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

June 2018

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Corrections and updates should be sent to CHPA via e-mail to MMcDonald@chpa.org.
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:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPR</td>
<td>Advance notice of proposed rulemaking</td>
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<tr>
<td>ER</td>
<td>Extended release</td>
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<tr>
<td>FM</td>
<td>Final monograph</td>
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<tr>
<td>NDA</td>
<td>New drug application</td>
</tr>
<tr>
<td>NPR</td>
<td>Notice of proposed rulemaking</td>
</tr>
<tr>
<td>TFM</td>
<td>Tentative final monograph</td>
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## A. Internal (Oral) Analgesics

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Analgesics</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Nov. 16, 1988)</td>
<td>aspirin</td>
<td>BAYER ASPIRIN, ECOTRIN, BUFFERIN</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>acetaminophen</td>
<td>TYLENOL, PEDIACARE, GOODY’S BACK &amp; BODY, LITTLE FEVERS BY LITTLE REMEDIES</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>carbaspirin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>salicylate and its salts (choline, magnesium, or sodium)</td>
<td>DOAN’S magnesium salicylate</td>
</tr>
<tr>
<td>OTC Monograph</td>
<td></td>
<td></td>
<td>acetaminophen with other analgesics</td>
<td>GOGDY’S BACK &amp; BODY PAIN</td>
</tr>
<tr>
<td>Combinations</td>
<td></td>
<td></td>
<td>acetaminophen with antacids</td>
<td>acetaminophen/aspirin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>aspirin with antacids</td>
<td>ALKA Seltzer EXTRA STRENGTH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>aspirin/citric acid/sodium bicarbonate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>combinations with cough and cold ingredients</td>
<td>See B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic</td>
</tr>
<tr>
<td></td>
<td>Proposed TFM amendment</td>
<td></td>
<td>combinations with diuretics</td>
<td>see L. Menstrual</td>
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<tr>
<td></td>
<td>(Dec. 24, 1991)</td>
<td></td>
<td>any analgesic with caffeine</td>
<td>EXCEDRIN EXTRA STRENGTH, ANACIN, VANQUISH, GOODY’S EXTRA STRENGTH</td>
</tr>
<tr>
<td>NDA</td>
<td>prior Jan. 1, 1982</td>
<td></td>
<td>acetaminophen suppositories</td>
<td>acetaminophen/aspirin/caffeine</td>
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<tr>
<td></td>
<td>May 18, 1984</td>
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<td>ibuprofen</td>
<td>ADVIL, MOTRIN</td>
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<td>TYLENOL ARTHRITIS PAIN</td>
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<tr>
<td></td>
<td>Sept. 19, 1989</td>
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<td>ibuprofen/pseudoephedrine</td>
<td>ADVIL COLD &amp; SINUS</td>
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<tr>
<td></td>
<td>Jan. 11, 1994</td>
<td></td>
<td>naproxen</td>
<td>ALEVE</td>
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<td>Oct. 6, 1995</td>
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<td>ketoprofen</td>
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<td>Jan. 14, 1998</td>
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<td>aspirin/acetaminophen/caffeine for migraine</td>
<td>EXCEDRIN MIGRAINE</td>
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<td></td>
<td>Nov. 29, 1999</td>
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<td>naproxen/pseudoephedrine (ER)</td>
<td>ALEVE-D SINUS &amp; COLD</td>
</tr>
<tr>
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<td>Feb. 25, 2000</td>
<td></td>
<td>ibuprofen for migraine</td>
<td>ADVIL MIGRAINE</td>
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<tr>
<td></td>
<td>Dec. 19, 2002</td>
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<td>ibuprofen/pseudoephedrine/chlorpheniramine</td>
<td>ADVIL ALLERGY SINUS</td>
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<tr>
<td></td>
<td>Dec. 21, 2011</td>
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<td>chlorpheniramine maleate/ibuprofen/phenylephrine</td>
<td>ADVIL ALLERGY &amp; CONGESTION RELIEF</td>
</tr>
<tr>
<td></td>
<td>May 27, 2010</td>
<td></td>
<td>ibuprofen/phenylephrine</td>
<td>ADVIL SINUS CONGESTION AND PAIN</td>
</tr>
<tr>
<td></td>
<td>Jun. 12, 2012</td>
<td></td>
<td>ibuprofen sodium</td>
<td>ADVIL</td>
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</tbody>
</table>
### B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td>Oral Antitussives</td>
<td>OTC Monograph</td>
<td>FM (Aug. 12, 1987)</td>
<td>chlophedianol</td>
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<td></td>
<td>Single Ingredients</td>
<td></td>
<td>codeine</td>
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<tr>
<td></td>
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<td></td>
<td>dextromethorphan</td>
<td>ROBITUSSIN DM, HOLD DM, VICKS DAYQUIL</td>
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<td></td>
<td></td>
<td></td>
<td>menthol</td>
<td></td>
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<tr>
<td></td>
<td>FM (June 3, 1994)</td>
<td></td>
<td>diphenhydramine</td>
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<td></td>
<td>NDA</td>
<td>Oct. 8, 1982</td>
<td>dextromethorphan (ER)</td>
<td>DELSYM ER</td>
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<td>April 29, 2004</td>
<td>dextromethorphan/guaifenesin (ER)</td>
<td>MUCINEX DM ER</td>
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<tr>
<td>Oral Nasal Decongestants</td>
<td>OTC Monograph</td>
<td>FM (Aug. 23, 1994)</td>
<td>pseudoephedrine</td>
<td>SUDAFED</td>
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<tr>
<td></td>
<td>Single Ingredients</td>
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<td>phenylephrine</td>
<td>SUDAFED PE</td>
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<tr>
<td></td>
<td>NDA</td>
<td>Sept. 13, 1982</td>
<td>pseudoephedrine (ER12 hours)</td>
<td>SUDAFED 12 HOURS</td>
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<td>Dec. 15, 1992</td>
<td>pseudoephedrine (ER 24 hours)</td>
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<tr>
<td>Oral First-Generation Antihistamines</td>
<td>OTC Monograph</td>
<td>FM (Dec. 9, 1992)</td>
<td>brompheniramine, chlorcyclizine, chlorpheniramine, dexamethaspheniramine, dexchlorpheniramine, diphenhydramine, phenindamine, pheniramine, pyrilamine, thonzylamine, triprolidine</td>
<td>BENADRYL ALLERGY, chlorpheniramine, CHLOR-TRIMETON</td>
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<tr>
<td></td>
<td>Single Ingredients</td>
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<td>doxylamine</td>
<td></td>
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<tr>
<td></td>
<td>NDA</td>
<td>prior Jan. 1, 1982</td>
<td>chlorpheniramine (ER)</td>
<td>CHLOR-TRIMETON 12 HOURS</td>
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<tr>
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<td></td>
<td>prior Jan. 1, 1982</td>
<td>chlorpheniramine/pseudoephedrine (ER)</td>
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<td>Sept. 13, 1982</td>
<td>dexamethaspheniramine/pseudoephedrine (ER)</td>
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<td></td>
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<td>May 22, 1987</td>
<td>dexamethaspheniramine/ pseudoephedrine/acetaminophen ER</td>
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<td>Aug. 21, 1992</td>
<td>clemastine</td>
<td>TAVIST ALLERGY</td>
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<td>March 1, 2001</td>
<td>clemastine/pseudoephedrine/acetaminophen</td>
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<tr>
<td>Oral Second-Generation Antihistamines</td>
<td>NDA</td>
<td>Nov. 27, 2002</td>
<td>loratadine</td>
<td>CLARITIN, ALAVERT</td>
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<tr>
<td></td>
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<td>Nov. 27, 2002</td>
<td>loratadine/pseudoephedrine (ER)</td>
<td>CLARITIN D 24 HOURS</td>
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<td></td>
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<td>Nov. 16, 2007</td>
<td>cetirizine</td>
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<td>Nov. 9, 2007</td>
<td>cetirizine/pseudoephedrine</td>
<td>ZYRTEC D</td>
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<tr>
<td></td>
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<td>Jan. 24, 2011</td>
<td>fexofenadine</td>
<td>ALLEGRA ALLERGY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Jan. 24, 2011</td>
<td>fexofenadine/pseudoephedrine</td>
<td>ALLEGRA D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Jan. 31, 2017</td>
<td>levocetirizine</td>
<td>XYZAL</td>
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<td>Oral Expectorants</td>
<td>OTC Monograph</td>
<td>FM (Feb. 28, 1989)</td>
<td>guaifenesin</td>
<td>MUCINEX</td>
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<td>Single Ingredients</td>
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<td>NDA</td>
<td>July 12, 2002</td>
<td>guaifenesin (ER)</td>
<td>MUCINEX ER</td>
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<td>guaifenesin/pseudoephedrine (ER)</td>
<td>MUCINEX D ER</td>
</tr>
<tr>
<td></td>
<td></td>
<td>April 29, 2004</td>
<td>guaifenesin/dextromethorphan (ER)</td>
<td>MUCINEX DM ER</td>
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</table>

*continued next page*
<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Cough and Cold Active Ingredients Combinations</td>
<td>OTC Monograph Combinations</td>
<td>FM (Dec. 23, 2002)</td>
<td>combinations of antitussive, decongestant, antihistamine, expectorant, analgesic, and oral demulcent active ingredients</td>
<td>TRIAMINIC DAYTIME phenylephrine/dextromethorphan</td>
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<td>ALLEREST PE phenylephrine/chlorpheniramine</td>
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<td></td>
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<td>DIMETAPP NIGHTTIME phenylephrine/diphenhydramine</td>
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<td>PERCOGESIC acetaminophen/diphenhydramine</td>
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<td>MUCINEX FAST-MAX NIGHT TIME COLD &amp; FLU acetaminophen/diphenhydramine/phenylephrine</td>
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<td>THERAFLU COLD &amp; FLU acetaminophen/pheniramine/phenylephrine</td>
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<td></td>
<td>BUCKLEY’S CHEST CONGESTION guaifenesin/menthol</td>
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<td>MUCINEX FAST-MAX COLD &amp; SINUS, MUCINEX SINUS-MAX PRESSURE &amp; PAIN acetaminophen/guaifenesin/phenylephrine</td>
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<td></td>
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<td>MUCINEX SINUS-MAX DAY NIGHT MAXIMUM STRENGTH acetaminophen/diphenhydramine/guaifenesin/phenylephrine</td>
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<td>MUCINEX FAST-MAX COLD, FLU AND SORE THROAT, MUCINEX SINUS-MAX SEVERE CONGESTION RELIEF, DAYQUIL SEVERE acetaminophen/dextromethorphan/guaifenesin/phenylephrine</td>
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B. Cold, Cough, Allely, Bronchodilator, and Antiasthmatic continued
<table>
<thead>
<tr>
<th>Product Category</th>
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<th>BRAND EXAMPLES</th>
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<tbody>
<tr>
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<td>MUCINEX FAST-MAX DAY TIME SEVERE CONGESTION &amp; COUGH and MUCINEX FAST-MAX NIGHT TIME COLD &amp; FLU MAXIMUM STRENGTH acetaminophen/dextromethorphan/diphenydramine/guaifenesin/phenylephrine</td>
</tr>
<tr>
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<td>NYQUIL SEVERE COLD &amp; FLU acetaminophen/dextromethorphan/doxylamine/phenylephrine</td>
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<td>MUCINEX FAST-MAX SEVERE CONGESTION &amp; COUGH, CHILDREN’S MUCINEX CONGESTION &amp; COUGH dextromethorphan/guaifenesin/phenylephrine</td>
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<td></td>
<td>CHILDRENS DIMETAPP COLD AND COUGH brompheniramine/dextromethorphan/phenylephrine</td>
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<td>ROBITUSSIN TO GO COUGH AND CHEST CONGESTION DM, DAYQUIL COUGH &amp; CONGESTION dextromethorphan/guaifenesin</td>
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<td>DAYQUIL HBP acetaminophen/dextromethorphan</td>
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<td></td>
<td></td>
<td>LODRANE-D brompheniramine/pseudoephedrine</td>
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<tr>
<td></td>
<td></td>
<td>TFM (Jan. 27, 1988)</td>
<td>CHLORASEPTIC TOTAL benzocaine/dextromethorphan/menthol</td>
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<td>Bronchodilators</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Oct. 2, 1986)</td>
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<td>PRIMATENE TABLETS, BRONKAID</td>
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<td></td>
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<td>epinephrine, racepinephrine</td>
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<td></td>
<td>OTC Monograph Oral Combinations</td>
<td>FM (Dec. 23, 2002)</td>
<td>ephedrine/guaifenesin</td>
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<tr>
<td>Topical Antitussives</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 12, 1987)</td>
<td>camphor</td>
<td>VICKS VAPOSTEAM</td>
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<td>menthol</td>
<td>FISHERMAN’S FRIEND, VICKS VAPODROPS</td>
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<td>OTC Monograph Combinations</td>
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<td>camphor/menthol</td>
<td>VICKS VAPORUB, MENTHOLATUM NIGHTTIME VAPORIZING RUB</td>
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## B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic  
*continued*

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

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
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<tbody>
<tr>
<td>Nighttime Sleep-Aids</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Feb. 14, 1989)</td>
<td>diphenhydramine</td>
<td>UNISOM, SOMINEX, NYTOL, ZzzQuil</td>
</tr>
<tr>
<td>OTC Monograph Combinations</td>
<td>TFM (Jun 13, 1978)</td>
<td></td>
<td>aspirin/diphenhydramine</td>
<td>BAYER PM</td>
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<td></td>
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<td>acetaminophen/diphenhydramine</td>
<td>TYLENOL PM, GOODY’S PM</td>
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<tr>
<td>NDA</td>
<td>Oct. 18, 1978</td>
<td>doxylamine</td>
<td></td>
<td>UNISOM</td>
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<td></td>
<td>Dec. 21, 2005</td>
<td>ibuprofen/diphenhydramine</td>
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<td>ADVIL PM</td>
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<tr>
<td></td>
<td>Jan. 17, 2014</td>
<td>naproxen sodium/diphenhydramine</td>
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<td>ALEVE PM</td>
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## D. Stimulants (Caffeine)

<table>
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<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td>Stimulants</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Feb. 29, 1988)</td>
<td>caffeine</td>
<td>NODOZ, VIVARIN</td>
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### E. Gastrointestinal

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid reducers - Antacids</td>
<td>OTC Monograph</td>
<td>FM (June 4, 1974)</td>
<td>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, silicates, sodium-based antacids, tartaric acid or its salts</td>
<td>TUMS, CHILDREN’S PEPTO-BISMOL, MAALOX CHILDREN’S calcium carbonate</td>
</tr>
<tr>
<td></td>
<td>Single Ingredients</td>
<td></td>
<td>combinations of antacids</td>
<td>PHILLIPS ORIGINAL magnesium hydroxide</td>
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<tr>
<td></td>
<td>OTC Monograph</td>
<td>FM (June 4, 1974)</td>
<td>combinations with any nonantacid laxative</td>
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<tr>
<td></td>
<td>Combinations</td>
<td></td>
<td>combinations with analgesics</td>
<td>MAALOX ADVANCED MAXIMUM STRENGTH, PHAZYME GAS AND ACID calcium carbonate/simethicone</td>
</tr>
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<td></td>
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<td>combinations with anti-flatulents</td>
<td>MAALOX, GELUSIL magnesium hydroxide/simethicone</td>
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<tr>
<td>Acid reducers - H₂ - Antagonists</td>
<td>NDA</td>
<td>April 28, 1995</td>
<td>famotidine</td>
<td>PEPCID</td>
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<td></td>
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<td>June 19, 1995</td>
<td>cimetidine</td>
<td>TAGAMET</td>
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<td>Dec. 19, 1995</td>
<td>ranitidine</td>
<td>ZANTAC</td>
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<td></td>
<td></td>
<td>May 9, 1996</td>
<td>nizatidine</td>
<td>AXID AR</td>
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<td>Oct. 16, 2000</td>
<td>famotidine/calcium carbonate/magnesium hydroxide</td>
<td>PEPCID COMPLETE</td>
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<tr>
<td>Acid reducers - Proton Pump Inhibitors</td>
<td>NDA</td>
<td>June 20, 2003</td>
<td>omeprazole</td>
<td>PRILOSEC OTC</td>
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<td></td>
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<td>May 18, 2009</td>
<td>lansoprazole</td>
<td>PREVACID</td>
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<td>Dec. 1, 2009</td>
<td>omeprazole/sodium bicarbonate</td>
<td>ZEGGERID OTC</td>
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<td>March 28, 2014</td>
<td>esomeprazole/magnesium</td>
<td>NEXIUM 24 HR</td>
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<tr>
<td>Antiflatulents</td>
<td>OTC Monograph</td>
<td>FM (June 4, 1974)</td>
<td>simethicone</td>
<td>GAS-X, LITTLE REMEDIES GAS RELIEF DROPS, PHAZYME</td>
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<tr>
<td></td>
<td>Single Ingredients</td>
<td></td>
<td>combinations with antacids</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTC Monograph</td>
<td>FM (June 4, 1974)</td>
<td>combinations with antacids</td>
<td>see above Antacids - combinations with antiflatulents</td>
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<tr>
<td></td>
<td>Combinations</td>
<td></td>
<td>combinations with antacids</td>
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<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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<tbody>
<tr>
<td>Antidiarrheals</td>
<td>OTC Monograph</td>
<td>FM (April 17, 2003)</td>
<td>bismuth subsalicylate</td>
<td>KAOPECTATE ANTI DIARRHEAL, PEPTO-BISMOL ORIGINAL</td>
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<td>Single Ingredients</td>
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<td>kaolin</td>
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<td></td>
<td>NDA</td>
<td>March 1, 1988</td>
<td>loperamide</td>
<td>IMODIUM A-D</td>
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<td></td>
<td></td>
<td>June 26, 1997</td>
<td>loperamide/simethicone</td>
<td>IMODIUM MULTI-SYMPTOM RELIEF</td>
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<tr>
<td>Bulk-Forming</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>polycarbophil</td>
<td>FIBERCON, EQUALACTIN</td>
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<td>Laxatives</td>
<td>Single Ingredients</td>
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<td>psyllium ingredients</td>
<td>METAMUCIL</td>
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<td>cellulose</td>
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<td></td>
<td>karaya</td>
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</tr>
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<td></td>
<td></td>
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<td>malt soup extract</td>
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<tr>
<td>Hyperosmotic</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>glycerin</td>
<td>FLEET LIQUID GLYCERIN</td>
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<td>Laxatives</td>
<td>Single Ingredients</td>
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<td>sorbitol</td>
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<td>NDA</td>
<td>Oct. 6, 2006</td>
<td>polyethylene glycol 3350</td>
<td>MIRALAX</td>
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<td>Lubricants</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>mineral oil</td>
<td>FLEET MINERAL OIL ENEMA, KONDREMUL</td>
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<td>Single Ingredients</td>
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<tr>
<td>Saline Laxatives</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>magnesium hydroxide</td>
<td>FLEET PEDIA-LAX CHEWABLE TABLETS</td>
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<tr>
<td></td>
<td>Single Ingredients</td>
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<td>sodium phosphate, sodium biphosphate</td>
<td>FLEET PEDIA-LAX ENEMA</td>
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<tr>
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<td></td>
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<td>magnesium citrate, magnesium sulfate</td>
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<tr>
<td>Stimulant</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>bisacodyl</td>
<td>DULCOLAX, ALOPHEN, CORRECTOL, FLEET BISACODYL ENEMA</td>
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<td>Laxatives</td>
<td>Single Ingredients</td>
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<td>sennosides</td>
<td>SENOKOT, EX-LAX</td>
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<td>castor oil</td>
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<td>dehydrocholic acid</td>
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<td>Stool Softeners</td>
<td>OTC Monograph</td>
<td>TFM (Sept. 2, 1993)</td>
<td>docusate</td>
<td>COLACE, PHILLIPS STOOL SOFTENER, SURFAK STOOL SOFTENER, DULCOLAX, PEDIA-LAX STOOL SOFTENER</td>
</tr>
<tr>
<td></td>
<td>Single Ingredients</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Carbon Dioxide-</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>carbon dioxide released from combined sodium biphosphate anhydrous, sodium acid pyrophosphate and sodium bicarbonate</td>
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<tr>
<td>Releasing</td>
<td>Single Ingredients</td>
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<td></td>
<td></td>
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<tr>
<td>Laxatives</td>
<td></td>
<td></td>
<td>carbon dioxide released from combined sodium bicarbonate and potassium bitartrate</td>
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<tr>
<td>Laxative Active</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 15, 1985)</td>
<td>combinations of laxatives</td>
<td>PERI-COLACE</td>
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<td>Ingredients</td>
<td>Combinations</td>
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</tr>
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<td>Combinations</td>
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### E. Gastrointestinals continued

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<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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<tbody>
<tr>
<td>Antiemetics</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (April 30, 1987)</td>
<td>cyclizine</td>
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<td>dimenhydrinate</td>
<td>DRAMAMINE ORIGINAL</td>
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<td></td>
<td></td>
<td></td>
<td>diphenhydramine</td>
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<td></td>
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<td>meclizine</td>
<td>BONINE, DRAMAMINE LESS DROWSY FORMULA</td>
</tr>
<tr>
<td>Anthelmintics</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 1, 1986)</td>
<td>pyrantel pamoate</td>
<td>PRONTO PLUS</td>
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<tr>
<td>Poison Treatment</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Jan. 15, 1985)</td>
<td>ipecac syrup</td>
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<td></td>
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<td>activated charcoal</td>
<td>EZ CHAR</td>
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### F. Analgesics, Anesthetics, Counterirritants, & Antipruritics (External Analgesics)

<table>
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<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td>Amine and Caine'-Type Ingredients (Local Anesthetics)</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>benzocaine, butamben picrate, dibucaine, dimethisoquin, dyclonine, lidocaine, pramoxine, tetracaine</td>
<td>SOLARCAINE, Icy HOT w/LIDOCAINEidendine, CeraVe ITCH RELIEF MOISTERIZING CREAM, pramoxine, CEPACOL SORE THROAT, dyclonine/glycerin</td>
</tr>
<tr>
<td>Alcohols and Ketones</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>benzyl alcohol, camphor, camphorated metacresol, juniper tar, menthol, phenol, phenolate sodium, resorcinol</td>
<td>CAMPHO-PHENIQUE, camphorated phenol</td>
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<tr>
<td>Antihistamines</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>diphenhydramine</td>
<td>EXTRA STRENGTH BENADRYL GEL</td>
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<td>Hydrocortisone Preparations</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>hydrocortisone</td>
<td>CORTIZONE, CORTAID, MONISTAT COMPLETE CARE ITCH RELIEF</td>
</tr>
<tr>
<td>Irritants That Produce Redness</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>allyl isothiocyanate, ammonia, methyl salicylate, turpentine oil</td>
<td>AFTER BITE ammonia</td>
</tr>
<tr>
<td>Irritants That Produce Cooling Sensation</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>camphor</td>
<td>BLUE STAR</td>
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<td>menthol</td>
<td>ICY HOT, ABSORBINE, BENGAY, STOPAIN</td>
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<tr>
<td>Irritants That Produce Vasodilation</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>histamine dihydrochloride</td>
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<td>methyl nicotinate</td>
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<tr>
<td>Irritants That Don't Produce Redness</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Feb. 8, 1983)</td>
<td>capsaicin</td>
<td>CAPZASIN, ZOSTRIX</td>
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<tr>
<td>Product Category</td>
<td>Regulatory Route</td>
<td>Monograph Status/ Date of NDA OTC Approval</td>
<td>Active Ingredients</td>
<td>BRAND EXAMPLES</td>
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<tr>
<td>Salicylates (Unknown Action)</td>
<td>OTC Monograph Single Ingredients</td>
<td>ANPR (Dec 4, 1979)</td>
<td>aspirin, glycol salicylate, salicylamide, trolamine salicylate</td>
<td>ASPERCREME, MOBISYL</td>
</tr>
<tr>
<td>Male Genital Desensitizer</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (June 19, 1992)</td>
<td>benzocaine</td>
<td>MALE DESENSITIZER PLEASURE BALM</td>
</tr>
<tr>
<td>External Analgesics Combinations</td>
<td>OTC Monograph Combinations</td>
<td>TFM (Feb. 8, 1983)</td>
<td>combinations of external analgesic active ingredients, combinations with skin protectant and topical antimicrobial active ingredients</td>
<td>BENADRYL ITCH STOPPING, BACTINE, IVAREST CREAM, CALADRYL CLEAR, CALADRYL, VAGISIL ANTI-ITCH, THERAGESIC, SATOGESIC, BOROLEUM, VAPORUB, CALADRYL</td>
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<tr>
<td></td>
<td>NDA</td>
<td>Feb. 20, 2008</td>
<td>methyl salicylate/menthol</td>
<td>SALONPAS PATCH</td>
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## G. Skin Treatment

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td>Skin Protectants</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (June 4, 2003)</td>
<td>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</td>
<td>AVEENO BABY, CeraVE THERAPEUTIC HAND, MONISTAT COMPLETE CARE CHAFING RELIEF dimethicone</td>
</tr>
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<td></td>
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<td></td>
<td>JOHNSON'S BABY, BalmEX DIAPER RASH, BOUDREAUX'S BUTT PASTE zinc oxide</td>
<td>CeraVe BABY DIAPER RASH CREAM dimethicone/zinc oxide</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>DESITIN MULTI-PURPOSE, CHAP-ET, CLOVERINE white petrolatum</td>
<td>DESITIN MULTI-PURPOSE, CHAP-ET, CLOVERINE white petrolatum</td>
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<tr>
<td>Skin Protectants</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (June 4, 2003)</td>
<td>aluminum acetate, aluminum sulfate, witch hazel</td>
<td>DOMEBORO aluminum acetate</td>
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<td>Astringents</td>
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<td>GOLDBOND MEDICATED BODY LOTION dimethicone/menthol</td>
<td>GOLDBOND MEDICATED BODY LOTION dimethicone/menthol</td>
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<td>BLISTEX MEDICATED LIP BALM dimethicone/oxybenzone/padimate O</td>
<td>BLISTEX MEDICATED LIP BALM dimethicone/oxybenzone/padimate O</td>
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<td></td>
<td>CHAPSTICK MEDICATED LIP BALM petrolatum/camphor/menthol/phenol</td>
<td>CHAPSTICK MEDICATED LIP BALM petrolatum/camphor/menthol/phenol</td>
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<td>SOFTLIPS LIP PROTECTANT dimethicone/octinoxate/oxybenzone/octisalate</td>
<td>SOFTLIPS LIP PROTECTANT dimethicone/octinoxate/oxybenzone/octisalate</td>
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<td>CHAPSTICK white petrolatum/padimate O</td>
<td>CHAPSTICK white petrolatum/padimate O</td>
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<td>FM (May 12, 1999)</td>
<td>combinations of sunscreen active ingredients</td>
<td>CHAPSTICK ULTRA SPF-30 octinoxate/octisalate/octocrylene/oxybenzone/white petrolatum</td>
<td>CHAPSTICK ULTRA SPF-30 octinoxate/octisalate/octocrylene/oxybenzone/white petrolatum</td>
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<td>FM (March 6, 2009)</td>
<td>aluminum sulfate tetradecahydrate combined with calcium acetate monohydrate in powder or tablet form to provide an aluminum acetate solution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cold Sore Treatment</td>
<td>OTC Monograph Combinations</td>
<td>NPR (Jan. 1, 1990)</td>
<td>combinations of skin protectant with external analgesic active ingredients</td>
<td>ANBESOL COLD SORE allantoin/camphor/benzocaine/white petrolatum</td>
</tr>
<tr>
<td>Combinations</td>
<td></td>
<td></td>
<td>CARMEX COLD SORE TREATMENT benzocaine</td>
<td>CARMEX COLD SORE TREATMENT benzocaine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>BLISTEX LIP OINTMENT dimethicone/camphor/menthol/phenol</td>
<td>BLISTEX LIP OINTMENT dimethicone/camphor/menthol/phenol</td>
</tr>
<tr>
<td></td>
<td>NDA</td>
<td>July 25, 2000</td>
<td>docosanol</td>
<td>ABREVA</td>
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<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
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<tbody>
<tr>
<td><strong>Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Dec. 4, 1991)</td>
<td>coal tar</td>
<td>NEUTROGENA T/GEL ORIGINAL, PSORIASIN, OXIPOR</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>pyrithione zinc</td>
<td>HEAD &amp; SHOULDERS, ZINCON MEDICATED DANDRUFF</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>salicylic acid</td>
<td>DENOREX, DERMAREST PSORIASIS</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>selenium sulfide</td>
<td>SELSUN BLUE MOISTURIZING</td>
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<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>FM (Dec. 4, 1991)</td>
<td>salicylic acid/sulfur</td>
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<tr>
<td></td>
<td></td>
<td>FM (March 6, 2007)</td>
<td>coal tar/menthol</td>
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<tr>
<td><strong>Acne Products</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 16, 1991)</td>
<td>resorcinol</td>
<td>CLEARASIL, CLEAN &amp; CLEAR, OXY SKIN, STRIDEX, PHISODERM, AMBI EVEN &amp; CLEAR, ACNEFREE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>salicylic acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>sulfur</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>FM (March 4, 2010)</td>
<td>benzoyl peroxide</td>
<td>CLEARASIL, CLEAN &amp; CLEAR, PANOXYL, OXY SENSITIVE, ACNEFREE</td>
</tr>
<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>FM (Aug. 16, 1991)</td>
<td>resorcinol/sulfur</td>
<td>ACNOMEL</td>
</tr>
<tr>
<td><strong>Corn, Callus, and Wart Removers</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 14, 1990)</td>
<td>salicylic acid</td>
<td>DR.SCHOLL'S, COMPOUND W, FREEZONE, MOSCO</td>
</tr>
<tr>
<td><strong>Poison Ivy, Oak &amp; Sumac Rash Prevention</strong></td>
<td>NDA</td>
<td>Aug. 26, 1996</td>
<td>bentoquatam</td>
<td>IVY BLOCK</td>
</tr>
<tr>
<td><strong>Antiperspirants</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Jun. 9, 2003)</td>
<td>aluminum chlorohydrate, aluminum chlorohydrex, aluminum zirconium, and derivatives thereof</td>
<td>SPEED STICK, GILLETTE, AXE, LADY SPEED STICK, TEEN SPIRIT</td>
</tr>
<tr>
<td><strong>Skin Bleaching Products</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Jan. 15, 1985)</td>
<td>hydroquinone</td>
<td>PALMER'S, AMBI</td>
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</tbody>
</table>
### G. Skin Treatment continued

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
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<tbody>
<tr>
<td><strong>Dermal Antifungals</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Sept. 23, 1993)</td>
<td>clioquinol</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>haloprogin</td>
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<td></td>
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<td></td>
<td>miconazole</td>
<td><strong>DESENEX, CRUEX, TING SPRAY POWDER</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>povidone-iodine</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>tolnaftate</td>
<td><strong>TINACTIN, TING, ODOR-EATERS</strong></td>
</tr>
<tr>
<td></td>
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<td></td>
<td>undecylenic acid and its salts (calcium, copper, and zinc)</td>
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<td></td>
<td>FM (Feb. 8, 2002)</td>
<td>clotrimazole</td>
<td><strong>LOTRIMIN</strong></td>
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<tr>
<td>NDA</td>
<td>Oct. 10, 1997</td>
<td>ketoconazole</td>
<td><strong>NIZORAL A-D</strong></td>
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<tr>
<td></td>
<td>March 9, 1999</td>
<td>terbinafine</td>
<td><strong>LAMISIL</strong></td>
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<tr>
<td></td>
<td>Dec. 7, 2001</td>
<td>butenafine</td>
<td><strong>LOTRIMIN ULTRA</strong></td>
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<tr>
<td><strong>Pediculicides</strong></td>
<td>OTC Monograph Combinations</td>
<td>FM (Dec. 14, 1993)</td>
<td>pyrethrum extract/piperonyl butoxide</td>
<td><strong>RID, PRONTO PLUS</strong></td>
</tr>
<tr>
<td>NDA</td>
<td>May 2, 1990</td>
<td>permethrin</td>
<td><strong>PERMETHRIN, NIX</strong></td>
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</tr>
<tr>
<td><strong>Sunscreens</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (May 21, 1999)</td>
<td>aminobenzoic acid (PABA), avobenzone, cinoxate, dioxybenzone, homosalate, menthol anthranilate (meradimate), octocrylene, octyl methoxy-cinnamate (octinoxate), octyl salicylate (octisalate), oxybenzone, padimate O, phenylbenzimidazole sulfonyl acid (ensulizide), sulisobenzone, titanium dioxide, trolamine salicylate, zinc oxide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>FM (May 21, 1999)</td>
<td>combinations of sunscreen active ingredients</td>
<td><strong>BAIN SOLEIL, COPPERTONE, BULL FROG, NEUTROGENA, CeraVe</strong></td>
</tr>
<tr>
<td>NDA</td>
<td>July 21, 2006</td>
<td>ecamsule/avobenzone/octocrylene</td>
<td><strong>ANTHELIOS SX</strong></td>
<td></td>
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</table>

### H. Hair Loss

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td><strong>Hair Grower</strong></td>
<td>NDA</td>
<td>Feb. 9, 1996</td>
<td>minoxidil</td>
<td><strong>ROGAINE</strong></td>
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</table>
## I. Topical Antiseptics and Antibiotics

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Antiseptics (applied topically to the skin to prevent infection or cross contamination)</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (June 17, 1994)</td>
<td>Handwash products: alcohol, povidone-iodine</td>
<td>PURELL alcohol</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Patient preoperative skin preparations: alcohol, iodine tincture, isopropyl alcohol, povidone-iodine</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Surgical hand scrubs: alcohol, povidone-iodine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NDA</td>
<td>Sept. 17, 1976</td>
<td>chlorhexidine gluconate</td>
<td>HIBICLENS, BETASEPT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nov. 29, 1985</td>
<td>povidone-iodine (sponge)</td>
<td></td>
</tr>
<tr>
<td>First Aid Antiseptics (to prevent infection in wounds, scrapes, and burns)</td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (July 22, 1991)</td>
<td>alcohol, benzalkonium chloride, benzenethonium chloride, camphor ated metacresol, camphor ated phenol in light mineral oil vehicle, eucalyptol, hexylresorcinol, hydrogen peroxide, iodine tincture, iodine topical solution, isopropyl alcohol, menthol, methylbenzenethonium chloride, methyl salicylate, phenol, povidone-iodine, thymol, chloroxylenol</td>
<td>BETADINE povidone-iodine</td>
</tr>
<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>TFM (July 22, 1991)</td>
<td>combination of alcohol, eucalyptol, menthol, methyl salicylate, and thymol</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>combinations with external analgesics</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>combinations with skin protectants</td>
<td></td>
</tr>
<tr>
<td>First Aid Antibiotics</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Dec. 11, 1987)</td>
<td>bacitracin, bacitracin zinc, chlortetracycline, neomycin sulfate, tetracycline</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>FM (Dec. 11, 1987)</td>
<td>combinations of antibiotic active ingredients (bacitracin, bacitracin zinc, neomycin sulfate, polymyxin B, oxytetracycline); combinations with 'caine'-type external analgesic ingredients</td>
<td>POLYSPORIN bacitracin zinc/polylymyxin B, NEOSPORIN PLUS polymyxin B/neomycin/pramoxine, BACTINE bacitracin/neomycin/polymyxin B/pramoxine</td>
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</tbody>
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### J. Anorectal

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Anesthetics</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 3, 1990)</td>
<td>bacitracin, bacitracin zinc, chlortetracycline, neomycin sulfate, tetracycline</td>
<td>AMERICAINE, benzocaine</td>
</tr>
<tr>
<td>Vasoconstrictor Active Ingredients</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 3, 1990)</td>
<td>ephedrine, epinephrine, phenylephrine</td>
<td>NUPERCAINAL, dibucaine</td>
</tr>
<tr>
<td>Protectant Active Ingredients</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 3, 1990)</td>
<td>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</td>
<td>TUCKS TOPICAL STARCH SUPPOSITORIES, topical starch</td>
</tr>
<tr>
<td>Analgesic, anesthetic, and antipruritic active ingredients</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 3, 1990)</td>
<td>camphor, juniper, menthol</td>
<td></td>
</tr>
<tr>
<td>Astringents</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 3, 1990)</td>
<td>calamine, witch hazel (hamamelis water), zinc oxide</td>
<td>TUCKS MEDICATED COOLING PADS, witch hazel</td>
</tr>
<tr>
<td>Kerotolytics</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (Aug. 3, 1990)</td>
<td>alcloxa, resorcinol</td>
<td></td>
</tr>
<tr>
<td>Anorectal Ingredient Combinations</td>
<td>OTC Monograph Combinations</td>
<td>FM (Aug. 3, 1990)</td>
<td>combinations of anorectal active ingredients</td>
<td>PREPARATION H MAXIMUM STRENGTH CREAM, hydrocortisone</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>PREPARATION H SUPPOSITORIES, cocoa butter/phenylephrine</td>
</tr>
<tr>
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<td>TRONOLANE CREAM, pramoxine/zinc oxide</td>
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### K. Vaginal Antifungals

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<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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<tbody>
<tr>
<td>Vaginal Antifungals</td>
<td>NDA</td>
<td>Nov. 30, 1990</td>
<td>clotrimazole</td>
<td>GYNE-LOTRIMIN</td>
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<td></td>
<td></td>
<td>Feb. 15, 1991</td>
<td>miconazole</td>
<td>MONISTAT</td>
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<tr>
<td></td>
<td></td>
<td>Dec. 21, 1995</td>
<td>butoconazole</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Feb. 11, 1997</td>
<td>tioconazole</td>
<td>VAGISTAT</td>
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<tr>
<td></td>
<td></td>
<td>Nov. 21, 2001</td>
<td>miconazole</td>
<td>MONISTAT 1-DAY OINTMENT</td>
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## L. Ophthalmics

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<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic Astringents</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (March 4, 1988)</td>
<td>zinc sulfate</td>
<td></td>
</tr>
<tr>
<td>Ophthalmic Demulcents</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (March 4, 1988)</td>
<td>cellulose derivatives (carboxym ethyl cellulose sodium, hydroxyethyl cellulose, hydroxypropyl methylcellulose [hypromellose], methylcellulose), dextran 70, gelatin, polyols (glycerin, polyethylene glycol 300 &amp; 400, polysorbate 80, propylene glycol), polyvinyl alcohol, povidone</td>
<td>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</td>
</tr>
<tr>
<td>Ophthalmic Emollients</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (March 4, 1988)</td>
<td>lanolin preparations, oleaginus ingredients (light mineral oil, mineral oil, paraffin, petrolatum, white ointment, white petrolatum, white wax, yellow wax)</td>
<td>SOOTHE XP light mineral oil/mineral oil</td>
</tr>
<tr>
<td>Ophthalmic Hypertonicity Agents</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (March 4, 1988)</td>
<td>sodium chloride</td>
<td>MURO 128</td>
</tr>
<tr>
<td>Ophthalmic Vasoconstrictors</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (March 4, 1988)</td>
<td>ephedrine, naphazoline, phenylephrine, tetrahydrozoline</td>
<td>VISIBLE ORIGINAL tetrahydrozoline, VISIBLE L.R., OPCON-A, VISINE-A, LUMIFY</td>
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<tr>
<td></td>
<td>NDA</td>
<td>March 31, 1989</td>
<td>oxymetazoline</td>
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<td></td>
<td>June 8, 1994</td>
<td>pheniramine/naphazoline</td>
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<td></td>
<td></td>
<td>Dec. 22, 2017</td>
<td>brimonidine tartrate</td>
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<tr>
<td>Ophthalmic Antihistamines</td>
<td>NDA</td>
<td>Oct. 19, 2006</td>
<td>ketotifen</td>
<td>ZADITOR, ALAWAY</td>
</tr>
<tr>
<td>Eyewashes</td>
<td>OTC Monograph Single Ingredients</td>
<td>FM (March 4, 1988)</td>
<td>water, tonicity agents, agents for establishing pH and buffering to achieve the same pH as tears, preservatives</td>
<td>ADVANCED EYE RELIEF EYE WASH purified water</td>
</tr>
<tr>
<td>Ophthalmics Combinations</td>
<td>OTC Monograph Combinations</td>
<td>FM (March 4, 1988)</td>
<td>combinations of ophthalmic active ingredients</td>
<td>CLEAR EYES COMPLETE 7 SYMPTOM RELIEF hypromellose/naphazoline/polysorbate 80/zinc sulfate, CLEAR EYES NATURAL TEARS polysorbate 80/povidone, CLEAR EYES TRIPLE ACTION polysorbate 80/povidone/tetrahydrozoline, CLEAR EYES MAXIMUM ITCHY EYE RELIEF glycerin/naphazoline/zinc sulfate, ROHTO COOL polysorbate 80/naphazoline, SOOTHE glycerin/propylene glycol</td>
</tr>
</tbody>
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### M. Otics (Ear Wax Removal Aids)

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td>Earwax Removal Aids</td>
<td>OTC Monograph</td>
<td>FM (Aug. 8, 1986)</td>
<td>carbamide peroxide</td>
<td>DEBROX, MURINE</td>
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<tr>
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<td>Single Ingredients</td>
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### N. Oral Healthcare

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<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticaries</td>
<td>OTC Monograph</td>
<td>FM (Oct. 6, 1995)</td>
<td>sodium fluoride</td>
<td>COLGATE, AIM, ACT, AQUAFRESH, CREST 3D WHITE, REMBRANDT, CREST ANTICAVITY FLUORIDE (rinse)</td>
</tr>
<tr>
<td></td>
<td>Single Ingredients</td>
<td></td>
<td>sodium monofluorophosphate</td>
<td>COLGATE, AQUAFRESH, REMBRANDT</td>
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<td></td>
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<td>stannous fluoride</td>
<td>CREST PRO-HEALTH, COLGATE GEL-KAM</td>
</tr>
<tr>
<td>Anesthetics/ Analgesics</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 27, 1988)</td>
<td>benzocaine</td>
<td>ORAJEL, ANBESOL, KANK-A LIQUID, ZILACTIN-B, BENZODENT, DENTEK PAIN RELIEF</td>
</tr>
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<td></td>
<td>Single Ingredients</td>
<td></td>
<td>benzyl alcohol</td>
<td>ZILACTIN EARLY RELIEF COLD SORE</td>
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<td>dyclinone</td>
<td>SUCRETS SORE THROAT</td>
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<td>hexylresorcinol</td>
<td>S.T. 37</td>
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<td>menthol</td>
<td>VICKS VAPODROPS, LUDEN’S MENTHOL</td>
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<td>phenol</td>
<td>CHLORASEPTIC SPRAY, CEPASTAT</td>
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<td>butacaine</td>
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<td>salicylic alcohol</td>
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<tr>
<td>Oral Astringents</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 27, 1988)</td>
<td>alum</td>
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<td>Single Ingredients</td>
<td></td>
<td>zinc oxide</td>
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</tr>
<tr>
<td>Debriding Agents/ Oral Wound Cleansers</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 27, 1988)</td>
<td>carbamide peroxide in anhydrous glycerin</td>
<td>GLY-OXIDE</td>
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<td></td>
<td>Single Ingredients</td>
<td></td>
<td>hydrogen peroxide</td>
<td>COLGATE PEROXYL, ORAJEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>sodium bicarbonate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>sodium perborate monohydrate</td>
<td></td>
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<tr>
<td>Oral Demulcents</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 27, 1988)</td>
<td>elm bark, gelatin, glycerin, pectin</td>
<td>LUDEN’S</td>
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<tr>
<td></td>
<td>Single Ingredients</td>
<td></td>
<td></td>
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<tr>
<td>Oral Mucosal Protectants</td>
<td>OTC Monograph</td>
<td>TFM (Jan. 27, 1988)</td>
<td>compound benzoin tincture</td>
<td>SENSODYNE, CREST SENSITIVITY</td>
</tr>
<tr>
<td></td>
<td>Single Ingredients</td>
<td></td>
<td>benzoain tincture</td>
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</tr>
<tr>
<td>Tooth Desensitizers</td>
<td>OTC Monograph</td>
<td>TFM (Sept. 24, 1991)</td>
<td>potassium nitrate</td>
<td>SENSODYNE, CREST SENSITIVITY</td>
</tr>
<tr>
<td></td>
<td>Single Ingredients</td>
<td></td>
<td>stannous fluoride</td>
<td>CREST PRO-HEALTH, COLGATE GEL-KAM</td>
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<tr>
<td></td>
<td>OTC Monograph</td>
<td>TFM (Sept. 24, 1991)</td>
<td>potassium nitrate and sodium fluoride</td>
<td>COLGATE SENSITIVE, SENSODYNE, CREST SENSITIVITY</td>
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<tr>
<td></td>
<td>Combinations</td>
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**continued next page**
### N. Oral Healthcare

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antigingivitis/Antiplaque Ingredients</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>ANPR (May 29, 2003)</td>
<td>cetylpyridinium chloride</td>
<td>ACT, CREST, COLGATE TOTAL MOUTHWASH</td>
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<tr>
<td></td>
<td>NDA</td>
<td>July 11, 1997</td>
<td>stannous fluoride</td>
<td>CREST PRO-HEALTH TOOTHPASTE</td>
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<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>ANPR (May 29, 2003)</td>
<td>combination of eucalyptol, menthol, methyl salicylate, and thymol</td>
<td>LISTERINE</td>
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<tr>
<td><strong>Oral Healthcare Ingredient Combinations</strong></td>
<td>OTC Monograph Combinations</td>
<td>ANPR (May 29, 2003)</td>
<td>combinations of oral healthcare active ingredients</td>
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</tr>
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<td>TFM (Jan. 27, 1988)</td>
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### O. Menstrual

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Menstrual Products</strong></td>
<td>OTC Monograph Single Ingredients</td>
<td>TFM (Nov. 16, 1988)</td>
<td>pamabrom [diuretic]</td>
<td>BACKAID MAX acetaminophen/pamabrom</td>
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<tr>
<td></td>
<td></td>
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<td>ammonium chloride [diuretic]</td>
<td>PAMPRIN acetaminophen/pamabrom/pyrilamine [antihistamine]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>caffeine [diuretic]</td>
<td>MIDOL COMPLETE acetaminophen/caffeine/pyrilamine [antihistamine]</td>
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<td></td>
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<td></td>
<td>antihistamines reserved</td>
<td>DIUREX WATER PILLS magnesium salicylate/caffeine</td>
</tr>
<tr>
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<td></td>
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<td>muscle relaxants reserved</td>
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<tr>
<td></td>
<td>OTC Monograph Combinations</td>
<td>TFM (Nov. 16, 1988)</td>
<td>combinations of diuretics with analgesics</td>
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<td>NDA</td>
<td>Jan. 11, 1994</td>
<td>naproxen sodium</td>
<td>MENSTRIDOL</td>
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<td>NDA</td>
<td>Jun. 12, 2012</td>
<td>ibuprofen sodium</td>
<td>ADVIL MENSTRUAL PAIN</td>
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</table>
### P. Contraceptives

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal Contraceptives</td>
<td>OTC Monograph</td>
<td>FM (Dec. 12, 1980)</td>
<td>nonoxynol-9</td>
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<td></td>
<td>Single Ingredients</td>
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<td>GYNOL II</td>
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<td>NDA</td>
<td>April 1, 1983</td>
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<td>nonoxynol-9</td>
<td>TODAY</td>
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<tr>
<td>Emergency Contraceptives</td>
<td>NDA</td>
<td>Aug. 24, 2006</td>
<td>levonorgestrel</td>
<td>PLAN B</td>
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<td>Jul. 10, 2009</td>
<td>levonorgestrel (ER)</td>
<td>PLAN B ONE-STEP</td>
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### Q. Nicotine Replacement Therapies

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Oral (Gum)</td>
<td>NDA</td>
<td>Feb. 9, 1996</td>
<td>nicotine polacrilex</td>
<td>NICORETTE</td>
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<tr>
<td>Nicotine Oral (Lozenge)</td>
<td>NDA</td>
<td>Oct. 31, 2002</td>
<td>nicotine polacrilex</td>
<td>COMMIT</td>
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<tr>
<td>Nicotine Transdermal Systems (Patch)</td>
<td>NDA</td>
<td>Aug. 2, 1996</td>
<td>nicotine</td>
<td>NICODERM CQ</td>
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<td>Nov. 12, 1999</td>
<td>nicotine</td>
<td>HABITROL</td>
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### R. Weight Loss Aids, Overactive Bladder, Miscellaneous External Drug

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Regulatory Route</th>
<th>Monograph Status/ Date of NDA OTC Approval</th>
<th>Active Ingredients</th>
<th>BRAND EXAMPLES</th>
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</thead>
<tbody>
<tr>
<td>Weight Loss Aids</td>
<td>NDA</td>
<td>Feb. 7, 2007</td>
<td>orlistat</td>
<td>ALLI</td>
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<tr>
<td>Overactive Bladder</td>
<td>NDA</td>
<td>Jan. 25, 2013</td>
<td>oxybutynin</td>
<td>OXYTROL FOR WOMEN</td>
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<tr>
<td>Ingrown Toenail Relief Drug Products</td>
<td>OTC Monograph</td>
<td>FM (May 7, 2003)</td>
<td>sodium sulfide</td>
<td>DR SCHOLL'S INGROWN TOENAIL PAIN RELIEVER</td>
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</tbody>
</table>
Guide to OTC Active Ingredients in the United States