseptics (to prevent infection in wounds, scrapes, and burns)	OTC Monograph Single Ingredients	TFM (July 22, 1991)	alcohol, benzalkonium chloride, benzethonium chloride, camphorated metacresol, camphorated phenol in light mineral oil vehicle, eucalyptol, hexylresorcinol, hydrogen peroxide, iodine tincture, iodine topical solution, isopropyl alcohol, menthol, methylbenzethonium chloride, methyl salicylate, phenol, povidone-iodine, thymol	BETADINE povidone-iodine
				IODEX iodine
		FM pending	chloroxylenol	
	OTC Monograph Combinations	TFM (July 22, 1991)	combination of alcohol, eucalyptol, menthol, methyl salicylate, and thymol	
			combinations with external analgesics	LANACANE FIRST AID benzethonium chloride/benzocaine
				FOILLE chloroxylenol/benzocaine
				GOLD BOND FIRST AID benzethonium chloride/menthol
				BACTINE FIRST AID benzalkonium chloride/lidocaine
			combinations with skin protectants	
First Aid Antibiotics	OTC Monograph Single Ingredients	FM (Dec. 11, 1987)	bacitracin, bacitracin zinc, chlortetracycline, neomycin sulfate, tetracycline	
	OTC Monograph Combinations	FM (Dec. 11, 1987)	combinations of antibiotic active ingredients (bacitracin, bacitracin zinc, neomycin sulfate, polymyxin B, oxytetracycline); combinations with 'caine'-type external analgesic ingredients	POLYSPORIN bacitracin zinc/poylymyxin B
				NEOSPORIN PLUS polymyxin B/neomycin/pramoxine
				BACTINE bacitracin/neomycin/polymyxin B/ pramoxine

J. Anorectal Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Local Anesthetics	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	benzocaine, benzyl alcohol, dibucaine, dyclinone, lidocaine, pramoxine, tetracaine	AMERICAINE benzocaine
				NUPERCAINAL dibucaine
Vasoconstrictor Active Ingredients	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	ephedrine, epinephrine, phenylephrine	
Protectant Active Ingredients	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	aluminum hydroxide gel, cocoa butter, glycerin, hard fat,kaolin, lanolin, mineral oil, petrolatum, topical starch, white petrolatum, calamine, cod liver oil, shark liver oil, zinc oxide	TUCKS TOPICAL STARCH SUPPOSITORIES topical starch
Analgesic, anesthetic, and antipruritic active ingredients	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	camphor, juniper, menthol	
Astringents	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	calamine, witch hazel (hamamelis water), zinc oxide	TUCKS WITCH HAZEL witch hazel
Kerotolytics	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	alcloxa , resorcinol	
Anorectal Ingredient Combinations	OTC Monograph Combinations	FM (Aug. 3, 1990)	combinations of anorectal active ingredients	PREPARATION H CREAM glycerin/phenylephrine/pramoxine/ white petrolatum
				PREPARATION H SUPPOSITORIES cocoa butter/phenylephrine/shark liver oil
				TUCKS OINTMENT mineral oil/pramoxine/zinc oxide
				TRONOLANE CREAM pramoxine/zinc oxide
				TRONOLANE SUPPOSITORIES hard fat/phenylephrine
Hydrocortisone	OTC Monograph Single Ingredients	Final Rule (Aug. 26, 2003)	hydrocortisone	PREPARATION H HYDROCORTISONE

K. Vaginal Antifungals

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Vaginal Antifungals	NDA	Nov. 30, 1990	clotrimazole	GYNE-LOTRIMIN
		March 13, 1991	miconazole	MONISTAT
		Dec. 26, 1995	butoconazole	FEMSTAT
		Feb. 11, 1997	tioconazole	VAGISTAT

L. Ophthalmics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Ophthalmic Astringents	OTC Monograph Single Ingredients	FM (March 4, 1988)	zinc sulfate	
Ophthalmic Demulcents	OTC Monograph Single Ingredients	FM (March 4, 1988)	cellulose derivatives (carboxymethylcellulose sodium, hydroxyethyl cellulose, hydroxypropyl methylcellulose [hypromellose], methylcellulose), dextran 70, gelatin, polyols (glycerin, polyethylene glycol 300 & 400, polysorbate 80, propylene glycol), polyvinyl alcohol, povidone	GENTEAL EYE DROPS, ROHTO HYDRA hypromellose
				ADVANCED EYE RELIEF LUBRICANT glycerin
Ophthalmic Emollients	OTC Monograph Single Ingredients	FM (March 4, 1988)	lanolin preparations, oleaginus ingredients (light mineral oil, mineral oil, paraffin, petrolatum, white ointment, white petrolatum, white wax, yellow wax)	SOOTHE light mineral oil
Ophthalmic Hypertonicity Agents	OTC Monograph Single Ingredients	FM (March 4, 1988)	sodium chloride	MURO
Ophthalmic Vasoconstrictors	OTC Monograph Single Ingredients	FM (March 4, 1988)	ephedrine, naphazoline, phenylephedrine, tetrahydrozoline	VISINE ORIGINAL tetrahydrozoline
	NDA	Mar. 31, 1989	oxymetazoline	VISINE L.R.
		June 08, 1994	pheniramine/naphazoline	OPCON-A, VISINE-A
		Jul. 11, 1994	antazoline/naphazoline	VASOCON
Ophthlamic Antihistamines	NDA	Oct. 19, 2006	ketotifen	ZADITOR, CLARITIN EYE
Eyewashes	OTC Monograph Single Ingredients	FM (March 4, 1988)	water, tonicity agents, agents for establishing pH and buffering to achieve the same pH as tears, preservatives	ADVANCED EYE RELIEF EYE WASH purified water
Ophthalmics Combinations	OTC Monograph Combinations	FM (March 4,1988)	combinations of ophthalmic active ingredients	CLEAR EYES SENSITIVITY dextran/hypromellose
				CLEAR EYES OINTMENT mineral oil/white petrolatum
				ROHTO COOL polysorbate/naphazoline

M. Otics (Ear Wax Removal Aids)

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Earwax Removal Aids	OTC Monograph Single Ingredients	FM (Aug. 8, 1986)	carbamide peroxide	DEBROX, MURINE

N. Oral Healthcare Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Anticaries	OTC Monograph Single Ingredients	FM (Nov. 6, 1995)	sodium fluoride	COLGATE, AIM, ACT, AQUAFRESH, CREST, MENTADENT, REMBRANDT
			sodium monofluorophosphate	COLGATE, AIM, SENSODYNE, AQUAFRESH, REMBRANDT
			stannous fluoride	CREST PRO-HEALTH
Anesthetics/ Analgesics	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	benzocaine	COLGATE ORABASE, ORAJEL, ANBESOL, KANK-A
			benzyl alcohol	ZILACTIN
			dyclinone	SUCRETS ORIGINAL
			hexylresorcinol	S.T. 37
			menthol	
			phenol	CHLORASEPTIC SPRAY
		TFM (Sept. 24, 1991)	butacaine	
			salicylic alcohol	
Oral Astringents	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	alum	
			zinc oxide	
Debriding Agents/ Oral Wound Cleansers	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	carbamide peroxide in anhydrous glycerin	
			hydrogen peroxide	COLGATE PEROXYL, ORAJEL
			sodium bicarbonate	
			sodium perborate monohydrate	
Oral Demulcents	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	elm bark, gelatin, glycerin, pectin	
Oral Mucosal Protectants	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	compound benzoin tincture	
			benzoin tincture	
Tooth Desensitizers	OTC Monograph Single Ingredients	TFM (Sept. 24, 1991)	potassium nitrate	SENSODYNE, CREST SENSITIVITY
		FM pending	stannuous fluoride	CREST PRO-HEALTH

N. Oral Healthcare Products

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antigingivitis/ Antiplaque Ingredients	OTC Monograph Single Ingredients	ANPR (May 29, 2003)	cetylpyridinium chloride	AIM, ACT, CREST, ORAJEL
	OTC Monograph Combinations	ANPR (May 29, 2003)	combination of eucalyptol, menthol, methyl salicylate, and thymol	LISTERINE
	NDA	July 11, 1997	sodium fluoride/triclosan	COLGATE TOTAL
Oral Healthcare Ingredient Combinations	OTC Monograph Combinations	ANPR (May 29, 2003)	combinations of oral healthcare active ingredients	SUCRETS, ORAJEL menthol/pectin
				CEPACOL, CHLORASEPTIC LOZENGES menthol/benzocaine
				CHLORASEPTIC phenol/glycerin

O. Menstrual Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Menstrual Products	OTC Monograph Single Ingredients	TFM (Nov. 16, 1988)	pamabrom [diuretic]	
			ammonium chloride [diuretic]	
			caffeine [diuretic]	
			antihistamines reserved	
			muscle relaxants reserved	
	OTC Monograph Combinations	TFM (Nov. 16, 1988)	combinations of diuretics with analgesics	WOMEN'S TYLENOL acetaminophen/pamabrom
				PAMPRIN acetaminophen/pamabrom/pyrilamine [antihistamine]
				MIDOL acetaminophen/caffeine/pyrilamine [antihistamine]
				DIUREX magnesium salicylate/caffeine
			ammonium chloride with caffeine or pamabrom	

P. Contraceptives

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Vaginal Contraceptives	OTC Monograph Single Ingredients	FM pending	nonoxynol-9	ORTHO OPTIONS, GYNOL II
	NDA	April 1, 1983	nonoxynol-9	TODAY
Emergency Contraceptives	NDA	Aug. 24, 2006	levonorgestrel	PLAN B

Q. Nicotine Replacement Therapy

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Nicotine Oral (Gum)	NDA	Feb. 9, 1996	nicotine polacrilex	NICORETTE
Nicotine Oral (Lozenge)	NDA	Oct. 31, 2002	nicotine polacrilex	COMMIT
Nicotine Transdermal Systems	NDA	July 3, 1996	nicotine	NICODERM, HABITROL

R. Weight Loss Aids

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Weight Loss Aids	NDA	Feb. 7, 2007	orlistat	ALLI

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