



yourhealth⁺
AT HAND
book

Guide to OTC Active Ingredients
in the United States

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Your Health at Hand Book: Guide to OTC Active Ingredients in the United States

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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 in 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 should consult the pertinent Code of Federal Regulations (CFR) and/or Federal Register notices 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 tentative final monograph (TFM).

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 *The National Library of Medicine's (NLM) DailyMed* website, websites of United States internet retailers [such as Amazon, Walmart, and drugstore.com (accessed July 2017 - April 2018)], and CHPA members. 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. Brand examples are listed in random order. Although not captured in this booklet, there are many OTC drug products that are manufactured as generics or store brands (e.g., Walmart Equate, CVS Health, Well at Walgreens) that also contain the active ingredients listed.

Date of NDA OTC Approval

The FDA *Orange Book*, *Drugs@FDA.gov*, other FDA sources, and the NLM DailyMed website 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, PEDIACARE, GOODY'S BACK & BODY, LITTLE FEVERS BY LITTLE REMEDIES
			carbaspirin	
			salicylate and its salts (choline, magnesium, or sodium)	DOAN'S magnesium salicylate
	OTC Monograph Combinations	TFM (Nov. 16, 1988)	acetaminophen with other analgesics	GOODY'S BACK & 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 <i>B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic</i>
			combinations with diuretics	see <i>L. Menstrual</i>
	Proposed TFM amendment (Dec. 24, 1991)	any analgesic with caffeine	EXCEDRIN EXTRA STRENGTH, ANACIN, VANQUISH, GOODY'S EXTRA STRENGTH acetaminophen/aspirin/caffeine	
			BAYER BACK AND BODY, BC, STANBACK aspirin/caffeine	
	NDA	prior Jan. 1, 1982	acetaminophen suppositories	aspirin/caffeine
		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 (ER)	ALEVE-D SINUS & COLD	
Feb. 25, 2000		ibuprofen for migraine	ADVIL MIGRAINE	
Dec. 19, 2002		ibuprofen/pseudoephedrine/ chlorpheniramine	ADVIL ALLERGY SINUS	
Dec. 21, 2011		chlorpheniramine maleate/ibuprofen/ phenylephrine	ADVIL ALLERGY & CONGESTION RELIEF	
May 27, 2010	ibuprofen/phenylephrine	ADVIL SINUS CONGESTION AND PAIN		
Jun. 12, 2012	ibuprofen sodium	ADVIL		

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

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)	chlorphedianol	
			codeine	
			dextromethorphan	ROBITUSSIN DM, HOLD DM, VICKS DAYQUIL
			menthol	
	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 (ER) 12 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, pyrillamine, thonzylamine, triprolidine	BENADRYL ALLERGY diphenhydramine
			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)	
		May 22, 1987	dexbrompheniramine/pseudoephedrine/acetaminophen ER	
		Aug. 21, 1992	clemastine	TAVIST ALLERGY
		March 1, 2001	clemastine/pseudoephedrine/acetaminophen	
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
		Jan. 24, 2011	fexofenadine	ALLEGRA ALLERGY
		Jan. 24, 2011	fexofenadine/pseudoephedrine	ALLEGRA D
		Jan. 31, 2017	levocetirizine	XYZAL
Oral Expectorants	OTC Monograph Single Ingredients	FM (Feb. 28, 1989)	guaifenesin	MUCINEX
	NDA	July 12, 2002	guaifenesin (ER)	MUCINEX ER
		June 22, 2004	guaifenesin/pseudoephedrine (ER)	MUCINEX D ER
		April 29, 2004	guaifenesin/dextromethorphan (ER)	MUCINEX DM ER

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B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic *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
				ALLEREST PE phenylephrine/chlorpheniramine
				DIMETAPP NIGHTTIME phenylephrine/diphenhydramine
				PERCOGESIC acetaminophen/diphenhydramine
				MUCINEX FAST-MAX NIGHT TIME COLD & FLU acetaminophen/diphenhydramine/phenylephrine
				THERAFLU COLD & FLU acetaminophen/pheniramine/phenylephrine
				BUCKLEY'S CHEST CONGESTION guaifenesin/menthol
				MUCINEX FAST-MAX COLD & SINUS, MUCINEX SINUS-MAX PRESSURE & PAIN acetaminophen/guaifenesin/phenylephrine
				MUCINEX SINUS-MAX DAY NIGHT MAXIMUM STRENGTH acetaminophen/diphenhydramine/guaifenesin/phenylephrine
				MUCINEX FAST-MAX COLD, FLU AND SORE THROAT, MUCINEX SINUS-MAX SEVERE CONGESTION RELIEF, DAYQUIL SEVERE acetaminophen/dextromethorphan/guaifenesin/phenylephrine

B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic *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	MUCINEX FAST-MAX DAY SEVERE COLD & NIGHT COLD FLU, MUCINEX SINUS-MAX DAY/NIGHT acetaminophen/dextromethorphan/ doxylamine/ guaifenesin/phenylephrine
				MUCINEX FAST-MAX DAY TIME SEVERE CONGESTION & COUGH and MUCINEX FAST-MAX NIGHT TIME COLD & FLU MAXIMUM STRENGTH acetaminophen/dextromethorphan/ diphenhydramine/ guaifenesin/phenylephrine
				NYQUIL SEVERE COLD & FLU acetaminophen/dextromethorphan/ doxylamine/phenylephrine
				MUCINEX FAST-MAX SEVERE CONGESTION & COUGH, CHILDREN'S MUCINEX CONGESTION & COUGH dextromethorphan/guaifenesin/ phenylephrine
				CHILDRENS DIMETAPP COLD AND COUGH brompheniramine/dextromethorphan/ phenylephrine
				ROBITUSSIN TO GO COUGH AND CHEST CONGESTION DM, DAYQUIL COUGH & CONGESTION dextromethorphan/guaifenesin
				DAYQUIL HBP acetaminophen/dextromethorphan
				LODRANE-D brompheniramine/pseudoephedrine
				TFM (Jan. 27, 1988)
Bronchodilators	OTC Monograph Single Ingredients	FM (Oct. 2, 1986)	ephedrine, racephedrine epinephrine, racepinephrine	
	OTC Monograph Oral Combinations	FM (Dec. 23, 2002)	ephedrine/guaifenesin	PRIMATENE TABLETS, BRONKAID
Topical Antitussives	OTC Monograph Single Ingredients	FM (Aug. 12, 1987)	camphor	VICKS VAPOSTEAM
			menthol	FISHERMAN'S FRIEND, VICKS VAPODROPS
	OTC Monograph Combinations	FM (Dec. 23, 2002)	camphor/menthol camphor/menthol/eucalyptus oil	VICKS VAPORUB, MENTHOLATUM NIGHTTIME VAPORIZING RUB

continued next page

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

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Topical Nasal Decongestants	OTC Monograph Single Ingredients	FM (Aug. 23, 1994)	ephedrine	
			naphazoline	
			oxymetazoline	AFRIN, VICKS SINEX, SUDAFED OM, NOSTRILLA, ZICAM SINUS RELIEF, MUCINEX SINUS-MAX FULL FORCE, DRISTAN 12 HR
			phenylephrine	NEO-SYNEPHRINE, LITTLE REMEDIES DECONGESTANT NOSE DROPS, 4-WAY
			propylhexedrine	BENZEDREX
			xylometazoline	
Topical Nasal Allergy Symptom Controllers	NDA	Jan. 3, 1997	cromolyn sodium	FLONASE ALLERGY RELIEF
Topical Nasal Allergy Steroid for Allergic Rhinitis	NDA	Oct. 11, 2013	triamcinolone acetonide	NASACORT ALLERGY 24HR
		July 23, 2014	fluticasone propionate	FLONASE ALLERGY RELIEF

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, NYTOL, ZzzQuil	
		OTC Monograph Combinations	TFM (Jun 13, 1978)	aspirin/diphenhydramine	BAYER PM
	acetaminophen/diphenhydramine			TYLENOL PM, GOODY'S PM	
	NDA		Oct. 18, 1978	doxylamine	UNISOM
			Dec. 21, 2005	ibuprofen/diphenhydramine	ADVIL PM
			Jan. 17, 2014	naproxen sodium/diphenhydramine	ALEVE 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	TUMS, CHILDREN'S PEPTO-BISMOL, MAALOX CHILDREN'S calcium carbonate
				PHILLIPS ORIGINAL magnesium hydroxide
	OTC Monograph Combinations	FM (June 4, 1974)	combinations of antacids	ALKA SELTZER GOLD citric acid/sodium bicarbonate/potassium bicarbonate
				MYLANTA aluminum hydroxide/magnesium hydroxide/simethicone
				ROLAIDS calcium carbonate/magnesium hydroxide
				GAVISCON aluminum hydroxide/magnesium carbonate
				combinations with any nonacid laxative
combinations with analgesics	See A. <i>Internal Analgesics</i>			
combinations with anti-flatulents	MAALOX ADVANCED MAXIMUM STRENGTH, PHAZYME GAS AND ACID 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	AXID AR
		Oct. 16, 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
		March 28, 2014	esomeprazole magnesium	NEXIUM 24 HR
Antiflatulents	OTC Monograph Single Ingredients	FM (June 4, 1974)	simethicone	GAS-X, LITTLE REMEDIES GAS RELIEF DROPS, PHAZYME
	OTC Monograph Combinations	FM (June 4, 1974)	combinations with antacids	see above Antacids - combinations with antiflatulents

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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	KAOPECTATE ANTI DIARRHEAL, PEPTO-BISMOL ORIGINAL
			kaolin	
	NDA	March 1, 1988	loperamide	IMODIUM A-D
		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	Oct. 6, 2006	polyethylene glycol 3350	MIRALAX
Lubricants	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	mineral oil	FLEET MINERAL OIL ENEMA, KONDREMUL
Saline Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	magnesium hydroxide	FLEET PEDIA-LAX CHEWABLE TABLETS
			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, CORRECTOL, FLEET BISACODYL ENEMA
			sennosides	SEKOT, EX-LAX
			castor oil	
			dehydrocholic acid	
Stool Softeners	OTC Monograph Single Ingredients	TFM (Sept. 2, 1993)	docusate	COLACE, PHILLIPS STOOL SOFTENER, SURFAK STOOL SOFTENER, DULCOLAX, PEDIA-LAX 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

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	
			dimenhydrinate	DRAMAMINE ORIGINAL
			diphenhydramine	
			meclizine	BONINE, DRAMAMINE LESS DROWSY FORMULA
Anthelmintics	OTC Monograph Single Ingredients	FM (Aug. 1, 1986)	pyrantel pamoate	PRONTO PLUS
Poison Treatment	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	ipecac syrup	
			activated charcoal	EZ CHAR

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, ICY HOT w/LIDOCAINE lidocaine
				CeraVe ITCH RELIEF MOISTERIZING CREAM pramoxine
				CEPACOL SORE THROAT dyclonine/glycerin
Alcohols and Ketones	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	benzyl alcohol, camphor, camphorated metacresol, juniper tar, menthol, phenol, phenolate sodium, resorcinol	CAMPHO-PHENIQUE camphorated phenol
Antihistamines	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	diphenhydramine	EXTRA STRENGTH BENADRYL GEL
			tripelennamine	
Hydrocortisone Preparations	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	hydrocortisone	CORTIZONE, CORTAID, MONISTAT COMPLETE CARE ITCH RELIEF
Irritants That Produce Redness	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	allyl isothiocyanate, ammonia, methyl salicylate, turpentine oil	AFTER BITE ammonia
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

continued next page

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

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Salicylates (Unknown Action)	OTC Monograph Single Ingredients	ANPR (Dec 4, 1979)	aspirin, glycol salicylate, salicylamide, trolamine salicylate	ASPERCREME, MOBISYL
Male Genital Desensitizer	OTC Monograph Single Ingredients	FM (June 19, 1992)	benzocaine	MALE DESENSITIZER PLEASURE BALM
			lidocaine	ENDURANCE RX MALE DESENSITIZER
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 ITCH STOPPING diphenhydramine/zinc acetate
				BACTINE lidocaine/benzalkonium chloride
				IVAREST CREAM diphenhydramine/calamine/benzyl alcohol
				CALADRYL CLEAR, IVAREST SPRAY pramoxine/zinc acetate
				LANACANE benzocaine/benzethonium chloride
				VAGISIL ANTI-ITCH benzocaine/resorcinol
				THERAGESIC, MENTHOLATUM DEEP HEATING methyl salicylate/menthol
				SATOGESIC methyl salicylate/camphor/menthol
				BOROLEUM camphor/menthol/white petrolatum
				VAPORUB camphor/methol/eucalyptus oil
CALADRYL calamine/pramoxine				
	NDA	Feb. 20, 2008	methyl salicylate/menthol	SALONPAS PATCH

G. Skin Treatment

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, CeraVE THERAPEUTIC HAND, MONISTAT COMPLETE CARE CHAFING RELIEF dimethicone
				JOHNSON'S BABY, BALMEX DIAPER RASH, BOUDREAUX'S BUTT PASTE zinc oxide
				CeraVe BABY DIAPER RASH CREAM dimethicone/zinc oxide
				DESITIN MULTI-PURPOSE, CHAP-ET, CLOVERINE white petrolatum
Skin Protectants Astringents	OTC Monograph Single Ingredients	FM (June 4, 2003)	aluminum acetate, aluminum sulfate, witch hazel	DOMEBORO aluminum acetate
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 dimethicone/menthol
				BLISTEX MEDICATED LIP BALM dimethicone/oxybenzone/padimate O
				CHAPSTICK MEDICATED LIP BALM petrolatum/camphor/menthol/phenol
		SOFTLIPS LIP PROTECTANT dimethicone/octinoxate/oxybenzone/octisalate		
		CHAPSTICK white petrolatum/padimate O		
		FM (May 12, 1999)	combinations of sunscreen active ingredients	CHAPSTICK ULTRA SPF-30 octinoxate/octisalate/octocrylene/oxybenzone/white petrolatum
		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 COLD SORE TREATMENT benzocaine
				BLISTEX LIP OINTMENT dimethicone/camphor/menthol/phenol
	NDA	July 25, 2000	docosanol	ABREVA

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Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products	OTC Monograph Single Ingredients	FM (Dec. 4, 1991)	coal tar	NEUTROGENA T/GEL ORIGINAL, PSORIASIN, OXIPOR
			pyrithione zinc	HEAD & SHOULDERS, ZINCON MEDICATED DANDRUFF
			salicylic acid	DENOREX, DERMAREST PSORIASIS
			selenium sulfide	SELSUN BLUE MOISTURIZING
			sulfur	
	OTC Monograph Combinations	FM (Dec. 4, 1991)	salicylic acid/sulfur	
		FM (March 6, 2007)	coal tar/menthol	
Acne Products	OTC Monograph Single Ingredients	FM (Aug. 16, 1991)	resorcinol	
			salicylic acid	CLEARASIL, CLEAN & CLEAR, OXY SKIN, STRIDEX, PHISODERM, AMBI EVEN & CLEAR, ACNEFREE
			sulfur	
		FM (March 4, 2010)	benzoyl peroxide	CLEARASIL, CLEAN & CLEAR, PANOXYL, OXY SENSITIVE, ACNEFREE
	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, COMPOUND W, FREEZONE, MOSCO
Poison Ivy, Oak & Sumac Rash Prevention	NDA	Aug. 26, 1996	bentoquatam	IVY BLOCK
Antiperspirants	OTC Monograph Single Ingredients	FM (Jun. 9, 2003)	aluminum chlorohydrate, aluminum chlorohydrate, aluminum zirconium, and derivatives thereof	SPEED STICK, GILLETTE, AXE, LADY SPEED STICK, TEEN SPIRIT
Skin Bleaching Products	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	hydroquinone	PALMER'S, AMBI

G. Skin Treatment *continued*

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Dermal Antifungals	OTC Monograph Single Ingredients	FM (Sept. 23, 1993)	clioquinol	
			haloprogin	
			miconazole	DESENEX, CRUEX, TING SPRAY POWDER
			povidone-iodine	
			tolnaftate	TINACTIN, TING, ODOR-EATERS
		FM (Feb. 8, 2002)	clotrimazole	LOTRIMIN
	NDA	Oct. 10, 1997	ketoconazole	NIZORAL A-D
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 PLUS
	NDA	May 2, 1990	permethrin	PERMETHRIN, NIX
Sunscreens	OTC Monograph Single Ingredients	FM (May 21, 1999)	aminobenzoic acid (PABA), avobenzone, cinoxate, dioxybenzone, homosalate, menthyl anthranilate (meradimate), octocrylene, octyl methoxycinnamate (octinoxate), octyl salicylate (octisalate), oxybenzone, padimate O, phenylbenzimidazole sulfonic acid (ensulozide), sulisobenzene, titanium dioxide, trolamine salicylate, zinc oxide	
	OTC Monograph Combinations	FM (May 21, 1999)	combinations of sunscreen active ingredients	BAIN SOLEIL, COPPERTONE, BULL FROG, NEUTROGENA, CeraVe
	NDA	July 21, 2006	ecamsule/avobenzone/octocrylene	ANTHELIOS SX

H. Hair Loss

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	
	NDA	Sept. 17, 1976	chlorhexidine gluconate	HIBICLENS, BETASEPT
		Nov. 29, 1985	povidone-iodine (sponge)	
First Aid Antiseptics (to prevent infection in wounds, scrapes, and burns)	OTC Monograph Single Ingredients	TFM (July 22, 1991)	alcohol, benzalkonium chloride, benzethonium chloride, camphor ated metacresol, camphor ated 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, chloroxylenol	BETADINE povidone-iodine
	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 PAIN AND ITCH benzalkonium chloride/lidocaine
			combinations with skin protectants	BACTINE FIRST AID benzalkonium chloride/lidocaine
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/poilymyxin B
				NEOSPORIN PLUS polymyxin B/neomycin/pramoxine
			BACTINE bacitracin/neomycin/polymyxin B/ pramoxine	

J. Anorectal

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)	bacitracin, bacitracin zinc, chlortetracycline, neomycin sulfate, tetracycline	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 MEDICATED COOLING PADS witch hazel
Kerolytics	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	alcloxa , resorcinol	
Hydrocortisone	OTC Monograph Single Ingredients	Final Rule (Aug. 26, 2003)	hydrocortisone	PREPARATION H HYDROCORTISONE
Anorectal Ingredient Combinations	OTC Monograph Combinations	FM (Aug. 3, 1990)	combinations of anorectal active ingredients	PREPARATION H MAXIMUM STRENGTH CREAM glycerin/phenylephrine/pramoxine/ white petrolatum
				PREPARATION H SUPPOSITORIES cocoa butter/phenylephrine
				TRONOLANE CREAM pramoxine/zinc oxide

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-LOTIRIMIN
		Feb. 15, 1991	miconazole	MONISTAT
		Dec. 21, 1995	butoconazole	
		Feb. 11, 1997	tioconazole	VAGISTAT
		Nov. 21, 2001	miconazole	MONISTAT 1-DAY OINTMENT

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 hypromellose
				ROHTO HYDRA hydroxyethyl cellulose
				ADVANCED EYE RELIEF DRY EYE LUBRICANT REJUVENATION glycerin/propylene glycol
				CLEAR EYES PURE RELIEF FOR DRY EYES glycerin
Ophthalmic Emollients	OTC Monograph Single Ingredients	FM (March 4, 1988)	lanolin preparations, oleaginous ingredients (light mineral oil, mineral oil, paraffin, petrolatum, white ointment, white petrolatum, white wax, yellow wax)	SOOTHE XP light mineral oil/mineral oil
Ophthalmic Hypertonicity Agents	OTC Monograph Single Ingredients	FM (March 4, 1988)	sodium chloride	MURO 128
Ophthalmic Vasoconstrictors	OTC Monograph Single Ingredients	FM (March 4, 1988)	ephedrine, naphazoline, phenylephrine, tetrahydrozoline	VISINE ORIGINAL tetrahydrozoline
	NDA	March 31, 1989	oxymetazoline	VISINE L.R.
		June 8, 1994	pheniramine/naphazoline	OPCON-A, VISINE-A
		Dec. 22, 2017	brimonidine tartrate	LUMIFY
Ophthalmic Antihistamines	NDA	Oct. 19, 2006	ketotifen	ZADITOR, ALAWAY
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
Ophthalmic Combinations	OTC Monograph Combinations	FM (March 4, 1988)	combinations of ophthalmic active ingredients	CLEAR EYES COMPLETE 7 SYMPTOM RELIEF hypromellose/naphazoline/ polysorbate 80/zinc sulfate
				CLEAR EYES NATURAL TEARS polyvinyl alcohol/povidone
				CLEAR EYES TRIPLE ACTION polyvinyl alcohol/povidone/ tetrahydrozoline
				CLEAR EYES PURE RELIEF MULTI-SYMPTOM glycerin/hypromellose/phenylephrine
				CLEAR EYES MAXIMUM ITCHY EYE RELIEF glycerin/naphazoline/zinc sulfate
				ROHTO COOL polysorbate 80/naphazoline
				SOOTHE glycerin/propylene glycol

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

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Anticaries	OTC Monograph Single Ingredients	FM (Oct. 6, 1995)	sodium fluoride	COLGATE, AIM, ACT, AQUAFRESH, CREST 3D WHITE, REMBRANDT, CREST ANTICAVITY FLUORIDE (rinse)
			sodium monofluorophosphate	COLGATE, AQUAFRESH, REMBRANDT
			stannous fluoride	CREST PRO-HEALTH, COLGATE GEL-KAM
Anesthetics/ Analgesics	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	benzocaine	ORAJEL, ANBESOL, KANK-A LIQUID, ZILACTIN-B, BENZODENT, DENTEK PAIN RELIEF
			benzyl alcohol	ZILACTIN EARLY RELIEF COLD SORE
			dyclinone	SUCRETS SORE THROAT
			hexylresorcinol	S.T. 37
			menthol	VICKS VAPODROPS, LUDEN'S MENTHOL
			phenol	CHLORASEPTIC SPRAY, CEPASTAT
		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	GLY-OXIDE
			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	LUDEN'S
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
		TFM (Sept. 24, 1991)	stannous fluoride	CREST PRO-HEALTH, COLGATE GEL-KAM
	OTC Monograph Combinations	TFM (Sept. 24, 1991)	potassium nitrate and sodium fluoride	COLGATE SENSITIVE, SENSODYNE, CREST SENSITIVITY

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Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antigingivitis/ Antiplateque Ingredients	OTC Monograph Single Ingredients	ANPR (May 29, 2003)	cetylpyridinium chloride	ACT, CREST, COLGATE TOTAL MOUTHWASH
			stannous fluoride	CREST PRO-HEALTH TOOTHPASTE
	NDA	July 11, 1997	sodium fluoride/tricolsan	COLGATE TOTAL TOOTHPASTE
	OTC Monograph Combinations	ANPR (May 29, 2003)	combination of eucalyptol, menthol, methyl salicylate, and thymol	LISTERINE
Oral Healthcare Ingredient Combinations	OTC Monograph Combinations TFM (Jan. 27, 1988)	ANPR (May 29, 2003)	combinations of oral healthcare active ingredients	SUCRETS dyclonine/menthol/pectin
				SUCRETS COMPLETE dyclonine/menthol
				CEPACOL, CHLORASEPTIC LOZENGES menthol/benzocaine
				CHLORASEPTIC TOTAL menthol/benzocaine/ dextromethrophan
				CHLORASEPTIC phenol/glycerin
		KANK-A SOFTBRUSH benzocaine/zinc chloride		
	TFM (Jan. 27, 1988)			

O. Menstrual

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	BACKAID MAX acetaminophen/pamabrom
				PAMPRIN acetaminophen/pamabrom/pyrilamine [antihistamine]
				MIDOL COMPLETE acetaminophen/caffeine/pyrilamine [antihistamine]
				DIUREX WATER PILLS magnesium salicylate/caffeine
				ammonium chloride with caffeine or pamabrom
NDA	Jan. 11, 1994	naproxen sodium	MENSTRIDOL	
NDA	Jun. 12, 2012	ibuprofen sodium	ADVIL MENSTRUAL PAIN	

P. Contraceptives

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Vaginal Contraceptives	OTC Monograph Single Ingredients	FM (Dec. 12, 1980)	nonoxynol-9	GYNOL II
	NDA	April 1, 1983	nonoxynol-9	TODAY
Emergency Contraceptives	NDA	Aug. 24, 2006	levonorgestrel	PLAN B
		Jul. 10, 2009	levonorgestrel (ER)	PLAN B ONE-STEP

Q. Nicotine Replacement Therapies

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 (Patch)	NDA	Aug. 2, 1996	nicotine	NICODERM CQ
	NDA	Nov. 12, 1999	nicotine	HABITROL

R. Weight Loss Aids, Overactive Bladder, Miscellaneous External Drug

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Weight Loss Aids	NDA	Feb. 7, 2007	orlistat	ALLI
Overactive Bladder	NDA	Jan. 25, 2013	oxybutynin	OXYTROL FOR WOMEN
Ingrown Toenail Relief Drug Products	OTC Monograph Single Ingredients	FM (May 7, 2003)	sodium sulfide	DR SCHOLL'S INGROWN TOENAIL PAIN RELIEVER



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