SPECIAL REPORT MARCH 2011

OTC REVIEW AND OUTLOOK

Global growth being driven by emerging markets

The global market for consumer-care products generated slower growth in 2010 than during the previous year, partially because of a weaker flu season in North America and Europe. However, emerging markets for OTC products continue to expand, lead by China. The markets in India and Latin America also remain on a solid growth pattern.

Driving forces in the U.S. over-the-counter market include Rx-to-OTC switches of former blockbuster brands as well as consumers' increasing usage of self medication. More than 300,000 OTC products are on the U.S. market, separated by the Food and Drug Administration into 80-plus classes based on their intended therapeutic uses. Leading therapeutic categories/medical-usage areas for OTC products include cholesterol therapy; contraception; cough, cold and allergy; dermatology; gastrointestinal disorders; pain management; sexual dysfunction; and weight management/obesity.

This first-time special report provides an overview of the worldwide consumer healthcare arena, profiles of some of the leading OTC companies, and various listings including FDA over-the-counter approvals as well as Rx-to-OTC switches.

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OTC REVIEW AND OUTLOOK

THE GLOBAL OTC MARKET

The worldwide consumer-care market grew more slowly in 2010 versus 2009. This performance was due mainly to a weak flu season in Europe and North America. The worldwide OTC market value in 2010 was about $115 billion, led by cough and cold preparations at around $20 billion. In terms of OTC market value for certain global markets:

- The United States was estimated to have topped $30 billion in 2010 and could exceed $35 billion in 2012.
- Europe generated about $44 billion in 2010. South Europe (Portugal, Spain, Italy, Greece and France) comes in at about 6.5 billion euros in a mature but extremely fragmented region. Eastern Europe (Czech Republic, Poland, Romania, Bulgaria, Hungary, Slovakia) registers more than 2 billion euros, with some countries generating annual double-digit growth.
- BRIC (Brazil, Russia, India and China) countries combined to produce about $21 billion for 2010 and are on track to near $24 billion in 2012.
- Japan generated more than $12 billion during 2010, but annual growth is in the low single digits.

A significant factor driving the OTC arena is emerging markets. During 2010, demand for consumer-care products in China and India markedly improved. China is considered the No. 2 consumer healthcare country after the United States. Solid market growth was registered in Latin America and other parts of Asia in 2010.

In addition to emerging markets, Rx-to-OTC switches will significantly help drive the consumer-health marketplace forward in the years to come. Because over-the-counter medicines are cost-effective first-line therapies for many ailments, the Rx-to-OTC switch process has a positive impact on America's healthcare system process by driving down overall healthcare costs. For instance, according to a study performed by researchers at **Northwestern University**, using OTC products to treat certain upper respiratory infections could save $4.75 billion per year.

More than 100 ingredients and dosage strengths have been switched from Rx to OTC status or have been newly approved by FDA during the past 35 years. This grouping includes some blockbuster prescription brands. For a listing of these products, please see page 65.

Another market driver is the growth in self medication by consumers. Each year consumers increasingly become more willing and better able to medicate themselves with the help of online sites and other resources. With this easily accessible and increased knowledge comes more self medication with OTC products.

Plus, with traditional healthcare costs rising higher, the aging population is increasingly looking for alternative self-care treatments. And as the overall population trends toward a healthier lifestyle, OTC products are becoming more popular.

The leading therapeutic categories/medical-usage areas for OTC products include cholesterol therapy; contraception; cough, cold and allergy; dermatology; gastrointestinal disorders; pain management; sexual dysfunction; and weight management/obesity.

Also helping drive the OTC landscape is the U.S. dietary supplement industry, which is valued at about $25.2 billion. This market is growing at a double-digit compound annual growth rate.

COMPANIES THAT ARE RX BRAND LEADERS AND OTC PRODUCT LEADERS

Seven of the top 10 pharma/biopharma companies based on 2009 revenue have a leading consumer-healthcare business: **Johnson & Johnson**, **Pfizer** Inc., **GlaxoSmithKline** Plc., **Novartis** AG, **sanofi-aventis**, **Merck** & Co., and **Bayer**. The following pages detail them and their consumer-health developments and strategies.

JOHNSON & JOHNSON

J&J has 250-plus operating companies in 57 countries and 114,000 employees. Johnson & Johnson has a diverse range of consumer products, prescription medicines, and medical devices and diagnostics marketed around the globe.

J&J reported 2010 global sales totaling $61.6 billion, down 0.5% compared to 2009. Global Consumer sales amounted to $14.59 billion in 2010, a 7.7% decline versus the previous year. There was an operational decrease of 8.9% and a positive impact from currency of 1.2% for this business segment in 2010. Domestic sales were down 19.3% to $5.52 billion versus 2009. International sales grew 1.2% to $9.07 billion, reflecting an operational drop of 1% and a positive currency impact of 2.2%.

According to J&J, it is the world's sixth-largest consumer-healthcare company. J&J's Consumer business breaks down into six segments. Sales in 2010 for OTC/Nutritionals decreased 19.2% year over year to $4.55 billion. Global Skin Care sales totaled $3.45 billion in 2010, down 0.4% versus 2009. Baby Care sales amounted to $2.21 billion, up 4.4%. Women's Health sales dropped 2.7% to $1.84 billion. Oral Care sales also dropped 2.7% in 2010, coming in at $1.53 billion. In the Wound Care/Other segment, sales in 2010 totaled $1.01 billion, down 10.4% versus 2009.

J&J's overall worldwide Consumer sales performance was significantly im-

JOHNSON & JOHNSON

Consumer Highlights

2010 Sales: $14.6 Billion
Ops Change: (8.9%)

6th Largest Consumer Health Care Company

- Growth impacted by OTC recalls and shutdown of manufacturing facility
- Strong results in emerging markets
- Continued to invest in science-based innovative products
- Iconic brands

Source: Johnson & Johnson

pacted by the previously announced recalls of certain OTC medicines and the suspension of manufacturing at the **McNeil Consumer Healthcare** Fort Washington, Pa., facility as well as the currency devaluation in Venezuela.

With respect to the McNeil Consumer Healthcare product recalls, J&J CEO William C. Weldon said on Jan. 25, 2011, "We have made a commitment to restoring these products to the levels of quality and compliance that consumers expect of Johnson & Johnson."

McNeil-PPC Inc.'s McNeil Consumer Healthcare in January 2011 began voluntarily recalling at the wholesale level certain lots of **Tylenol 8 Hour**, **Tylenol Arthritis Pain**, and Tylenol upper-respiratory products. Also voluntarily recalled are certain lots of **Benadryl**, **Sudafed PE**, and **Sinutab** products. The impacted regions are the U.S., Caribbean, and Brazil.

These products were manufactured at the McNeil plant in Fort Washington, Pa., before April 2010, when production at the facility was halted. McNeil is initiating the recall as a precautionary measure after an extensive review of past production records pinpointed instances where equipment cleaning procedures were insufficient or that cleaning was not adequately documented. J&J said it is very unlikely that this impacted the quality of these products.

McNeil Consumer Healthcare additionally initiated as of January 2011 a voluntary recall of certain product lots of **Rolaids Multi-Symptom Berry Tablets** distributed in the United States to update the labeling. McNeil initiated the recall after determining that the product labeling does not include the language "Does not meet USP" as required by regulation.

Both recalls were initiated at the wholesale level. No action is required by consumers or healthcare providers, and consumers can continue to use the products. These actions were not undertaken on the basis of adverse events.

McNeil identified the inadequacies as part of a thorough, proactive product quality and process assessment of all of its produced products. McNeil has implemented a Comprehensive Action Plan at its U.S. manufacturing sites to improve the quality systems at those locations. This product assessment is a key milestone in the plan's implementation, and the actions undertaken as a result of the assessment are part of McNeil's continuing commitment to ensure that all its products meet the high quality standards expected by consumers.

During November 2010, J&J recalled about 4 million packages of **Children's Benadryl** allergy tablets and roughly 800,000 bottles of junior-strength **Motrin** caplets due to manufacturing lapses.

J&J's McNeil unit withdrew more than 40 types of children's OTC liquid medicines during April 2010, forcing a suspension of production at a manufacturing plant. As a result, 2010 sales were reduced by about $600 million, according to industry reports. The U.S. House Oversight and Government Reform Committee has investigated Johnson & Johnson's recall handling as well as a separate incident involving Motrin tablets.

In January 2010, J&J pulled 500 lots of drugs, including Rolaids, Motrin and some types of Tylenol, because of possible contamination from a chemical on shipping and packing materials. That recall was expanded in June 2010 after consumer complaints of a musty odor as well as reports of diarrhea, nausea and vomiting after people used the products.

J&J provided an update in January 2011 regarding McNeil Consumer Healthcare remediation and announced completion of the internal assessment phase of the comprehensive action plan. In July 2010, McNeil Consumer filed with FDA a Comprehensive Action Plan on quality improvement and "made a commitment to restore its operations to the level of quality and compliance that people expect of all Johnson & Johnson companies."

As part of this commitment, McNeil undertook a thorough investigation of historical records dating back to 2007 for products sold in America and produced in McNeil's internal manufacturing network. For every product, McNeil looked at whether the right processes had been identified and followed, and evaluated whether quality standards had been met. This assessment has been completed, which is a important milestone in the Comprehensive Action Plan.

The assessment identified various areas for improvement that are being addressed. For example, McNeil identified instances in which equipment cleaning procedures were insufficient or cleaning were inadequately documented. These issues took place at McNeil's Fort Washington, Pa., manufacturing plant, before April 2010 when production halted.

McNeil additionally discovered one product for which the labeling did not include all info required by regulations. In line with the company's unqualified dedication to quality and compliance, McNeil announced in January 2011 a wholesale-level recall of products affected by these issues. This recall did not result from adverse events.

"Steps we have taken under the Comprehensive Action Plan constitute an uncompromising and systematic effort to review quality and manufacturing practices at McNeil," Mr. Weldon stated. "They help us assure that moving forward, any of our products in the marketplace live up to the trusted standards and expectations that consumers have for all products coming from a Johnson & Johnson company, anywhere in the world."

As a continuing part of this effort, McNeil is performing assessments at other locations that manufacture its products. If these reviews point out any additional issues, McNeil intends to take whatever steps are necessary to ensure that its prod-

ucts meet world-class quality standards, including potential market action.

During February 2011, **Johnson & Johnson Consumer Companies** Inc.'s breakthrough **Cytomimic** Technology was featured in a scientific poster at the 69th Annual Meeting of the American Academy of Dermatology in New Orleans. This esteemed, award-winning, innovative technology stems from decades of research to harness the power of bioelectricity to improve skin rejuvenation. Cytomimic Technology will additionally be featured in scientific exhibits at the World Congress of Dermatology in Seoul, Korea during May 2011.

"Just one year after the unveiling of Cytomimic Technology for use in anti-aging at this prestigious forum, we are excited to present new clinical data on its potential to stimulate tissue repair," stated Dr. Ying Sun, a Distinguished Research Fellow and Science Leader at Johnson & Johnson Consumer Companies. "Injured skin naturally generates a low level electrical signal to promote healing. The application of Cytomimic technology has clinically demonstrated the ability to mimic this healing signal for potential tissue healing and rejuvenation applications."

A clinical trial was performed to determine if the biomimetic technology mimics the endogenous healing signal generated by the skin. Cytomimic Technology, consisting of a proprietary galvanic coupling of elemental zinc and copper, was assessed on the forearms of healthy males and females older than 18 years. The technology was compared to untreated skin, zinc oxide as well as zinc chloride. After cleansing, a small amount of each material was placed within defined 1.5-mm diameter circles and measured for electric fields covering the skin using a non-invasive instrument based on a vibrating probe technique. This technology has shown anti-inflammatory activity, collagen and elastin production, and clinically proven safety and effectiveness in reducing photoaging signs.

"Bioelectricity is found in every single body system and cell in the body," Dr. Sun stated. "Combining this knowledge with our innovative technology, we can potentially continue to expand and find new uses and platforms for Cytomimic Technology to address countless additional needs in tissue repair applications."

The clinical trial shows that the topical application of biomimetic signaling technology to the skin provides an electric field profile similar to that of the endogenous electric field that the skin generates at a wound site.

This patented technology was discovered in 2004 by Dr. Sun and his colleagues Dr. Jue-Chen Liu and Jeannette Chantalat. Johnson & Johnson Consumer Companies holds 10 U.S. patents for this technology, which are active until 2023. Multiple U.S. and international applications are pending.

J&J's Consumer segment includes a wide array of products used in the baby care, skin care, oral care, wound care and women's healthcare fields, as well as nutritional & OTC pharma products and wellness & prevention platforms.

- The Baby Care franchise includes the JOHNSON'S Baby line of products.
- Major brands in the Skin Care franchise include the AVEENO; CLEAN & CLEAR; JOHNSON'S Adult; NEUTROGENA; RoC; LUBRIDERM; DABAO; and Vendôme product lines.
- The Oral Care franchise includes the LISTERINE and REACH oral care lines of products.
- The Wound Care franchise includes BANDAID brand adhesive bandages and Neosporin First Aid products.
- Major brands in the Women's Health franchise are the CAREFREE Pantiliners; o.b. tampons and STAYFREE sanitary protection products.
- The nutritional and over-the-counter lines include SPLENDA , No Calorie Sweetener; the broad family of TYLENOL acetaminophen products; SUDAFED cold, flu and allergy products; ZYRTEC allergy products; MOTRIN IB ibuprofen products; and PEPCID AC Acid Controller from Johnson & Johnson • Merck Consumer Pharmaceuticals Co.

These products are marketed to the general public and sold to retail outlets and distributors worldwide.

Source: Johnson & Johnson

Bioelectricity is the body's native electrical signaling process that helps direct physiological activities at the cellular level, including the skin's own rejuvenation process. Applied topically, Cytomimic Technology can aid in the rejuvenation and maintenance of healthy-looking skin.

As people age bioelectrical signals naturally diminish, which can result in decreased cell-to-cell communication, production of essential proteins such as collagen and elastin, and in healing abilities. This can lead to fine lines and wrinkles, loss of firmness and sagging skin.

The science of Cytomimic is centered on creating and delivering biological levels of electricity directly to the skin, naturally stimulating the intrinsic rejuvenation process. This innovation is based on the design of a proprietary technology – energized micro-particles of zinc and copper – captured in a unique delivery system that assists in stimulating the body's own rejuvenation processes. When activated by moisture, these energized micro-particles act as "miniaturized batteries" that aid in jump-starting healthy skin function. These micro-particles remain on the skin's surface and mimic the body's native electrical signals, to rebuild and restore youthful-looking skin.

Cytomimic represents a major advancement in skin care as the first technology designed to deliver electricity at a scale that safely simulates the body's own bioelectricity levels in the form of a topical treatment. This leads to improved cell activity, evidenced *in vitro* by enhanced expression of collagen and elastin; accelerated improvement in reducing the signs of aging, even in the delicate skin around the eyes; improved skin texture, firmness and radiance; and demonstrated anti-inflammatory activity to address a potential cause of aging

J&J Consumer Companies has evaluated Cytomimic on 1,000-plus individuals/subjects in clinical and safety trials for more than 3.5 years. The technology has shown improvement of the skin's appearance within minutes of application and continued improvements over time.

Cytomimic is clinically proven to significantly reduce the hallmark signs of aging, in some cases in as little time as 30 minutes, by diminishing the appearance of bags under the eyes and periorbital fine lines and wrinkles; reducing the look of dark circles; reducing the look of fine lines and wrinkles; lifting appearance of the eyes;

The Pfizer Consumer Healthcare business includes the following types of OTC products: pain-management therapies, cough/cold/allergy remedies, dietary supplements, hemorrhoidal care, and other personal-care items.

- Dietary supplements include Centrum brands (including Centrum, Centrum Silver, Centrum Men's and Women's, Centrum Performance, Centrum Cardio and Centrum Kids) and Caltrate.
- Pain management consists of the Advil brands (including Advil, Advil PM, Advil Liqui–Gels, Children's Advil, Infant's Advil, Advil Migraine) and ThermaCare.
- The Respiratory line contains Robitussin, Advil Cold & Sinus, Advil Congestion Relief, and Dimetapp.
- The Personal Care segment includes ChapStick and Preparation H.

Source: Pfizer

reducing the appearance of crow's feet wrinkles; improving radiance and brightness; lifting, firming, and enhancing the look of jawline contours; and improving skin softness and smoothness.

PFIZER

New York-based Pfizer's diversified worldwide healthcare portfolio includes human and animal biologic and small-molecule medicines and vaccines, nutritional products, and many well-known consumer brands. Pfizer's 2010 revenue came in at $67.8 billion, up 36% versus the 2009 amount. Revenue for 2010 was significantly impacted by $18.1 billion, or 37%, due to legacy **Wyeth** products, and by $1.1 billion, or 2%, due to foreign exchange. The performance was negatively impacted by $1.4 billion, or 3%, due to legacy Pfizer products.

Pfizer in 2009 acquired the biopharma giant Wyeth, which was an active OTC player. Wyeth's consumer healthcare business is reflected in the significant growth generated by **Pfizer Consumer Healthcare** during 2010. Sales for the Pfizer business segment totaled $2.77 billion compared to $494 million during 2009. Wyeth OTC products include the pain reliever **Advil**, the calcium supplement **Caltrate** and the multivitamin **Centrum**.

According to Pfizer, its Consumer Healthcare business ranks No. 5 among all OTC entities worldwide. Pfizer sells two of the world's top 10 selling OTC brands, Centrum and Advil. The Consumer Healthcare unit has strong positions in various geographic markets, with its highest revenue volume in the U.S., Canada, China, Italy, Germany, Brazil and Australia.

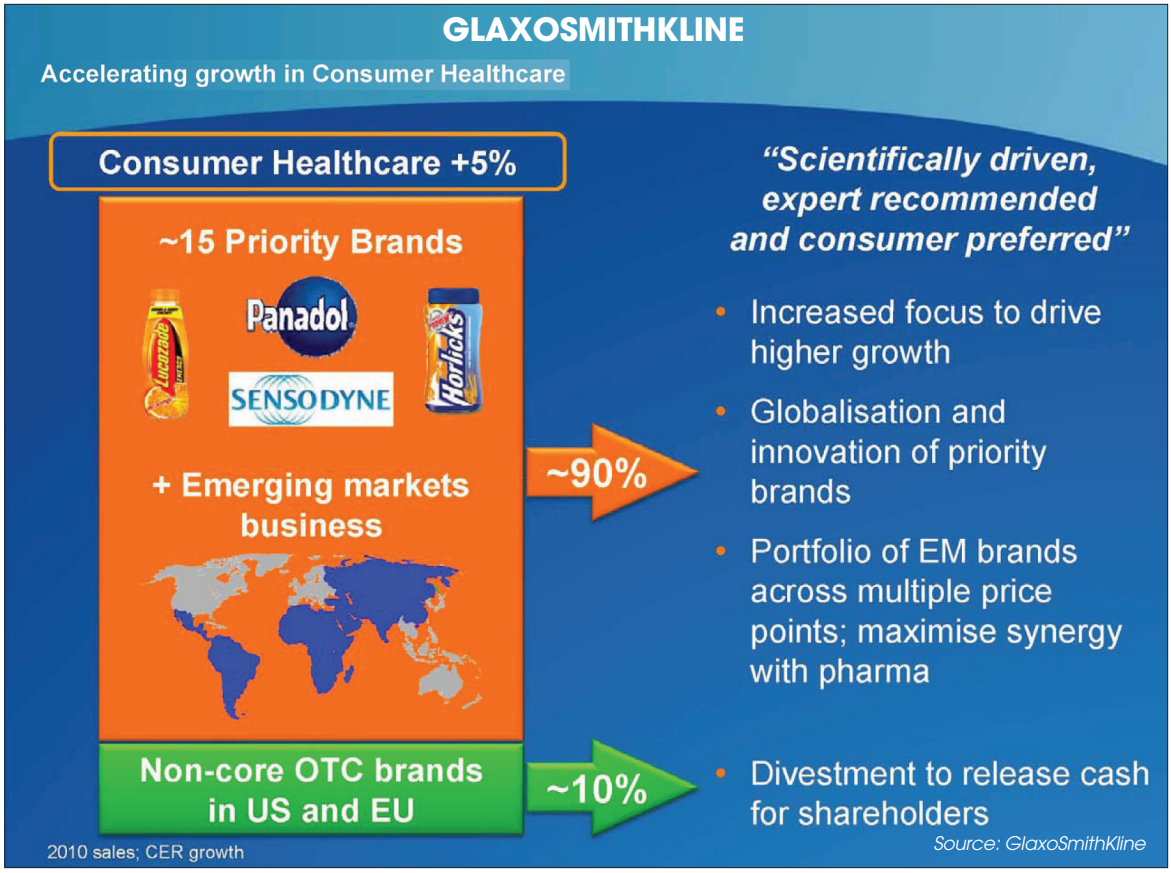
Pfizer agreed during February 2011 to buy **Ferrosan**'s consumer healthcare business from **Altor 2003 Fund** GP Ltd. Ferrosan's portfolio includes dietary supplements and lifestyle products.

Copenhagen, Denmark-based Ferrosan is an innovative and long-established consumer healthcare company with a portfolio of leading brands. Since 1920, the company has grown to serve a broader market including Russia, the Ukraine, Poland, Turkey and many countries in Central and Eastern Europe.

"Ferrosan is an excellent strategic fit that strengthens our presence in dietary supplements with a new set of compelling brands and product pipeline," stated Paul Sturman, president, Pfizer Consumer. "The transaction will mark an important step towards expanding Ferrosan's brands through Pfizer's global footprint. As an immediate result of this acquisition, we will gain greater distribution and scale for Pfizer's well-known brands such as Centrum and Caltrate in Ferrosan's regions."

Ferrosan's product portfolio includes **Multi-tabs**, a popular multivitamin brand, **Bifiform**, a leading probiotic, **Fri Flyt/Active Omega**, an Omega 3 product, and **Imedeen** premium oral skin-care brands. These brands rank among the top-selling products in their respective categories.

According to Ferrosan President Ola Erici, "We are very pleased that Ferrosan's innovative portfolio of leading brands will be joining Pfizer. We expect that, as part of the Pfizer portfolio, our products will



build on their industry-leading positions and become available in more countries around the world. And, at the same time, Pfizer will be able to leverage its footprint in key Ferrosan markets with new Pfizer products."

The deal is subject to customary closing conditions. The transaction is anticipated to be completed in second-quarter 2011. Financial terms were undisclosed.

GLAXOSMITHKLINE

GSK is one of the top research-based pharma companies worldwide. GSK's turnover for 2010 decreased 1% to £28.4 billion, with pharma down 2% year over year to £23.4 billion. Consumer Healthcare sales in 2010 advanced 5% versus 2009 to £5.01 billion. According to the company, the 5% improvement significantly outpaced market growth estimated to be 2%.

OTC medicines represented GSK's leading Consumer Healthcare segment in 2010 with sales of £2.46 billion, up 3% at constant exchange rates. Oral healthcare sales in 2010 were £1.6 billion (up 6% CER). Nutritional healthcare came in at £952 million (up 9% CER).

GSK maintains leading positions in all of the company's key consumer product areas. On a global scale, GSK ranks No. 2 in OTC medicines and No. 3 in Oral healthcare. GSK's Nutritional healthcare is No. 1 in the U.K., Ireland and India.

According to GSK, the leading force behind its consumer-healthcare business is science. The company has four dedicated consumer-healthcare R&D centres and consumer-healthcare regulatory affairs. The business segment offers leading-edge capability in scientific innovation and marketing excellence.

GSK's consumer-healthcare business includes well-known brands such as **Panadol** for pain relief, **NiQuitin** for smoking cessation, and the oral healthcare products **Aquafresh** and. **Sensodyne**.

In 2010, GlaxoSmithKline announced that its Consumer Healthcare segment going forward will have an increased concentration around 'priority' brands and emerging markets. Additionally, non-core OTC brands with yearly sales of roughly £500 million will be divested.

On March 1, 2011, **GlaxoSmithKline Consumer Healthcare** introduced new **Sensodyne Repair & Protect**. The new product is being launched in 50-plus European and International markets in 2011.

The breakthrough formulation is the first everyday fluoride toothpaste that contains patented **NovaMin** technology. This technology is scientifically proven to repair sensitive teeth by forming a tooth-like layer over exposed dentine. This process helps continually repair and protect sensitive areas.

Sensitive teeth are common, affecting 81% of U.K. adults. However, many do not know that the twinges they experience are a sign of sensitivity that results from exposed dentine. Rather than addressing the problem, many sufferers attempt to ignore the twinges or develop ways to avoid them, without realizing that their teeth have vulnerable areas.

"Tooth sensitivity is caused when the dentine is exposed," according to Professor David Bartlett. "This dentine that makes up most of the tooth is porous, with thousands of tiny channels running through it to a nerve in the center. A layer of hard enamel on the crown of a tooth protects the underlying dentine, but if this dentine is exposed, a tooth can become sensitive and vulnerable."

GlaxoSmithKline Consumer Healthcare Products

Brand	Products	Application	Markets	Competition
Oral healthcare				
Aquafresh	toothpastes, toothbrushes, mouthwashes	prevention of caries, gum disease and bad breath	global	Colgate-Palmolive's Colgate, Procter & Gamble's Crest
Sensodyne	toothpastes, toothbrushes	prevention of dental sensitivity	global	Colgate-Palmolive sensitivity toothpastes
Biotene	mouthwash, gel	treat dry mouth	many markets	none
Polident, Poligrip, Corega	denture adhesive, denture cleanser	to improve comfort of fitted dentures and to clean dentures	global	Fixodent
OTC medicines				
Panadol	tablets, capulets, infant drops	paracetamol-based treatment of headache and joint pain, fever, cold symptoms	global, except U.S.	Nurofen
NicoDerm, NiQuitin CQ, Nicabate; also Nicorette (U.S. only)	gum, patch, mini lozenge, original lozenge	treatment of nicotine withdrawal as an aid to quitting smoking	global	Novartis' Nicotinell, retailers' own brands
Nutritional healthcare				
Lucozade	energy and sports drinks	energy and hydration	U.K., Ireland, some other markets	various sports drinks
Horlicks	malted, milk-based drinks and foods	nutrition	U.K., Ireland, India	Ovaltine, Milo
Ribena	blackcurrant juice-based drink	vitamin C-delivering health drink	U.K., Ireland, some other markets	Robinsons

Source: GlaxoSmithKline

The NovaMin technology was initially developed to help stimulate bone regeneration, which seeks out the regions of teeth that are sensitive. The technology forms a tooth-like layer over exposed dentine that is 50% harder than healthy dentine, helping to continually repair and protect with twice-a-day brushing.

NovaMin reacts rapidly with water, so a challenge for GlaxoSmithKline Consumer Healthcare was to develop a non-water based formula that could be used in an everyday fluoride-based toothpaste. After being exposed to water or saliva, NovaMin releases calcium and phosphate ions, which are the building blocks for teeth that are naturally attracted to exposed dentine. The ions bind themselves to the collagen in the exposed dentine, and from first use, start to form a protective mineral layer that mimics the tooth's natural make-up.

"Sensodyne Repair & Protect is a technological advance in everyday dental care," according to Dr. Teresa Layer, VP of Oral Healthcare R&D Future Teams for GlaxoSmithKline Consumer Healthcare. "With twice-daily brushing it helps to continuously repair exposed dentine and provides substantive protection from sensitivity."

Sensodyne Repair & Protect should be used twice a day like a regular toothpaste, which will continually help repair sensitive teeth and help prevent sensitivity. The product additionally provides the benefits of an ordinary daily fluoride toothpaste, such as all-round protection, cleaning and freshness.

NOVARTIS

Concentrated purely on healthcare, Novartis' diverse product portfolio includes innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer-health products. Novartis claims to be the only company with top markets positions in these fields.

In February 2011, Novartis announced that its Consumer Health division would be separated into two segments: OTC and Animal Health. The separate businesses join these already-established Novartis divisions: Pharmaceuticals, **Sandoz** (generics), and Vaccines & Diagnostics. Additionally, following the completion of the merger between Novartis and **Alcon** Inc., **Ciba Vision** Corp. and Novartis ophthalmic medicines will be combined into the new Alcon eye-care division.

As of March 2, 2011 Naomi Kelman is heading the Novartis OTC Division and has become a permanent attendee to the Executive Committee of Novartis (ECN). Ms. Kelman reports to Novartis CEO Joseph Jimenez. Ms. Kelman came to Novartis from Johnson & Johnson, where she held several leadership roles within the Consumer and Medical Device & Diagnostic sectors. Her successful leadership spanning several businesses showed a strong concentration on innovation, and as a result delivered strong financial results.

"With the upcoming Alcon merger, we have decided to put additional focus on two important businesses which today comprise the Consumer Health Division: OTC and Animal Health, by streamlining and simplifying our decision-making process," Mr. Jimenez stated on Feb. 17, 2011. "We look forward to Naomi joining our leadership team – her experience in consumer businesses, combined with her drive for results make her well suited to run our OTC business."

Novartis Group's continuing operations generated 2010 net sales of $50.6 billion. Novartis invested $9.1 billion (or $8.1 billion excluding impairment and amortization charges) on R&D during 2010. With headquarters in Basel, Switzerland, Novartis employs 119,000 full-time-equivalent associates (including 16,700 Alcon associates) and operate in 140-plus countries.

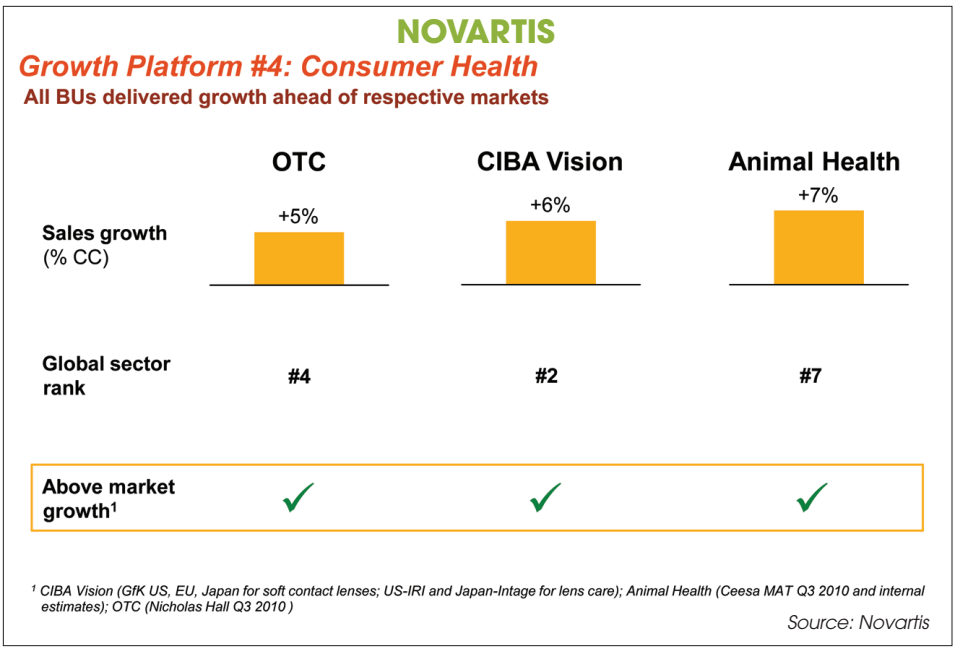
Novartis' Consumer Health sales for 2010 totaled $6.2 billion, up 7% (+6% cc) versus 2009. All of the Consumer Health businesses generated growth ahead of their respective markets for 2010.

According to Novartis, the group's OTC business ranked No. 4 in the global sector during 2010. All regions contributed to Novartis' 2010 sales growth in the OTC segment (+5% cc), supported by double-digit increases of the key brands **Voltaren**, **Nicotinell** and **Excedrin**. Voltaren Gel gained FDA clearance during November 2007 as the first approved topical prescription treatment for pain associated with osteoarthritis. Nicotinell is a Nicotine Replacement Therapy (NRT) for treating smoking addiction. Excedrin has been a leader in headache pain for almost 50 years.

During second-quarter 2010, the heartburn treatment **Pantoloc Control** was successfully introduced in 14 European markets. Pantoloc Control is anticipated to continue to support growth in Novartis' gastrointestinal franchise. Novartis launched the OTC proton-pump inhibitor (PPI) through a joint-marketing pact with the product's originator **Nycomed**.

Based in Zurich, Switzerland, Nycomed is a privately owned, worldwide pharma company. During 2009, Nycomed ranked No. 28 among global pharma companies and was the 16th-largest provider of OTC medicines, according to the company. For more details about Nycomed, please see page 26.

Pantoprazole is the first PPI and second product ever approved by the European Medicines Agency's Committee for Medicinal Products for Human Use for OTC status through the EU's centralized procedure. The first successful pan-European



switch was GlaxoSmithKline's weight-loss drug **alli**. The EMA cleared the switch of pantoprazole to OTC status in June 2009, one month after the Rx drug lost patent protection in 12 European countries, according to reports.

Pantoprazole is the active chemical in the Rx blockbuster brand **Protonix/Pantozol/Pantoloc**. These brands are marketed worldwide by Nycomed and **Pfizer** Inc. (via its 2009 acquisition of Wyeth).

Retail sales of **Prevacid24HR** have spurred Novartis' U.S. OTC business into the fastest-growing in its peer group. Prevacid24HR contains 15 milligrams of lansoprazole, which is the main chemical in the blockbuster Rx medicine **Prevacid/Takepron** (lansoprazole). Prevacid/Takepron is marketed worldwide by Japan's **Takeda** Pharmaceutical Co. The non-prescription version treats frequent heartburn that for 24 hours.

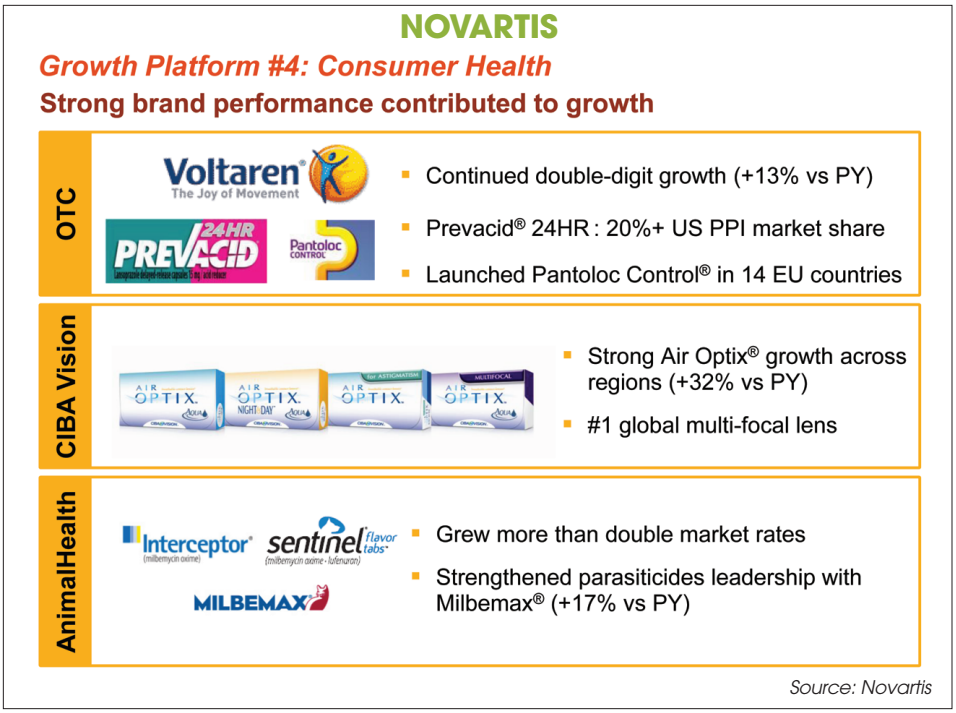
During fourth-quarter 2010, Prevacid24HR became one of the world's top 20 OTC brands and Novartis' second-leading OTC brand in the United States.

The company's leading OTC product is **Excedrin**. The Novartis brand established itself as a top four brand in its category and as the No. 2 fastest-growing brand among its competitors during 2010. Containing acetaminophen, aspirin and caffeine, Excedrin treats pain due to headaches, backaches, colds and arthritis.

Novartis is acquiring some OTC eye-care products via its acquisition of Alcon. The most expensive healthcare M&A transaction of 2010, Novartis' acquisition of Alcon occurred in various stages. Announced on the fourth day of 2010, Novartis agreed to purchase 52% of Alcon shares at a value of $28.3 billion. Having already acquired 25% of Alcon during July 2008, Novartis as a result had attained 77% majority ownership of the eye-care leader. Then during December 2010, Novartis obtained the remaining minority stake of 23% for $12.9 billion. Through the two transactions that combine for a value of $41.2 billion (and a total of $51.6 billion when including the initial 25% deal in 2008), Novartis becomes the premiere player in the worldwide eye-health arena.

Novartis and Nestlé first entered into the 77% majority-stake deal during April 2008 as part of a two-phase process. The total cost to Novartis for the 77% majority stake of Alcon was $38.7 billion, or $168 per share. During July 2008 and as the first phase, Novartis acquired a 25% stake in Alcon for $10.4 billion. The $168 per share reflects a 17% premium over $143.18, which was agreed by Novartis and Nestlé to be Alcon's market price during April 2008.

Based in Hunenberg, Switzerland, Alcon is the largest and most profitable eye-care company with more than 15,500 employees in 75 countries. For 2009, the company had sales of $6.5 billion, operating income of $2.3 billion, and net income of $2 billion. Alcon's product range includes pharmaceutical, surgical and consumer eye-care products to treat diseases, disorders and other conditions of the eye.



Alcon is the worldwide leader in IOLs based on the **AcrySof** family, which exceeded $1 billion in 2008 sales. Alcon's portfolio of specialty medicines covers various eye diseases such as glaucoma and conditions in the front of the eye like infections and allergies. Alcon also provides a portfolio of contact-lens-care products, OTC dry-eye drops and ocular vitamins. Emerging markets has been a key growth driver for the company.

"The full merger is the logical conclusion of our initial strategic investment in Alcon," stated Daniel Vasella, M.D., Novartis chairman. "With this step Novartis takes full ownership, becoming the global leader in eye care, a rapidly expanding, innovative platform based on the growing needs of an aging population."

According to Mr. Jimenez, "The growth synergies here are significant, as Alcon will be the eye-care development engine for our best-in-class research organization, and will leverage the Novartis market-access capabilities outside the U.S. I am very pleased that we were able to come to this agreement and will be able to provide Alcon employees the full benefits of being part of the Novartis Group."

According to Novartis, the eye-care industry offers additional growth opportunities underpinned by the increasing unmet needs of emerging markets and an aging population. The Alcon and Novartis eye-care portfolios address a wide array of these unmet needs. The companies have complementary pharma portfolios for diseases in the front and back areas of the eye as well as strong lens-care brands around the globe. Alcon is a worldwide leader in ophthalmic surgical products. Novartis possesses a broad contact lens portfolio and advanced eye-care technologies as well as an early-stage pipeline of innovative ophthalmic medicines.

The merger is anticipated to be finalized during first-half 2011. Implementation is expected to take six months from the closing of the merger. Following the completed merger, Alcon will be the new eye-care division of Novartis. Pro-forma sales of the new division for 2009 totaled $8.7 billion. The business will include Ciba Vision and ophthalmic medicines.

A worldwide leader that generates more than three-fourths of its yearly sales from contact lenses, Ciba has been growing due in part to new product introductions in the **Air Optix** family of monthly silicone hydrogel lenses and the **Dailies**

Novartis OTC Overview

Novartis OTC is a world leader in offering products for treating and preventing common medical conditions and ailments to enhance people's overall health and well-being. The OTC business is carried out by various affiliated companies in 50-plus countries.

The OTC segment concentrates on a group of strategic global brands in leading product categories that include treatments for cough/cold/respiratory (Triaminic, Otrivin, TheraFlu/NeoCitran); pain relief (Excedrin, Voltaren); smoking cessation (Habitrol/Nicotinell); dermatology (Lamisil, Fenistil); and gastrointestinal (Benefiber, Prevacid24HR, Pantoloc Control).

Pantoloc Control (pantoprazole 20 mg) was introduced across 14 European markets during May 2010 after having been centrally approved in June 2009 by the EMA for treating frequent heartburn. Pantoloc Control is a strategic addition to the Novartis OTC product portfolio. The company anticipates that the brand will drive strong growth of Novartis' OTC Digestive Health category.

Source: Novartis

range of disposable lenses. Ciba offers an array of lens-care products.

Novartis now is the clear-cut leading force in the eye-care segment. **Bausch & Lomb** Inc. is regarded as the No. 2 player in the worldwide eye-health market. Bausch & Lomb is committed to bringing visionary ideas to eye health. The corporation's core businesses include contact lenses and lens-care products, ophthalmic surgical devices and instruments, as well as ophthalmic pharmaceuticals. Founded during 1853, Bausch & Lomb is based in Rochester, N.Y., and has 10,000-plus employees. The company's products are sold in more than 100 countries. For more details about Bausch & Lomb, please see page 18.

SANOFI-AVENTIS

A leading global pharma entity, sanofi-aventis generated 2010 sales of EUR30.38 billion. The company's broad portfolio of pharma products covers Rx medicines, generics, consumer healthcare and animal health. Sanofi-aventis is a global leader in human vaccines. With a broad and balanced presence in traditional and emerging markets, sanofi-aventis has 102,000 employees in 100 countries.

Sanofi-aventis became a significant force in the OTC arena upon its acquisition of **Chattem** Inc. This transaction was ranked as the ninth-largest M&A transaction of 2009 by PharmaLive editors.

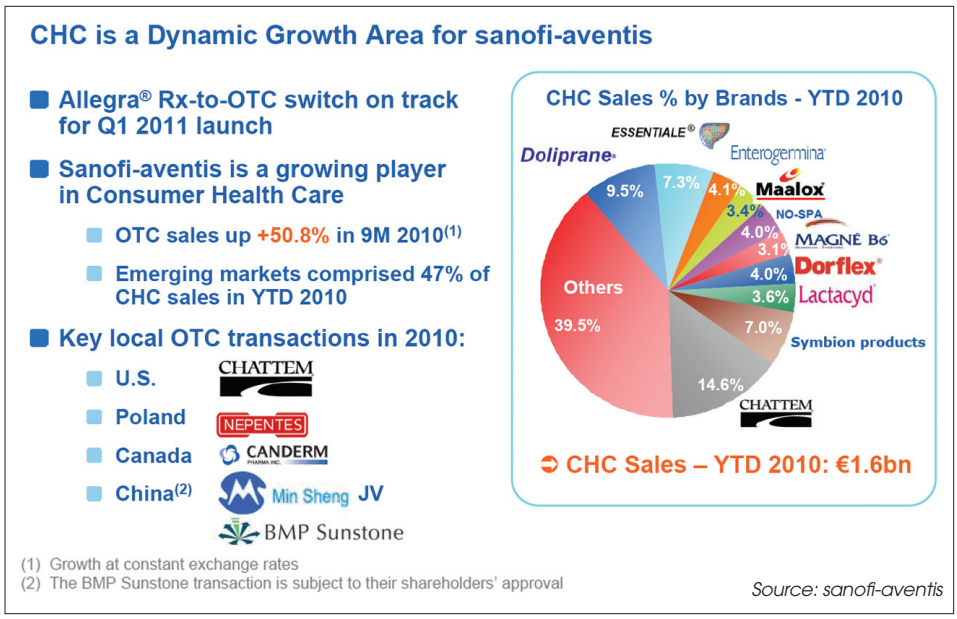
Near the end of December 2009, sanofi-aventis entered into a definitive deal to acquire 100% of the outstanding shares of Chattem in a cash tender offer for $93.50 per share, or $1.9 billion. The pact created the world's fifth-largest consumer healthcare company in terms of product revenue by joining the operations of Chattem with sanofi-aventis' strong international presence in the sector.

Chattem has been a top marketer and manufacturer of a broad portfolio of branded OTC healthcare products, toiletries and dietary supplements. Chattem's products target niche market segments and are among the market leaders in their respective categories across food, drug and mass merchandisers. Chattem has regularly shown the ability to sustain regular growth in terms of sales and profit via the development of its own brands and the successful integration of acquired products. The 130-year-old company's well-known brands include **Gold Bond**, **Icy Hot**, **ACT**, **Cortizone-10**, **Selsun Blue** and **Unisom**. Chattem carries out a portion of its business via subsidiaries in the United Kingdom, Ireland and Canada. For 2008, Chattem recorded revenue of $455 million and had 488 employees.

OTC and consumer brands are core growth platforms identified in sanofi-aventis' broader strategy for generating sustainable growth. Although the Group generated roughly EUR1.4 billion in global OTC sales during 2009, a direct U.S. presence had yet to be established for sanofi-aventis until the arrival of Chattem.

"The acquisition of Chattem will be a significant milestone in sanofi-aventis' transformation strategy and will provide us with the ideal platform in the U.S. consumer healthcare market, which represents 25% of the current worldwide opportunity," according to Christopher A. Viehbacher, sanofi-aventis CEO, at the time of the acquisition announcement. "In addition, we believe our ability to convert prescription medicines to OTC products will be enhanced by Chattem's leading sales, marketing and distribution channels. We have great respect for Chattem's world-class management team, which has an excellent track record of sales and earnings growth based on building strong brands. With the potential access to switch products such as **Allegra**, I believe this team will take Chattem to even higher levels."

"This transaction offers immediate and significant value for Chattem's shareholders and important benefits to our employees, customers and community," said Chattem CEO Zan Guerry at the time of the acquisition. "I am excited to work with the sanofi-aventis team to cap-



ture the significant growth opportunities this combination creates, as highlighted by the planned launch of Allegra. Chattem will form the base of a new consumer healthcare business in the United States for sanofi-aventis, and the headquarters, manufacturing and leadership team will continue to be based in Chattanooga."

Mr. Guerry and Chattem's senior-management team agreed to lead sanofi-aventis' U.S. consumer health division following the close of the transaction. Sanofi-aventis is dedicated to Chattem's current operations and entrepreneurial spirit as it builds a sizeable presence in the U.S. consumer-healthcare sector. Sanofi-aventis has maintained both of Chattem's existing manufacturing facilities and continued construction on a third. The corporate brand of Chattem remained intact.

Editor's note: For more details regarding the top 10 M&A industry deals of 2010, 2009 and other significant transactions throughout the healthcare arena, please visit PharmaLive.com/Special_Reports (Mergers & Acquisitions, Partnerships, & Collaborations Review and Outlook).

During December 2009, sanofi-aventis management announced that the company would seek to convert the antihistamine Allegra (fexofenadine HCl) from a prescription drug to an OTC product. Upon Allegra's conversion, Chattem would assume responsibility for the brand as part of becoming the platform for sanofi-aventis' U.S. OTC and consumer healthcare business. As a prescription medicine for allergies and other conditions, Allegra generated blockbuster sales throughout the last decade.

The Chattem acquisition has provided sanofi-aventis with a new platform that enables the conversion of prescription medicines to over-the-counter products. Allegra represents sanofi-aventis' first Rx-to-OTC conversion.

During January 2011, FDA approved the Allegra family of allergy medication products for OTC use in adults and children 2 years of age and older. **Allegra-D**, which relieves nasal congestion and sinus pressure, was made available without a prescription at the pharmacy counter for use in adults and children 12 years of age and older. Allegra and Allegra-D were introduced during March 2011 in their original Rx strengths without a prescription.

More than 40 million American adults suffer from indoor and outdoor allergies. Allegra provides fast, non-drowsy, 24-hour relief of allergy symptoms: sneezing; runny nose; itchy, watery eyes; and itchy nose or throat. The product has provided allergy sufferers with relief of symptoms for nearly 15 years.

"Leveraging our U.S. Consumer Healthcare platform to convert prescription medicines to OTC products is a key growth driver for sanofi-aventis to become a diversified healthcare company also in the United States," says Hanspeter Spek, president, Global Operations. "The approval of Allegra for OTC use further validates our vision to increase our presence in the U.S. consumer healthcare market."

Mr. Guerry says, "We're pleased to provide U.S. consumer access to Allegra, the No. 1 U.S.-prescribed allergy treatment, allowing allergy sufferers to conveniently obtain a safe and effective medication without a prescription,"

The Allegra family of OTC products is available without a prescription for allergy sufferers in drug, grocery, mass merchandiser and club stores throughout America. This includes **Allegra 24-Hour** and **12-Hour Tablets** for adults and children 12 years of age and older; **Children's Allegra 12-Hour Tablets** for 6 years of age or older, and **Liquid** for use in 2 years of age and older; **Children's Allegra 12-Hour Orally Disintegrating Tablets** for use in 6 years of age and older; and **Allegra-D 24-Hour** and **12-Hour Allergy and Congestion Extended Release Tablets** (with a decongestant) for use in children 12 years of age and older.

The Chattem acquisition is part of a strategy by sanofi-aventis to diversify, particularly into sectors with stable product revenue as the company will face patent expirations in the next few years, including the blockbuster brands **Plavix** and **Avapro**. For 2010, sanofi-aventis reported sales of EUR6.9 billion for Plavix/Iscover and EUR2.06 billion for Avapro/**Aprovel/Karvea**.

Sanofi-aventis' transformation strategy was evident in the third quarter of 2009 as the company reinforced platforms for growth and forged ahead with its policy of R&D alliances and targeted acquisitions. On Oct. 30, 2009, the Group announced the signing of a deal to acquire all shares of **Laboratoire Oenobiol**, the French leader in nutritional supplements for health and beauty. During 2008, Oenobiol reported turnover of EUR58 million, of which 85% was generated in France.

Sanofi-aventis made another OTC company acquisition during 2010. On Oct. 28 of that year, a deal was struck in which **Sanofi Pasteur**, the vaccines division of sanofi-aventis, agreed to acquire all outstanding shares of **BMP Sunstone** Corp. for cash consideration of $10 per share, or a total of $520.6 million on a fully diluted basis. The acquisition was structured as a merger of BMP Sunstone, which as a result becomes a wholly owned subsidiary of sanofi-aventis.

The price per share represented a 30% premium above the closing price of BMP Sunstone's shares as of Oct. 27, 2010. BMP's board of directors unanimously approved the deal.

BMP generated sales of $147 million in 2009. Almost 60% of those sales derived from the consumer-healthcare segment, where BMP has had access to retailers, county hospitals and community clinics in Tier III and Tier IV markets. In this area, BMP has established two of China's most recognized brands: "Hao Wa Wa" (**Good-Baby**), which has been recognized as the No. 1 pediatric Cough & Cold brand in China, and "Kang Fu Te" (**Confort**), a hygiene brand for women's healthcare.

Following the October 2010 establishment of the joint-venture **Hangzhou Sanofi Minsheng** Consumer Healthcare Co. Ltd. in partnership with **Minsheng** Pharmaceutical Co. Ltd., the acquisition of BMP gives sanofi-aventis a leading consumer-healthcare presence in China with a strong position in Vitamins & Minerals Supplements and Cough & Cold. These are the two largest categories of that market.

"The acquisition of BMP Sunstone will not only leverage our consumer-healthcare business in China, but will also bring us unique access to new expanding distribution channels which are expected to account for a third of the pharmaceutical market in China in the coming years" Mr. Viehbacher stated. "This transaction represents another strategic move for sanofi-aventis to reinforce its leadership position in China."

BMP CEO David (Xiao Ying) Gao said, "This transaction offers immediate and significant value for BMP Sunstone stockholders and important benefits to our employees and customers. I am excited to work with the sanofi-aventis team to capture the significant growth opportunities this new combination will create in the consumer-healthcare market in China."

Consumer healthcare is one of the core growth platforms pinpointed in sanofi-aventis' strategy for attaining sustainable growth. As of October 2010, Sanofi-aventis was the No. 5 consumer-healthcare company worldwide, and it continues to expand its presence in this field via organic and external growth.

With an estimated size of EUR12 billion in 2010, the consumer-healthcare market in China represents the second largest worldwide after No. 1 United States. China's consumer-healthcare market has grown at a CAGR of 11% since 2005. This trend is expected to continue during the coming years, spurred by continued urbanization and improvement of patients' affordability, a rising trend of self-medication, and the development of pharmacy chains and expanded retail offerings of consumer healthcare products.

Sanofi-aventis was the first foreign pharma company to debut offices in China. Sanofi-aventis has become one of the fastest-growing healthcare companies in that vast country with 5,000 people in 200-plus cities. From prevention to treatment, sanofi-aventis is uniquely set up to take on public-health needs in China. Sanofi Pasteur is a leading vaccines there.

Sanofi-aventis as of October 2010 had three manufacturing facilities in China: in Beijing, Hangzhou, and Shenzhen. Sanofi-aventis is constructing three new facilities, each set to start commercial production in 2012, to meet the growing demand of the Chinese market. The company is engaged in integrated R&D in China from drug target identification to late-stage clinical development. Sanofi-aventis' China R&D Center and Asia Pacific R&D Center are located in Shanghai.

Sanofi-aventis' Consumer Health Care business generated 2010 sales of EUR2.22 billion, up 45.7% at constant exchange rates year over year. Growth was lead by Emerging Markets, where net sales advanced 44.4% at constant exchange rates to EUR1.05 billion. These figures consolidate the consumer-health products of **Zentiva** NV from April 2009, Oenobiol as of December 2009, Chattem as of February 2010, and **Nepentes** SA from August 2010. On a constant structure basis and at constant exchange rates, the division recorded 2010 sales growth of 6.9%, driven by Emerging Markets.

On March 11, 2009, sanofi-aventis successfully completed its offer for the Eastern European generic player Zentiva. As of Dec. 31, 2009, sanofi-aventis held about 99.1% of Zentiva's share capital. The total purchase amount was EUR1.2 billion,

SANOFI-AVENTIS CONSUMER HEALTH CARE

Consumer Health Care (CHC) is a core growth platform identified in sanofi-aventis' broader strategy for achieving sustainable growth. In 2010, the business recorded CHC sales of EUR2.22 billion; nearly half of sanofi-aventis' CHC sales were in emerging markets, 28% in Europe, and 14% in the United States.

Organic growth in 2010 was supported by sanofi-aventis' CHC portfolio, which provides the company with a strong presence in the analgesics, gastrointestinal, and cough & cold areas.

• Doliprane consists of a range of paracetamol formulas to fight pain and fever. Due to a wide offering in terms of dosages (from 2.4% paracetamol suspension up to 1-g formulas) and pharmaceutical forms (suspension, tablets, powder, suppositories), Doliprane covers the needs of the patients from baby to elderly. Doliprane is sold primarily in France. In August 2010, DolipraneLib (500-mg paracetamol tablets) was launched in France in new easy-to-carry packaging.

• Magne B6 is a product containing magnesium and vitamin B6, which was granted its first marketing authorization in France during 1970. The product has now been granted marketing authorizations in more than 40 countries. MagneB6 has various therapeutic indications from irritability, anxiety and sleep problems to female health issues like premenstrual syndrome or menopause discomfort.

MagneB6 is available in tablets as well as vials of oral solution.

• Enterogermina consist of 2 billion Bacillus clausii spores in a ready-to-drink oral suspension in vials of 5 ml and in capsules. Launched in liquid form during 1958 in Italy, the new 2 billion dosage was launched in 2001; the capsule form was introduced during 2006. Enterogermina is indicated in the prevention and the treatment of intestinal imbalance during acute or chronic intestinal disorders (from babies to adults). Enterogermina is sold primarily in Europe and has been enjoying strong growth in Latin America.

• Essentiale is a herbal preparation for liver therapy. The product is made of highly purified essential phospholipids extracted from soybeans and contains a high percentage of phosphatidylcholine, a major constituent of cellular membrane. Essentiale is used to treat symptoms such as lack of appetite, sensation of pressure in the right epigastrium, toxico-nutritional liver damage, as well as hepatitis. Essentiale is mainly sold in Russia (37% growth) and some South East Asian countries.

• Maalox is a well-established brand consisting of two antacids: aluminium hydroxide and magnesium hydroxide. The product is available in several pharmaceutical forms — tablets, suspension, and stick packs — to provide consumer choice. Maalox was first launched in France during 1972 and is present in 55 countries, including in Europe, Latin America, Russia and some Asian countries.

• NoSpa contains drotaverine hydrochloride. The product is indicated in abdominal spastic pain such as intestinal spasm, menstrual pain, or vesical spasm. NoSpa is sold primarily in Russia and Eastern Europe.

• Lactacyd consists of a range of liquid soaps for feminine hygiene. Lactacyd is sold mainly in Brazil (28% growth) as well as Asia.

• Chattem's U.S. products are mainly branded consumer healthcare products, toiletries and dietary supplements across niche market segments. Well known brands include Gold Bond, Icy Hot, ACT, Cortizone-10, Selsun Blue and Unisom.

• In January 2011, FDA approved the Allegra family of allergy medication products for OTC use in adults and children 2 years of age and older. The Allegra family of OTC products are available in drug, grocery, mass merchandiser and club stores nationwide as of March 2011. This switch constitutes a key step in sanofi-aventis' U.S. CHC growth strategy.

Source: sanofi-aventis

including acquisition-related costs. Following the buyout of the remaining noncontrolling interests, sanofi-aventis held a 100% equity interest in Zentiva effective Dec. 31, 2010. Sanofi-aventis previously had a 24.9% interest in Zentiva, which was accounted for as an associate by the equity method.

The August 2010 acquisition of a 100% equity interest in the Polish company Nepentes for PLN 425 million (EUR106 million) was intended to diversify sanofi-aventis' consumer health portfolio in Poland, and in Central and Eastern Europe generally.

MERCK

Merck is a worldwide healthcare leader known as **MSD** outside the United States and Canada. Through Rx medicines, vaccines, biologic therapies, as well as consumer-care and animal-health products, the company has a presence in 140-plus countries via 94,000 employees. In 2010, Merck generated sales of $46 billion and GAAP net income of $861 million.

Merck's Consumer Care sales totaled $1.3 billion in 2010. This performance reflects continued strong performance of various key brands such as **Dr. Scholl's** and **Coppertone**. Consumer Care includes footcare and suncare consumer products as well as OTC medicines.

Dr. Scholl's and Coppertone came to Merck through the company's 2009 acquisition of **Schering-Plough** Corp. On March 9 of that year, the two companies agreed to a reverse merger transaction amounting to $41.1 billion. The acquisition provided Merck with patent-protected blockbusters and a strong product pipeline. With Schering-Plough's 18 Phase III projects, the new Merck became one of the leading R&D players. Schering-Plough also provided Merck with a significant consumer-products presence.

Merck's Consumer Care business includes the company's U.S. and Canada consumer-product sales. Consumer-product sales for the rest of the world under MSD are included in the company's Human Health segment. For 2010, global Human Health sales (which includes the prescription-drug business) totaled $39.81 billion and Consumer Care sales amounted to $1.34 billion.

Merck's leading consumer-care product in 2010 was **Claritin**, which was acquired from the Schering-Plough transaction. The former prescription blockbuster generated 2010 OTC sales of $401 million for Merck. Including 2009 sales from Schering-Plough, Claritin OTC produced $367 million during that year.

Claritin is the leading physician-recommended and pediatrician-recommended non-drowsy OTC brand for allergies. The Claritin Rx-to-OTC switch during 2002 was the largest such switch ever as well as the first for a non-drowsy antihistamine.

Claritin offers powerful non-drowsy allergy relief for 12 hours or 24 hours in various forms, including Claritin Tablets; **Claritin Liqui-Gels**, an easy-to-swallow liquid-filled capsule; as well as **Claritin RediTabs** tablets, a quickly dissolving tablet for patients ages 6 years and older. **Claritin 12-Hour RediTabs** tablets offer the flexibility to manage allergy symptoms all day or night.

Claritin-D is available behind-the-counter in 12-hour or 24-hour extended-release tablets. Claritin-D includes the decongestant pseudoephedrine for powerful nasal congestion relief.

Dr. Scholl's is the leading brand of footcare products in the U.S., providing comfort to millions for more than a century. The brand offers more than 120 footcare products. According to Merck, Dr. Scholl's uses the latest podiatric medicine and research to revolutionize the way Americans think of and care for their feet.

Dr. Scholl's For Her is the first full line of footcare products designed specifically for women. Products range from pedicure-related to heel insoles.

Dr. Scholl's For Her Fast Flats was launched in August 2010. The compact and foldable shoes fit discreetly in a purse and come with a wristlet for easy storage and portability. The spare pair is convenient for nights out, weddings, traveling through airports, and other times when a long trek in heels is uncomfortable. As of August 2010, Fast Flats was the only brand of portable flats available at most drug and mass retailers in America. The flats come in female sizes 5-6, 7-8, and 9-10.

Merck Consumer Care introduced Dr. Scholl's **Custom Fit Orthotic** Centers during July 2010. These kiosks help people find customized solutions for their tired, achy feet. The kiosks use revolutionary **Foot-Mapping** Technology to measure arch type and the areas where people put the most pressure on to recommend the most appropriate Custom Fit Orthotic.

The FootMapping Technology was developed by Dr. Scholl's scientists and evaluated in five clinical trials. The technology uses 2,000-plus pressure sensors to measure foot areas where the most pressure is applied, arch type and foot length. Based on these criteria, the technology recommends the Dr. Scholl's Custom Fit Orthotic that is best suited for one's feet. They offer all-day relief of tired, achy feet and eliminate foot discomfort immediately.

"Fifty percent of adults suffer from tired, achy feet, especially if they have jobs that keep them on their feet all day," according to Dr. Leslie Campbell, a podiatrist at the **Plano Physician's Group** in Plano, Texas, and a consultant to the makers of Dr. Scholl's. "A customized solution can make a real difference in foot comfort, and these revolutionary Dr. Scholl's Custom Fit Orthotic Inserts are a great, affordable way for people to relieve their tired, achy feet."

The Coppertone line of products in-

MERCK CONSUMER CARE

The Consumer Care segment of Merck develops, manufactures and markets OTC, foot-care and sun-care products. The segment's main brands include:

Over-the-Counter Products
Claritin non-drowsy antihistamines; MiraLax treatment for occasional constipation; Coricidin HBP decongestant-free cold/flu medicine for people with high blood pressure; Afrin nasal decongestant spray; and Zegerid OTC treatment for frequent heartburn.

Foot Care
Dr. Scholl's foot-care products; Lotrimin topical antifungal products; and Tinactin topical antifungal products and foot & sneaker odor/wetness products.

Sun Care
Coppertone sun care lotions, sprays and dry oils; and Solarcaine sunburn-relief products.

Source: Merck

cludes sun-care lotions, sprays and dry oils. The brand dates back to 1944.

The Coppertone Solar Research Center in Memphis, Tenn., is one of the largest corporate facilities for testing sunscreen effectiveness and performance. Suncare scientists carry out hundreds of tests on sunscreen formulas at the center every year to ensure products meet both consumers' needs and rigorous testing standards. The R&D team oversees the development of a many different global suncare products that are manufactured and marketed worldwide, including in Europe and Japan.

During April 2010, **Zegerid OTC** for treating frequent heartburn became available in drug stores, grocery stores, mass merchandisers and club stores throughout America. FDA approved Zegerid during December 2009 for OTC use. Please see page 15 for more details.

BAYER

Germany's Bayer is a worldwide enterprise with core competencies in the areas of healthcare, nutrition and high-tech materials. The Bayer Group generated 2010 sales of EUR35.09 billion, up 12.6% compared to 2009. The three primary business areas are HealthCare, CropScience, and MaterialScience.

Bayer HealthCare AG is a researcher, developer, manufacturer and marketer of innovative products for disease prevention, diagnosis and treatment. Sales in 2010 for the HealthCare business grew 5.8% to EUR16.91 billion. The currency-adjusted and portfolio-adjusted increase was 1.7%. The HealthCare subgroup is divided into the Pharmaceuticals and Consumer Health segments.

Within the HealthCare business, Pharmaceuticals sales for 2010 rose 4.2% (Fx&p adj. 0.9%) to EUR10.91 billion. Bayer's Consumer Health Sales improved 8.8% (Fx&p adj. 3.4%) to EUR6.01 billion versus 2009, with all regions – particularly North America – contributing to the growth. The Consumer Health segment consists of the Consumer Care, Medical Care and Animal Health divisions.

In the non-prescription medicines business (Consumer Care), the pain reliever **Aleve** recorded the highest 2010 sales growth at 18.7% (Fx adj.). The **Bepanthen/Bepanthol** line of skincare products additionally performed very well, with sales up advancing 12% (Fx adj.). Business in Bayer's Medical Care Division was hampered by the negative trend in the U.S. diabetes-care market (blood-glucose meters, etc.), where sales of the division declined 20.3 % (Fx adj.) due to price and volume reasons. On the other hand, the Animal Health Division "posted a very satisfactory trend, benefiting from a 14.6% (Fx adj.) increase in sales of the **Advantage** line of flea, tick and worm control products that was driven by gains in the United States."

For 2011, Bayer anticipates for its Consumer Health segment above-market sales growth after adjusting for currency and portfolio effects. Sales and EBITDA before special items are projected to rise by mid-single-digit percentages.

Bayer's Consumer Health segment primarily markets OTC products. The Consumer Care division is a leading player in the nonprescription-drug market. The Consumer Care product range includes the pain relievers **Aspirin** and Aleve as well as the dermatology products **Canesten** and Bepanthen/Bepanthol. Nutritionals include **Supradyn**, **One A Day**, **Berocca** and **Redoxon**; antacids; and cough-and-cold products.

According to Bayer, its Consumer Care division is the No. 2 OTC company worldwide. Based in Morristown, N.J., **Bayer Consumer Care** has operations in 140-plus countries. Formed in 1995, the division has benefitted from significant growth and development of its **Intendis** prescription dermatology business.

Intendis is an integrated pharma business with headquarters located in Berlin, Germany. As part of Bayer HealthCare, Intendis is committed to dermatology. The company is concentrated on the development and marketing of high-quality, innovative topical therapies targeted to treat skin disorders. Intendis' product portfolio consists of treatments for eczema disorders, including atopic dermatitis as well as psoriasis, acne, rosacea, hemorrhoids and fungal skin infections (mycoses).

Although the Consumer Care division's sales and distribution channels outside Europe are generally supermarket chains, drugstores and other large retailers, pharmacies are the usual distribution channel in Europe.

Bayer is considered one of the leading companies in the market for blood-glucose-monitoring devices. The company's Medical Care division offers user-friendly blood-glucose-monitoring devices such as the single-strip **Contour** system and the multi-strip **Breeze** system. Bayer additionally markets the Contour usb meter, which features integrated diabetes-management software and direct plug-in to computers, as well as the **A1CNow** system for determining long-term blood glucose control (A1c). Outside Europe, these products are mainly sold to consumers via pharmacies, drugstores, mass merchants, hospitals or wholesalers. In Europe, they are primarily sold through pharmacies.

Within the Medical Care segment, Bayer is the world's leading supplier of contrast-agent injection systems for diagnostic and therapeutic medical procedures in computed tomography, magnetic resonance imaging and molecular imaging as well as mechanical systems for remov-

Bayer's Best-Selling Consumer Health Products

Product	2010 € million	2009 € million	% Change	Fx adj. Change
Contour (Medical Care)	602	601	0.2	(4.5)
Aspirin* (Consumer Care)	418	400	4.5	0.2
Advantage product line (Animal Health)	408	336	21.4	14.6
Aleve/naproxen (Consumer Care)	273	217	25.8	18.7
Bepanthen/Bepanthol (Consumer Care)	212	186	14.0	12.0
Canesten (Consumer Care)	210	188	11.7	7.7
One A Day (Consumer Care)	178	153	16.3	10.0
Baytril (Animal Health)	166	149	11.4	5.8
Supradyn (Consumer Care)	138	136	1.5	0.7
Breeze (Medical Care)	125	138	(9.4)	(13.6)
Totals	2,730	2,504	9.0	4.2
Proportion of Consumer Health sales	45%	45%		

Notes: Fx adj. = currency-adjusted
** Total Aspirin sales = €776 million (2009: €715 million), including Aspirin Cardio, which is reflected in sales of the Pharmaceuticals segment.*
Source: Bayer

ing thrombi from blood vessels. Bayer offers service products for these systems. The products are marketed to cardiologists, radiologists and vascular surgeons in hospitals and out-patient clinical sites via a worldwide direct sales organization that is supplemented in some cases by local distributors.

The Animal Health division concentrates on the health of companion animals and livestock, for which bayer we provides pharmaceuticals and grooming products. The largest product line is **Advantix** and Advantage for the prevention and treatment of flea infestation in dogs and cats, followed by **Baytril** for the control of infectious diseases, **Drontal** and **Drontal Plus** wormers, and **Baycox** to treat pig coccidiosis.

Bayer Animal Health has leading positions in individual countries and product segments. Bayer is the world's No. 4 animal-health company based on sales. Depending on local regulatory frameworks, its animal-health products may be available to end users as prescribed by a veterinarian or prescription-free from veterinarians, pharmacies or retail stores.

In February 2011, Erica L. Mann was named president of Bayer Consumer Care. She additionally was appointed a member of the Bayer HealthCare executive committee. Ms. Mann join the company effective March 14, 2011. She most recently was president and general manager of Pfizer Nutritional Health, a worldwide business unit with operations in 80-plus countries.

Ms. Mann joined Pfizer upon its acquisition of Wyeth, where as senior VP of Nutrition she helped form the shape and strategic direction of that new business unit. As managing director of Wyeth Australia & New Zealand, she launched a range of significant medicines and nutritionals. Ms. Mann additionally steered Wyeth's Pharmaceutical business in South Africa for more than a decade as managing director and CEO. She holds the distinction of being the first female CEO of a pharma company in that country.

"Over the past 25 years, Ms. Mann has become noted in the industry for her strong record of delivering business results. Her outstanding experience and insights will drive Consumer Care to take advantage of the sustained growth forecast for the OTC market," according to Dr. Jorg Reinhardt, chairman of Bayer HealthCare's board of management and chairman of Bayer's HealthCare executive committee. "I am confident that she will continue to drive the exceptional growth experienced under the leadership of Gary Balkema, who has made the decision to retire after 16 years with Bayer at the end of March."

GASTROINTESTINAL DISORDERS

One of the most competitive therapeutic categories in the OTC product arena is gastrointestinal disorders. In late March 2010, the OTC heartburn-treatment category received another competitor: Zegerid OTC.

The Merck drug was approved by FDA in December 2009 and provides a unique alternative for the 50-plus million Americans suffering from frequent heartburn. Zegerid OTC is the only over-the-counter proton-pump inhibitor product with two active ingredients. The patented dual-ingredient formulation joins together a prescription-strength acid-reducing medicine (omeprazole) and a secondary ingredient (sodium bicarbonate) that enables efficient absorption.

Zegerid OTC capsule is available as its original 20-mg prescription-strength version. The prescription medicine has a significant six-plus year track record with physicians. The Rx brand is marketed by **Santarus** Inc., which is losing revenue for the product due to the availability of generic versions. **Par Pharmaceutical Companies** Inc. introduced a generic version of Zegerid Capsule during late June 2010. Other generic players have done the same, including privately-held, Cincinnati-based **Prasco** Laboratories.

Santarus reported that net product sales for Zegerid brand prescription products and sales of the authorized generic version of Zegerid Capsule totaled $11 million in third-quarter 2010. In comparison, net product sales were $31.5 million for Zegerid brand prescription products during July-September 2009. Before generic competition set in, yearly U.S. sales of Zegerid capsule amounted to about $195 million.

San Diego-based Santarus is a specialty biopharma company concentrated on acquiring, developing and commercializing proprietary products that address the needs of patients treated by physician specialists.

Woodcliff Lake, N.J.-based Par Pharmaceutical Companies develops, manufactures, markets and distributes high-quality pharmaceuticals via two divisions. **Par Pharmaceutical** Inc. of Spring Valley, N.Y., is the generic drug division. **Strativa** Pharmaceuticals Inc. of Woodcliff Lake is the proprietary products division.

On Sept. 24, 2010, **Perrigo** Co. announced a filing an Abbreviated New Drug Application (ANDA) with FDA for omeprazole 20mg/sodium bicarbonate 1,100mg. Also, the company provided prior notice of this filing to **Schering-Plough HealthCare** Products Inc., a subsidiary of Merck, and the Curators of the **University of Missouri**, the listed patent owner. Merck is the owner of the brand regulatory approval.

Four days earlier, Schering-Plough filed suit alleging patent infringement in the U.S. District Court of New Jersey to prevent Perrigo from proceeding with the commercialization of the product. This action formally started the process under the Hatch-Waxman Act. Santarus and the Curators of the University of Missouri, licensor and owner of the patents, were joined in the lawsuits as co-plaintiffs. In connection with litigation relating to Zegerid brand prescription products, the U.S. District Court for the District of Delaware ruled during April 2010 that the same patents that are the subject of the aforementioned action were invalid due to obviousness. An appeal of that decision was filed during May 2010, and the appeal reportedly is pending.

Perrigo's product is generically equivalent to Schering-Plough's Zegerid OTC (omeprazole 20 mg/sodium bicarbonate 1,100mg) antacid indicated for the treatment of frequent heartburn. Annual sales for the OTC brand are estimated to be about $60 million.

"This filing is an example of our focus on bringing new Rx-to-OTC switch products to market," said Joseph C. Papa, chairman and CEO of Perrigo. "It is a great addition to our diverse offering of gastrointestinal products."

Perrigo is a top worldwide healthcare supplier that develops, manufactures and distributes OTC and generic prescription pharmaceuticals, infant formulas, nutritional products, active pharmaceutical ingredients (API), as well as pharma and medical diagnostic products. Perrigo is the world's No. 1 store-brand manufacturer of OTC pharma products and infant formulas. The Allegan, Mich.-based company's primary markets and locations of

manufacturing and logistics operations are the United States, Israel, Mexico, the United Kingdom and Australia. Perrigo reported sales of $1.36 billion for the six-month period ended Dec. 25, 2010, compared to $1.11 billion year over year.

ALLERGIES

Perrigo is an active competitor in the allergy OTC market. On July 26, 2010, the company gained final U.S. approval to manufacture and market **OTC Cetirizine Cherry Syrup**, 1mg/ml. Shipments started during Perrigo's fiscal first-quarter 2011, which ended Sept. 25, 2010. Cherry joined Perrigo's already-available grape flavor cetirizine syrup in its product portfolio, giving patients a choice of flavors.

The product is marketed under store-brand labels and is comparable to McNeil Consumer Healthcare's **Zyrtec Children's Allergy Syrup**. That Pfizer brand is indicated for indoor and outdoor allergy relief. Brand sales for the Zyrtec line of products, which includes cherry syrup, were reportedly $580 million during the 52-week period ended July 4, 2010.

Zyrtec is not the only high-profile allergy OTC brand that has been targeted by Perrigo. During June 2010, the company acquired the exclusive U.S. store brand rights to sell and distribute OTC versions of **Fexofenadine** HCl 180 mg and 60-mg tabs, as well as Fexofenadine HCl 60 mg and **Pseudoephedrine** 120 mg tabs. These products represent the generic versions of **sanofi-aventis** SA's Allegra and Allegra D-12 products.

As of June 2010, the world's leading generic company **Teva** Pharmaceutical Industries Ltd. had Rx approval for these products. Teva and sanofi-aventis, one of the top pharma players globally, have settled their Paragraph IV/Hatch-Waxman litigation.

Allegra 180 mg, 60 mg, and Allegra D-12 are indicated for relieving symptoms associated with seasonal allergies. Sanofi-aventis applied to FDA for the Rx-to-OTC switch of these products. Before generic competition entered the Fexofenadine Rx market during 2005, Allegra 180 mg and 60 mg had joint yearly sales of $1.5 billion. For 2009, Allegra D-12 reportedly recorded sales of $600 million.

"This is another example of Perrigo's strategic focus on making quality healthcare more affordable to American consumers by introducing new Rx-to-OTC switch products," Mr. Papa said.

OTHER ACQUISITIONS

Perrigo announced on March 1, 2010, the singing of a definitive deal to acquire **Orion** Laboratories Pty. Ltd. for $48 million in cash. Located in Perth, Western Australia, the privately held company is a leading supplier of over-the-counter store-brand pharmaceuticals in Australia and New Zealand. Orion manufactures and distributes pharma products supplied to hospitals in Australia. The acquisition is expected to add $30-plus million in yearly sales and be accretive to Perrigo's earnings in the first year.

"The acquisition of Orion expands our global presence, complements our existing business and increases value for our shareholders," Mr. Papa commented. "By leveraging Orion's product pipeline and local marketing and distribution expertise, Perrigo is expanding its ability to meet the

world's growing need for quality, affordable healthcare."

Perrigo additionally confirmed on March 1, 2010, that it closed the previously announced sale of the Israeli Consumer Products business to **Emilia** Group on Feb. 26th, 2010. The proceeds from this divestiture were used to fund the strategic acquisition of Orion.

DOSING CONTROVERSY

During December 2010, controversial results were released from an **NYU** one-year research study on pediatric dosing instructions on liquid medication. The findings were revealed in the *Journal of the American Medical Association*'s December issue. A comprehensive review of 200 of the leading children's liquid medications found inconsistencies across all the medications, with many having a problem.

Under the direction of Dr. H. Shonna Yin, assistant professor of pediatrics at NYU School of Medicine, researchers found that one-quarter of the OTC liquid medications do not contain a dosing device like a cup, dropper, or dosing spoon for administering medication. "We also found that 99% had markings on the dosing device and directions on the label that do not match up exactly," according to Dr. Yin.

Cornell University in early 2010 reported gross inadequacy of dosing with a household spoon that conclusively leads to overdosing and underdosing. These finding came after FDA called for greater consistency in dosing during November 2009.

AccuDial Pharmaceutical Inc., the maker of **Children's AccuDial** pediatric medications, during 2007 recognized that children were not being accurately dosed. The widespread amount of parents that were unintentionally overdosing and underdosing their children, and arriving at all hours at hospital emergency rooms across the country, was reaching epidemic proportions.

As a result, AccuDial created a next-generation solution. The company developed the only patented rotating weight-based dosing system designed specifically to properly calculate and administer children's pediatric liquid medications. The product's dosing label dials in a child's weight in two-pound increments and shows the correct weight-based dose in milliliters (mL).

The medicine is then administered with an accurately calibrated dosing spoon in mL and ½ mL that is included in each package. AccuDial offers parents a foolproof method of minimizing dosing errors, with weight-specific dosing and a perfectly matched dosing spoon.

AccuDial is the industry leader in meeting the critical issue of inaccurate dosing of OTC children's medications. "Measuring dosages using a specific formula based on weight is standard practice among health care professionals such as doctors, nurses, and pharmacists," stated Bob Terwilliger, CEO of AccuDial, in December 2010. "Children's AccuDial is a game changer in the pharmaceutical industry with its line of eight children's medications, with weight-specific dosing, available in more than 4,000 pharmacies and stores across Canada. AccuDial expects to have products available in U.S. pharmacies next year."

AccuDial Pharmaceutical intends to change the way liquid medications will be dosed on a worldwide scale. AccuDial is the only brand with a patented rotating weight-based dosing system designed to administer OTC medications safely and effectively.

OTC COMPANIES REVIEW

THIS SECTION OF THE REPORT PROFILES IN ALPHABETICAL ORDER SOME OF THE WORLD'S LEADING COMPANIES AS WELL AS UP-AND-COMERS IN THE OTC ARENA; SOME COMPANIES WERE ALREADY DETAILED ON THE PRECEDING PAGES OF THIS REPORT.

AccuDial Pharmaceutical Inc.

AccuDial was formed in 2007 for the purpose of commercializing patented pediatric weight-based dosing products. With headquarters in Palm Beach, Fla., the company markets and sells its products in Canada, with plans to expand to the United States and Europe,

AccuDial reported net revenue of $125,324 for the fiscal year ended Sept. 30, 2010, its first revenue since the company's inception in 2007. Product development costs for 2010 totaled $462,170, increasing from $160,969 in 2009. Net loss increased from $1.9 million in 2009 to $5.8 million in 2010. The company recorded net loss per share of 13 cents in 2010, compared with net loss per share of 5 cents in 2009.

AccuDial launched eight OTC products in Canada during January 2010. These products include pediatric medications for pain & fever, allergy, and cough & cold. The company anticipated that Children's AccuDial would be available in 50% of Canadian pharmacies by the end of March. AccuDial's family of OTC products was approved by Health Canada in 2009.

To oversee Canadian operations of AccuDial products, Christopher Vounasis was named director of Canadian Sales & Marketing in June 2010. Mr. Vounasis joins the company from **PendoPharm**, the OTC division of **Pharmascience** Inc., one of the largest Canadian generic pharma manufacturers. His most recent position at PendoPharm was national sales manager, where he worked with retail outlets in Canada and expanded the sales force to achieve impressive growth.

The company announced in March 2010 that its initial financing, a private placement for 4 million shares at $1 per share, successfully closed.

quick facts

11300 U.S. Highway One
Suite 202
Palm Beach Gardens, FL 33408
Phone: 561-429-6886
Website: www.accuratedose.com
Year established: 2007

Some Key Products:
AccuDial for children's cough, cold and allergy symptoms

Bausch & Lomb Inc.

Bausch & Lomb is a multi-national company dedicated to bringing visionary ideas to eye health. With headquarters in Rochester, N.Y., Bausch & Lomb employs about 13,000 people and has products available in more than 100 countries.

The company markets a broad range of products such as contact lenses, lens-care solutions as well as prescription and over-the-counter pharmaceuticals.

Bausch & Lomb's OTC portfolio includes **Soothe and Soothe XP** eye drops to treat and prevent dry eye, **Ocuvite** vitamins to promote eye health, and **Renu** brand contact lens solution.

In March 2010, Bausch & Lomb relaunched **Renu Fresh multi-purpose contact solution**. The solution comes in a clear bottle, allowing consumers to see how much solution is remaining.

Bausch & Lomb launched **PreserVision Eye Vitamin and Mineral Supplement based** on the **AREDS 2** formula in the United States in April 2010. The product supplements omega-3 fatty acids, lutein and zeaxanthin, which studies show support eye health when included in a diet.

The company announced the U.S. launch of **Soothe Xtra Hydration lubricant eye drops** on May 4, 2010. Soothe Xtra Hydration moisturizes and restores the deficient aqueous and mucin layers of the tear film to provide lasting comfort. This eye product builds on the success of the Soothe XP protection formula to offer patients a comprehensive OTC portfolio for dry eye.

Months after their launch though, Bausch & Lomb initiated a voluntary recall for the Soothe Xtra Hydration drops beginning in January 2011. A small number of consumer reports citing the presence of possible foreign matter in the tips of the bottles led to the recall. The company recalled all lots of the product and informed the FDA of this voluntary recall. At the time of the recall, about 1.3 million bottles had been distributed in the United States.

In September 2010, Bausch & Lomb announced it completed acquisition of worldwide rights to assets and intellectual property for **Miochol-E** from affiliates of Novartis. Miochol-E is an injectable miotic pharmaceutical used during curtain eye surgeries to constrict the pupil. In the majority of worldwide markets there are only two injectable miotics available, of which Miochol-E is one.

In June 2010, Bausch & Lomb began searching for a buyer for its One Bausch & Lomb Place address in New York. The company will remain in Rochester, where it was founded 157 years ago. Bausch & Lomb only occupies five of the 20 floors of the building. The building will be sold with the assumption that Bausch & Lomb will remain a tenant in its current space.

Ideally, Bausch & Lomb will eventually transfer its corporate offices to the company's Optics Center, also located in Rochester.

quick facts

One Bausch & Lomb Place
Rochester, NY 14604
United States
Phone: 585-338-6000
Fax: 585-338-6007
Website: www.bausch.com
Year established: 1853
No. of employees: 13,000

Some Key Consumer-Health Products:
Soothe eye drops for dry eye
Ocuvite for eye health
Renu contact solution

Bayer AG

Bayer is a global enterprise with 108,700 employees working in the fields of health care, nutrition and high-tech materials. With headquarters in Germany, Bayer aims to create value through innovation, growth and high earning power.

Bayer experienced a 12.6% increase in sales for 2010, coming in at €35.09 billion compared with €31.17 billion for full-year 2009. Research and development expenses also grew, increasing from €2.75 billion for 2009 to €3.05 billion during 2010. Net income for full-year 2010 came in at €1.31 billion, versus €1.36 billion in the 2009 period. Earnings per share were €1.57 during 2010, down from €1.70 year over year.

Bayer's consumer-health segment, which chiefly offers non-prescription OTC products, generated total sales of €6.01 billion for 2010, up from €5.52 billion during 2009. The company's best selling OTC products include the Contour Meter, Aspirin and Aleve. Contour sales totaled €602 million in 2010, up 0.2% from 2009. Aspirin sales increased 4.5% from 2009 to €418 million for 2010. Aleve/naproxen sales increased 25.8% to €273 million.

In the Consumer Health segment for 2011, Bayer anticipates above-market growth in sales after adjusting for currency and portfolio effects. Sales and EBITDA before special items are projected to increase by mid-single-digit percentages.

Bayer's Consumer Health segment includes non-prescription medicines, dermatology products, blood-glucose meters, medical devices and its animal-health business. The goal of the Consumer Care Division is to build on its position in the worldwide OTC medicines market.

The division's strategy is intended to fully leverage the growth potential of proven brands such as Aspirin. Bayer is pursuing a clear course of expansion in fast-growing regions such as central and eastern Europe and Asia/Pacific. The company plans to additionally bolster its business in areas with growth potential.

Bayer Consumer Health intends to continue to take advantage of external growth opportunities in the form of strategically relevant acquisitions or in-licensing. One such growth opportunity is provided by the exclusive licensing deal with **Astra-**

quick facts

51368 Leverkusen
Germany
Phone: +49 214 30 1
Website: www.bayer.com
Year established: 1863
No. of employees: 108,700

Some Key OTC Products:
Contour Meter for insulin monitoring
Aspirin for pain relief
Aleve for pain relief

Zeneca Plc. for the marketing of omeprazole under the **Losec Pro**, **Antra** or **Mopralpro** trademarks as a nonprescription medication to treat heartburn. This product has been introduced in seven markets as of early 2011, and launches are planned in additional countries.

Bayer underwent a management change in April 2010 when Dr. Jörg Reinhardt was appointed CEO of Bayer HealthCare. Dr. Reinhardt, who replaced Arthur Higgins, was previously chief operating officer at Novartis AG.

On October 1, 2010, Werner Wenning handed over the chairmanship of the Bayer AG board to Dr. Marjin Dekkers. Mr. Wenning stepped down after 45 years of service with Bayer.

Commenting on his successor, Mr. Wenning said, "He is the right man in the right place at the right time. In these last nine months Mr.. Dekkers, you have seen and learned more about Bayer than some people do in 25 years with the company."

Gary Balkema, head of the Consumer Care Division, retired in March 2011. His successor is Erica L. Mann. Ms. Mann most recently served as president and general manager of Pfizer Nutritional Health, a worldwide business unit with operations in 80-plus countries. She was also a member of the Pfizer Senior Management Team.

Beiersdorf AG

Beiersdorf is a leading international skin and beauty-care company. Since its founding in 1882, Beiersdorf continually works to further strengthen consumer trust in its brands with more than 20,000 dedicated employees, outstanding research and development activities, and innovative products.

The company's total sales grew in 2010 to €6.19 billion compared with €5.75 billion for 2009. Global sales of **Nivea**, the company's largest brand, recorded organic growth of 1.8% for 2010. The brands **La Prairie** and **Eucerin** recorded growth of 7.5% and 5.9%, respectively.

Research and development expenses for 2010 were €152 million compared with €149 million in 2009. Net profit for 2010 totaled €326 million, down from €380 million during the year before. Earnings per share for 2010 also decreased, totaling €1.40 in 2010 compared with €1.65 in 2009.

For 2001, Beiersdorf will invest heavily in its skin and body-care brands. 2011 will be another year of transition in which Beiersdorf will systematically implement its updated strategy in the company and on the markets using its package of investments and measures.

On April 1, 2010, Barbara Saunier assumed the role of chief information officer of Beiersdorf. She succeeded Dr. Ernst Gadermann in the position, who retired in March 2010.

Effective May 1, 2010, the executive board of Beiersdorf was reorganized into three functional and three regional areas of responsibility. Thomas-B. Quaas remains chairman of the executive board, with Pieter Nota continuing to be responsible for Marketing and Innovation. Dr. Bernhard Düttmann remains in charge of finance as well as taking on the Human Resources portfolio. Markus Pinger takes charge of the Americas region as well as continuing in charge of the global supply chain. James C. Wei is heading up the Asia region, with Peter Feld named for the Europe region.

Beiersdorf expanded its global presence by establishing **Beiersdorf Vietnam Limited** in November 2010. With this affiliate, Beiersdorf has laid the groundwork for further growth in Southeast Asia and meeting the rising demand for skin care in Vietnam.

In December 2010, Beiersdorf sold its selective skin-care brand **Juvena** and its premium hair-care brand **Marlies Möller** to **Troll Cosmetics** GmbH in Austria. Financial details of the transaction were not disclosed. This move is in line with Beiersdorf's "Focus on Skin Care. Closer to Markets." strategy, which puts the focus on a small number of global skin-care brands. "Selling the two brands will allow Beiersdorf to focus its resources within the selective market on developing La Prairie, the global premium skin-care brand," said Thomas-B. Quaas, chairman of the executive board of Beiersdorf.

quick facts

Unnastraße 48
D-20245 Hamburg
Germany
Phone: +49 40 4909 0
Fax: +49 40 4909 3434
Website: www.beiersdorf.com
Year established: 1882
No. of employees: 20,525

Some Key Products:
Nivea
La Prairie
Eucerin

Boehringer Ingelheim GmbH

Boehringer Ingelheim is a global group of companies with over 41,000 employees operating in two main business areas: Human Pharmaceuticals and Animal Health. The Human Pharmaceuticals segment is further broken down into Prescription Medicines, Consumer Health Care, Biopharmaceuticals and Operations.

The company reported net sales of €12.7 billion ($17.7 billion) in 2009, up from €11.6 billion ($16.2 billion) in 2008. Net income for 2009 totaled €1.8 billion ($2.5 billion), increasing from €1.4 billion ($2 billion) in 2008. Research and development costs were €2.2 billion ($3.1 billion) in 2009 compared with €2.1 billion ($2.9 billion) in 2008.

Boehringer's Consumer Health Business is a core business segment, contributing 10% to total net sales. In 2009, the self-medication business had net sales of €1.3 billion ($1.8 billion). The consumer-care segment concentrates on nine core brands including **Antistax**, **Binsolvon**, **Dulcolax** and **Zantac**.

In February 2010, Boehringer announced its intention to acquire all outstanding shares in **SSP** Co. Ltd., a Japanese subsidiary. A tender offer was issued by **Boehringer Ingelheim Japan Investment GK** (BIJI), a newly established Japanese company established for this purpose. As of April 13, 2010, 93.8% of out-

standing shares were tendered for total consideration of €611 million. SSP can expect benefits in new product development. Boehringer will be able to enhance its global Consumer Health Care business by sharing knowledge on Japanese consumers, skills and know-how on marketing and relationship management.

Boehringer inaugurated "module 2" of its new inhaler factory in September 2010. The new 12,000-square-meter building doubles the company's production capacity for **Respimat** inhalation devices to 20 million. The Respimat Soft Inhaler is a highly efficient device that delivers medication for the treatment of respiratory diseases. In 2010, Respimat was launched in 20 countries with a pharmaceutical for the treatment of chronic obstructive pulmonary disease.

The development of the investigational compound **flibanserin** was discontinued in October 2010. The company continues to believe in the value of the product, which was intended for the treatment of Hypoactive Sexual Desire Disorder (HSDD). The response of authorities as well as the complexity and extent of further questions to be addressed to achieve registration of flibanserin impacted the company's decision to focus on other pipeline products.

"The decision was not made lightly, considering the advanced stage of development," said Professor Andreas Barner, chairman of the board of managing directors and responsible for the corporate board division Pharma Research, Development and Medicine. "We remain convinced of the positive benefit-risk ratio of flibanserin for women suffering with HSDD."

In early 2011, Boehringer and **Eli Lilly** and Co. announced an agreement to jointly develop and commercialize a portfolio of diabetes compounds. Under the terms of the agreement, Lilly will make an initial one-time payment to Boehringer Ingelheim of €300 million. Boehringer Ingelheim is eligible to receive up to a total of €625 million in success-based regulatory milestones for **linagliptin** and **BI10773**. Lilly is eligible to receive up to a total of $650 million in success-based regulatory milestones on its two basal insulin analogues. Should Boehringer Ingelheim elect to opt-in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, Lilly would be eligible for up to $525 million in opt-in and success-based regulatory milestone payments. The companies will share continuing development costs equally.

Upon successful regulatory approval of any product resulting from the alliance, the companies will equally share in the product's commercialization costs and gross margin. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration.

Also in January 2011, Boehringer announced an agreement under which the company will acquire the rights in substantially all assets at Amgen's development and manufacturing facility in Fremont, Calif. The agreement was expected to close in March 2011.

The Fremont facility is a state-of-the-art 100,000-square-foot manufacturing facility with pilot plant and process development labs. The site currently has about 360 employees.

quick facts

Binger Strasse 173
55216 Ingelheim am Rhein
Germany
Phone: +49 6132 77 0
Fax: +49 6132 72 0
Website:
www.boehringer-ingelheim.com
Year established: 1885
No. of employees: 41,534

Key Consumer-Health Products:
Antistax for leg health issues
Binsolvon for cough symptoms
Dulcolax for intestinal irregularity
Zantac for heartburn

C.B. Fleet Co.

Since 1869, C.B. Fleet has spread its reach around the globe, never forgetting its heritage as a hometown family-run business. The company offers products in feminine care, gastro care, skin care, oral rehydration, and oral care.

Fleet named Jeffrey Rowan as its new president and CEO. Mr. Rowan previously served as Fleet's chief operating officer. He succeeded Douglas Bellaire, who led the company from 1996. Mr. Bellaire now serves as the vice chairman of the company's board of directors.

"I'm very optimistic about the future of Fleet Laboratories," according to Mr. Rowan. "We've been placing focus on improving organizational efficiency and strategic alignment, in preparation for our next phase of expansion in the U.S. and abroad. We anticipate growth will come from both our existing brand portfolio, as well as potential acquisitions of businesses in strategically important markets."

In March 2010, Fleet launched **Fleet Naturals Cleansing Enema**, the first enema designed for elective cleansing for men and women. Fleet Naturals is clinically tested and doctor recommended. The product is drug free and fragrance free.

On August 24, 2010, Fleet selected Dallas-based **The Richards Group** as the company's agency of record. The Richards Group is responsible for brand planning, creative development, digital design, public relations, and media buying and planning for Fleets **Summer's Eve** brand of feminine-care products and gastro-care products.

The Richards Group is the largest independent branding agency in the United States. Its clients include Amstel Light, Bridgestone, Chick-fil-A, Firestone, and The Home Depot. Total billings for the agency in 2009 amounted to $1.28 billion.

quick facts

4615 Murray Place
Lynchburg, VA 24502
United States
Phone: 434-528-4000
Website: www.cbfleet.com
Year Established: 1869

Key Products:
Fleet Laxatives for constipation
Clinomyn Toothpaste for oral care
Vera Lotion for skin care

Cardium Therapeutics Inc.

Cardium Therapeutics is a medical-technology company focused primarily on the development and commercialization of medical devices and novel therapeutics for cardiovascular and ischemic disease, wound healing and tissue repair. The company's innovative pipeline is divided into two units, **Cardium Biologics** and **Tissue Repair** Co.

The company reported no revenue for the nine-month period ended Sept. 30, 2010. Research and development costs for the period totaled $1.9 billion, dropping from $3.5 billion for the first nine months of 2009. The company reported a net loss of $5.2 million for the first three quarters of 2009, compared with a net loss of $21 million for the same 2009 period. Loss per share for the first three quarters of 2010 totaled 7 cents, compared with 44 cents for the same time frame in 2009.

In June 2010, Cardium and **Devro** Medical Ltd. entered into a multi-year supply agreement for highly-refined fibrillar bovine Type I collagen. Under the agreement, the collagen component of **Excellegan** will be manufactured at Devro's new cGMP facility.

Cardium and **BioZone** Laboratories Inc. entered into a co-development and strategic licensing agreement in November 2010 for the formulation, manufacture and licensing of up to 20 advanced skin care formulations and other products for Cardium's **MedPodium** line. Under the agreement, Cardium is identifying a line of products applying BioZone technology incorporated into its **QuSome**, **Inflacin**, **LipCeutical**, **LipSpra** and other formulation and delivery technologies. Cardium will receive a royalty-free license for a portfolio of 20 products selected by Cardium using BioZone technology. In exchange, Cardium will pay $1 million through the issuance of shares of its common stock.

Early in 2010, Cardium received a letter from the American Stock Exchange indicating that the company had become noncompliant in regard to certain listing requirements. The company was not delisted, but instead afforded an opportunity to submit a supplement to the initial compliance plan in which Cardium Therapeutics would establish its compliance by June 2010.

In March 2010, Cardium announced that its listing compliance plan had been accepted by NYSE AMEX LLC, formerly the American Stock Exchange. The exchange then notified Cardium that, based on the information provided by the company, Cardium had made a reasonable demonstration of its ability to regain compliance. The company received a letter on July 7, 2010, stating that it had resolved all matters relating to Cardium's exchange listing compliance.

Cardium launched **Linee**, a dietary supplement used to manage weight loss, to its MedPodium line in November 2010. The product is intended to be taken before meals to help manage appetite and control hunger as part of a comprehensive weight management program.

quick facts

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Suite 250
San Diego, CA 92130
United States
Phone: 858-436-1000
Fax: 858-436-1001
Website: www.cardiumthx.com
No. of employees: 13

Some Key Products:
Excellagen for tissue repair
MedPodium wellness products

Colgate-Palmolive Co.

Colgate-Palmolive seeks to deliver strong, consistent business results by providing consumers on a global basis with products to make their lives healthier and more enjoyable. The company focuses on Oral, Personal and Home care as well as pet nutrition, offering products in more than 200 countries.

Colgate-Palmolive recorded net sales of $11.6 billion for the nine-month period ended Sept. 30, 2010, compared with $11.2 billion for the same period in 2009. Net income for the 2010 period was $1.6 billion, a slight decrease from $1.7 billion in the first nine months of 2009. Earnings per share dropped from $3.16 for the first three quarters of 2009 to $3.07 in the 2010 same time frame.

Net sales in the Oral, Personal and Home care segment were $10.1 billion for January-September, up 4% from the first three quarters of 2009.

Colgate-Palmolive introduced its **Colgate Proclinical** toothpaste in March 2010. This toothpaste contains professional formulas that allow consumers to achieve a whiter smile with professionally inspired formulas from the comfort of their home. The product comes in three variations: Daily Whitening, Daily Cleaning and Daily Renewal.

In December 2010, Stephen C. Patrick stepped down as chief financial officer after 14 years in the position. Dennis Hickey, previously the company's corporate controller, was appointed to the role of CFO beginning on Jan. 1, 2011.

"Colgate has greatly benefited from Steve's outstanding financial leadership," commented CEO Ian Cook on the change, "His strategic insights, keen financial understanding and vast Colgate knowledge have helped us advance our key financial performance measures to world-class levels. We look forward to Dennis' financial leadership as CFO, utilizing his 33 years of Colgate experience and his proven capabilities as a financial leader."

quick facts

300 Park Ave.
New York, NY 10022
United States
Phone: 212-310-2575
Website: www.colgate.com
Year established: 1993
No. of employees: 38,100

Some Key Products:
Colgate Orabase for canker-sore pain
Peroxyl Rinse for canker sores
Phos-Flur Rinse for cavity prevention

Galderma SA

Galderma is a 50:50 joint venture between **L'Oreal** and **Nestlé** SA. Galderma is focused on dermatological products for several skin conditions such as acne, rosacea, psoriasis and melasma. The Swiss company distributes 11 major brands in 70-plus countries.

Nestlé reported its 2010 Pharma sales totaled CHF 6 billion. All Nestlé constituents, including Galderma, reportedly performed well in 2010. L'Oreal reported Galderma achieved record sales in 2010, with a like-for-like increase of 16.1% (and 23% based on reported figures).

On Sept. 14, 2010, Galderma launched **Cetaphil Restoraderm**, a product formulated specifically for the needs of eczema and atopic dermatitis skin. Both Cetaphil Restoraderm Skin Restoring Body Wash and Skin Restoring Moisturizer soothe itching associated with these diseases and enhance the skin's ability to restore hydration and repair the epidermal barrier.

In January 2011, Galderma launched **Emerval**, a complete range of nine scientifically advanced and clinically proven hyaluronic acid dermal fillers. Commercialization of the product, indicated for the treatment of facial lines, contouring and volume loss, is scheduled for 2011 in the United Kingdom, France, Germany, Italy, Spain, Brazil and Argentina.

Galderma launched a bid for the Swedish company **Q-Med** in December 2010. Galderma believes the acquisition of Q-Med will enable the company to accelerate its development in the highly dynamic segment of corrective and aesthetic dermatology, which Q-Med specializes in. As of Feb. 10, 2011, 77.79% of Q-Med shareholders supported the deal, leading to an extension on the offer of 15 days and an increase in the offer to SEK79 per share.

quick facts

World Trade Center
Avenue de Gratta-Paille 1
Lausanne, 1000
Switzerland
Phone: +41 21 642 78 00
Fax: +41 21 642 78 01
Website: www.galderma.com
No. of employees: 3,000

Some Key Products:
Benzac for the treatment of acne
Nutraderm for dry skin
Cetaphil for skin care and protection

GelStat Corp.

GelStat is a consumer-healthcare company dedicated to cost-effective development and marketing of OTC and other non-prescription consumer healthcare products. The company markets **GelStat Migraine** and **GelStat Sleep Aid**. GelStat believes that its current and planned products will potentially offer consumers improved efficacy, safety and/or convenience relative to existing products.

GelStat's products have innovative formulations joined with uniquely advantageous delivery systems. Thess combinations provide consumers with clinically proven products that have improved efficacy, safety and convenience. In line with this strategy, two clinical studies have been carried out with GelStat Migraine, each yielding positive results.

The company reported net revenue of $35,181 for the nine-month period ended Sept. 30, 2010, compared with $41,532 for the same 2009 period. Net loss for the January-September 2010 period came in at $285,478 and the company reported a loss per share of 0.01 cent.

Gelstat's third product, **GelStat Arthritis**, is fully developed. The company expects the product to reach the marketplace during the first half of 2011.

quick facts

3557 SW Corporate Parkway
Palm City, FL 34990
United States
Phone: 772-283-0020
Fax: 772-219-3579
Website: www.gelstatmigraine.com

Key Products:
GelStat Migraine for migraine pain relief
GelStat Sleep Aid sleep supplement

GlaxoSmithKline Plc.

GlaxoSmithKline is an industry leader with an estimated 7% of the world's pharmaceutical market. GSK, with headquarters in the United Kingdom and operations in the United States, is one of the few pharmaceutical companies researching medicines and vaccines for the World Health Organization's three priority disease: HIV/AIDS, Tuberculosis and Malaria.

GSK's sales for 2010 totaled $44 billion, down from $44.4 billion in 2009. Research and development costs amounted to $6.9 billion in 2010, compared with $6.4 billion in 2009. Net profit for the year fell from $8.9 billion in 2009 to $2.9 billion in 2010. Earnings per share also fell in 2010 to 49 cents from $1.69 during the previous year.

GSK's OTC products accounted for $3.8 billion in sales during 2010, slightly increasing from $3.6 billion in 2009.

During 2010, GSK's **Avandia**, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, came under scrutiny in the United States and Europe. The drug was alleged to increase ischemic cardiovascular issues or cause myocardial ischemic events. GSK rejected those allegations as well as any suggestion that there was a lack of publicly available clinical-trials results related to Avandia for independent scientific scrutiny.

Both the U.S. and European regulatory agencies conducted reviews of the benefit-risk profile of Avandia. As a result of these reviews, the European Medicines Agency suspended the marketing authorizations for Avandia and all related products containing its active ingredient rosiglitazone maleate. The EMA said this suspension will remain in place until convincing data is provided that identify a group of patients

in whom the benefits of the medicine outweigh its risks.

In the United States, Avandia and all rosiglitazone-containing products remain available with additional safety labelling and restrictions for use. The FDA also requires a Risk Evaluation and Mitigation Strategy (REMS) program with additional measures to ensure the safe use of the medicine.

In July 2010, GlaxoSmithKline finalized an agreement for and **Aptuit** Inc. to acquire operations at GSK's Medicines Research Center in Verona, Italy. Under the agreement, Aptuit retains the facility's 500-member staff, and gains their scientific expertise and knowledge. Financial terms of the agreement were not disclosed.

Another of GSK's research centers was acquired in September 2010, when GlaxoSmithKline and **Galapagos** reached an agreement for a state-of the-art research center in Zagreb, Croatia. Under the agreement, Galapagos received the center along with its 130 staff. Galapagos will also provide GSK R&D services under a three year fee-for-fee service contract to the value of $14 million.

In June 2010, GSK and **Medivir** announced an exclusive agreement to commercial the cold-sore treatment **Xerclear** (acyclovir and hydrocortisone) for over-the-counter use in key global markets. Under the terms of the agreement, GSK gained exclusive rights to commercialize and distribute Xerclear as part of the **Zovirax** franchise. The agreement includes Europe, Russia, Japan, India, Australia and New Zealand, and excludes North and South America, China, South Korea and Israel.

GSK assumes responsibility for funding continuing and future development of Xerclear in all included territories. GSK also is responsible for a $3 million up-front and pre-launch milestones and up to double-digit royalties on sales to Medivir.

GSK acquired **Nanjing MeiRui** Pharma Co. Ltd. (MeiRui) in December 2010. The company paid a cash consideration of $70 million. This move is intended to further expand GSK's presence in China, one of the fastest-growing and most significant of the emerging markets.

GlaxoSmithKline announced the appointment of Philippe Fauchet as president of GSK Japan in February 2010. Mr. Fauchet previously worked at sanofi-aventis, where he served as senior VP of business development.

In March 2010, GSK announced a succession plan for the Consumer Healthcare division in which Emma Walmsley was appointed president of Consumer Healthcare Europe and president designate, Worldwide Consumer Healthcare. Ms. Walmsley replaced Manfred Scheske in Europe, and will replace John Clark as president of Worldwide Consumer Healthcare within two years.

Another succession plan was announced in September 2010 to replace Chief Financial Officer Julian Heslop, who is retiring from the company at the end of March 2011. Mr. Heslop will be replaced by Simon Digemans, who was appointed chief financial officer designate in January 2011.

quick facts

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United Kingdom
Phone: +44 208 047 5000
Fax: +44 208 047 7897
Website: http://www.gsk.com
Year established: 2000
No. of employees: 13,500

Some Key OTC Products:
Tums for heartburn relief
Stanback for pain relief
Abreva for cold sores

Hisamitsu Pharmaceutical Inc.

Founded in 1847, Hisamitsu is a leading company in the field of drugs for external use, actively seeking to enhance people's health via the provision of pharma products, particularly pain-relieving patches.

The company reported sales of ¥102.6 billion ($1.3 billion) for the nine-month period ended Oct. 31, 2010. This represents a 4.3% increase over the same period ended in October 2009. Research and development costs rose 48.2% to ¥9.5 billion ($116.2 million) for the nine-month period ended in October 2010. The company's net profit for the first three quarters of the October 2010-ended period totaled ¥16.7 billion.

Hisamitsu's OTC business reported sales of ¥14.2 billion ($204.2 million) for the first three quarters of fiscal 2010, representing a decrease of 12.4 %. The company attributes this decrease in sales to market reduction around the world.

Several OTC products saw a decrease in sales. **Salonpas** sales dropped 9.5% to ¥4.6 billion ($56.2 million) for the first three quarters of 2010. **Feitas** product sales dropped to ¥2.9 billion ($35.5 million), a decrease of 8.4 %. **Salonship** product sales totaled ¥2.6 billion ($31.8million) and **Butena** rock products totaled ¥1.1 billion ($13.5 million), a decrease of 12.8% and 11.9%, respectively. **Air Salonpas** products posted a positive gain in sales, increasing 7.8% to ¥1.5 billion ($18.3 billion).

Hisamitsu launched its **Fentanyl Transdermal System** in the United States in March 2010. The product, which was approved by FDA in October 2009, is indicated for the management of chronic pain. The product was launched by **Apotex** Corp., Hisamitsu's exclusive distributor for the product in the United States.

In April 2010, Hisamitsu received marketing approval of **Fentos Tape**, a transdermal long-acting cancer-relief pain patch. The product is jointly marketed with **Kyowa Hakko Kirin** Co. Ltd. This patch has drug-release properties suitable for a single daily application. Since Fentos has a clinical advantage of allowing easier adherence to the basic principles of opioid analgesics ("by the clock") that require evaluation of pain and observation of the presence of adverse reactions every 24 hours, and scheduled ad-

quick facts

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Japan
Phone: +81 3 5293 1720
Fax: +81 3 5293 1724
Website: www.hisamitsu.co.jp
Year established: 1847
No. of employees: 2,600

Some Key OTC Products:
Salonpas for pain relief
Keplat Patch for pain relief

ministration at a predetermined time of the day, it is expected to exert stable and sustained analgesic effects.

In May 2010, Hisamitsu applied to have its stock delisted from the Osaka Stock Exchange. The company cited the small volume of stock being traded on the Osaka Stock Exchange as the reason for the application. It expects the delisting to have no effect on shareholders. Hisamitsu continues to trade on the Tokyo, Nagoya and Fukuoka Stock Exchanges.

Johnson & Johnson

Johnson & Johnson is a manufacturer of healthcare products as well as a provider of related services for the consumer, pharmaceutical, medical devices, and diagnostics markets. J&J employs more than 115,000 employees in consumer products, medical devices and diagnostics, and prescription products.

The company reported sales of $61.59 billion for 2010, down 0.5% versus 2009. Research expenses amounted to $6.84 billion during 2010, representing a 2% decrease compared to 2009. Overall net income for 2010 was $13.33 billion, increasing 8.7% from the year-before amount. Diluted earnings per share increased from $4.40 in 2009 to $4.78 in 2010.

J&J's global Consumer sales totaled $14.6 billion for 2010 represented – down 7.7% versus 2009 – consisting of an operational 8.9% decrease and a positive currency impact of 1.2%. Domestic sales in 2010 dropped 19.3%. International sales increased 1.2% versus 2009, reflecting an operational 1% decrease and a 2.2% positive currency impact.

In January 2010, J&J company McNeil-PPC announced that its Consumer Healthcare Division was voluntarily recalling certain OTC products in the Americas, the United Arab Emirates, and Fiji. The recall came following an investigation of consumer reports of an unusual odor that was associated with temporary and non-serious gastrointestinal events. These events include nausea, stomach pain, vomiting or diarrhea. Brands included in the recall include **Children's Motrin**, **Motrin IB**, various strengths of Tylenol, Benadryl, Rolaids, **Simply Sleep** and **St. Joseph Aspirin**.

McNeil followed up this recall in June 2010 with a recall of five additional product lots. The involved lots included four product lots of **Benadryl Allergy Ultratab Tablets** and one lot of **Extra Strength Tylenol**. These products were omitted from the original recall. Another 21 more lots of medicines related to the January 2010 issue of a moldy odor were recalled in July 2010.

An additional product lot of **Tylenol 8 hours caplets** sold in the United States and Puerto Rico was recalled during October 2010.

As a result of the recalls, McNeil announced in June 2010 that it did not anticipate having sources of supply before the end of the year at its Fort Washington, Pa., manufacturing facility. Operations at the facility were suspended as a result of the recall, and the company has conducting a comprehensive quality assessment across its manufacturing operations. McNeil identified corrective actions that will be implemented before manufacturing resumes at the Fort Washington plant.

McNeil initiated another voluntary recall in April 2010, this time focusing on certain Children's and infant's liquid products manufactured in the United States that are distributed in the United States, Canada, Dominican Republic, UAE, Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad & Tobago and Kuwait. The recall was initiated because some of the products may not meet quality standards. Brands included in the recall are **Tylenol Infant Drops**, **Children's Tylenol**, Children's Motrin, **Children's Zyrtec** and Children's Benadryl.

In December 2010, McNeil initiated a voluntary recall of all lots of **Rolaids Extra Strength Softchews**, **Rolaids Extra Strength plus Gas Softchews** and **Rolaids Multi-Symptom plus Anti-Gas Softchews.** The recall was initiated following consumer reports of foreign materials in the products, such as metal and wood particles. These particles may have been introduced into the products during the manufacturing process at a third-party manufacturer.

In January 2011, McNeil Consumer Healthcare initiated a wholesale product recall of certain product lots produced at the Fort Washington facility before operations were suspended. The recall is a precautionary measure after a review of the facility found instances where equipment-cleaning procedures were insufficient or cleaning was not adequately documented.

Following this last recall, J&J announced that McNeil Consumer Healthcare completed its internal assessment of its manufacturing standards and processes. The assessment was part of a commitment made by McNeil to restore its operations to the level of quality and compliance expected by all Johnson & Johnson companies. McNeil thoroughly reviewed historical records as far back as 2007, investigating products sold in the United States and produced in McNeil's internal manufacturing network. McNeil examined whether the right processes had been identified and followed, and evaluated whether quality standards had been met.

McNeil identified several areas for improvement, such as instances where equipment-cleaning procedures were insufficient or cleaning was not adequately documented. McNeil also discovered a product for which the labeling did not all required information.

"Steps we have taken under the Comprehensive Action Plan constitute an uncompromising and systematic effort to review quality and manufacturing practices at McNeil," Mr. Weldon said. "They help us assure that moving forward, any of our products in the marketplace live up to the trusted standards and expectations that consumers have for all products coming from a Johnson & Johnson company, anywhere in the world."

McNeil is additionally carrying out as-

quick facts

One Johnson & Johnson Plaza
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United States
Phone: 732-524-0400
Fax: 732-524-6735
Website: www.jnj.com
Year established: 1887
No. of employees: 115,500

Some Key OTC Products:
Tylenol for pain relief
Mylanta for heartburn and indigestion
Benadryl for allergy symptoms

sessments at additional manufacturing locations.

During March 2010, Johnson & Johnson Consumer Companies unveiled the Cytomimic Technology at the 68th annual meeting of the American Academy of Dermatology. Cytomimic is a proprietary technology that combines essential minerals to deliver biological levels of electric signals similar to the skin's natural bioelectricity. The technology is intended to rejuvenate, repair and renew skin. Clinical studies demonstrate improvement of the skin's appearance starting within minutes of application and continued improvements over time.

Matrixx Initiatives Inc.

Matrixx is a high-growth over-the-counter health-care company that markets and sells products with am emphasis on those that use unique and novel delivery systems. Matrixx sells products under the **Zicram** brand through various subsidiaries.

Net sales for the nine-month period ended Dec. 31, 2010. were $44.8 million, a 27% decrease from $61 million for the same period in 2009. This decrease in sales is mainly attributable to the higher inventory positions retailers maintained associated with the H1N1 flu outbreak. Research and development costs amounted to $1.2 million for April-December 2010, versus $1.9 million for the last three quarters of calendar-year 2009. Matrixx reported a net loss of $8.4 million for the first nine months of its fiscal 2011, compared to a net loss of $13.9 million for the same period in fiscal 2011. Net loss per share totaled 91 cents for the nine month period ended Dec. 31, 2010, compared with a net loss of $1.51 for the same 2009 period.

On Dec. 14, 2010, Matrixx entered into an agreement with **Wonder Holdings Acquisition** Corp. and **Wonder Holdings** Inc., both affiliates of **H.I.G.** Capital LLC. Under the merger, H.I.G.'s affiliates commenced a tender offer to purchase for cash all of the outstanding shares of Matrixx common stock, including the associated preferred stock purchase rights, at a price of $8.00 per share. Pursuant to the terms of the merger, Matrixx solicited alternate acquisition proposals until Jan. 22, 2011. As of that date, despite interest from 132 parties, Matrixx received no other offers. As a result, Matrixx may not encourage or solicit proposals from third parties.

On Feb. 2, 2011, the purchaser increased the price to $8.75 per share and extended the expiration of the offer until Feb. 14, 2011, at 11:59 p.m. The company's board of directors unanimously approved the merger agreement and resolved to recommend that Matrixx stockholders accept the offer, tender their shares in connection with the offer, and approve and adopt the merger agreement.

In May 2010, Matrixx appointed William J. Barba as VP of finance and accounting. Mr. Barba previously served as the company's treasurer and director of plannin, since July 2007.

quick facts

8515 E. Anderson Drive
Scottsdale, AZ 85255
United States
Phone: 602-385-8888
Website: www.matrixxinc.com
Year established: 1991
No. of employees: 29

Some Key Products:
Zicam for cough and cold symptoms

Merck & Co.

Merck is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in more than 20 therapeutic categories.

The company reported total sales of $46 billion for 2010, increasing from $27.4 billion in fiscal 2009. Research and development costs also increased, totaling $10.9 billion in 2010 compared with $5.8 billion in 2009. Earnings per share dropped in 2010 to 28 cents, down from $5.65 in 2010. The significant differences between 2010 and 2009 are due to the Schering-Plough acquisition.

Management expects full-year 2011 revenue to grow in the low to mid-single digit percent range versus 2010. For 2011, Merck is targeting full year non-GAAP EPS in the range of $3.64 to $3.76, excluding certain items, and a GAAP EPS range of $2.05 to $2.33. The 2011 non-GAAP EPS range does not include purchase accounting adjustments, restructuring and merger-related costs.

Merck's Consumer Care sales rose from $149 million in 2009 to $1.3 billion in 2010, greatly benefitting form the Schering-Plough deal. Strong performances came from key OTC brands, including the Schering-Plough products Dr. Scholl's and Coppertone. With Schering-Plough, Merck's revamped Consumer Care segment includes footcare and suncare consumer products as well as various over-the-counter medicines.

Merck announced on April 1, 2010, that Zegerid OTC is available in drug stores, grocery stores, mass merchandisers and club shores nationwide. Zegerid OTC is a new over-the-counter option for treating frequent heart burn without the need for a prescription. Zegerid OTC, originally approved for over-the-counter use in 2009, is available in the original 20-mg prescription strength formula. Zegerid OTC is a 14-

quick facts

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P.O. Box 100
Whitehouse Station, NJ 08889
United States
Phone: 908-423-1000
Website: www.matrixxinc.com
Year established: 1891
No. of employees: 100,000

Some Key OTC Products:
Claritin for seasonal allergy symptoms
Zegerid OTC for heartburn
Dr. Scholl's for foot care and pain relief

day treatment course taken once a day to treat frequent heartburn as directed.

In February 2010, Merck announced the appointment of Bridgette P. Heller as executive VP and president of Merck's consumer health business. Ms. Heller replaced Stanley F. Barshay who postponed his retirement to help with the Schering-Plough transition period.

As leader of Merck's consumer healthcare business, Ms. Heller is leveraging the company's consumer products brands to capitalize on new growth opportunities. This includes expanding the consumer business in markets outside the United States. Merck's consumer health division includes **Afrin**, Claritin, Coppertone, Dr. Scholl's and **Lotrimin**, among others.

Merck announced additional senior management appointments during April 2010. Kenneth C. Frazier was elected as president of Merck, moving from his position as president of Global Human Health. Adam H. Schechter replaced Mr. Frazier as the president of Global Human Health.

Effective Jan. 1, 2011, Mr. Frazier also became CEO of Merck. He succeeded Richard T. Clark, who had served as CEO since 2005 and continues as board chairman. Mr. Clark additionally was president of Merck before Mr. Frazier took over duing 2010. According to Merck, these changes are the result of a long-term, thoughtful succession planning process led by Mr. Clark and the board of directors.

Merck launched its Dr. Scholl's Custom Fit Orthotic Centers nationwide in July 2010. These kiosks use FootMapping Technology to measure arch type and recommend the most appropriate Custom Fit Orthotic. Dr. Scholl's Custom Orthotics provide all-day relief of tired, achy feet, eliminating foot discomfort immediately.

Nycomed International Management GmbH

Nycomed is a privately owned global pharmaceutical company with headquarters in Zurich, Switzerland, The company has affiliates in more than 50 countries and employs 12,000 associates worldwide. The company ranks 28th among global pharmaceutical companies and is the 16th largest provider of OTC products.

Nycomed reported net sales of €3.17 billion for 2010, compared with €3.23 billion in 2009. Research and development expenses for 2010 totaled €212.2 million, decreasing from €198.6 million in 2009. The company recorded a net loss of €229.1 million during 2010, compared with a net profit of €232.7 million in 2009.

Net turnover for OTC in 2010 was €372.9 million, an 8.7% increase over €343.2 million in 2009. This acceleration is driven mainly by sustained double-digit growth in emerging markets, primarily Latin America and Russia, and strong performance of Nycomed's OTC focus areas of gastroenterology and respiratory.

In September 2010, the joint venture company **Zydus Nycomed** (between **Zydus Cadila** and Nycomed), commissioned its pharmaceutical ingredient manufacturing facility at Navi Mumbai. India The plant initially is manufacturing Pantoprazole, **Urapidil** and **Lornoxicam**. The company will be producing eight APIs at the plant by 2011. The plant's manufacturing of Pantoprazole, Nycomed's key product for acid-related gastrointestinal disease, makes the company one of the largest end-to-end manufacturers of that API in India.

On November 1, 2010, Nycomed announced that it had acquired 51.34% of **Guangdong Techpool** Bio-Pharma Co. Ltd. This move significantly expands its presence in China. **Shanghai Pharmaceutical** Group holds 40.8% of the shares. As the majority owner, Nycomed plans to fully consolidate the business moving forward. Nycomed and Techpool will continue to expand their footprint in China, concentrating on five main brands: **Ulinastatin**, **Kallikrein**, Pantoloc, **Ebrantil** and **Actovegin**.

Nycomed expanded its presence in Latin America during February 2011 by acquiring **Laboratorios Farmacol** SA, a Colombia-based pharmaceutical company. Farmacol has a strong presence in the areas of gastroenterology, respiratory and gynecology. Nycomed expects Farmocal to provide access to the high-growth (+14%) Columbian market, which is Latin America's fifth-largest pharmaceutical market.

In April 2010, Nycomed and Merck entered into a co-promotion agreement for **Daxas** (roflumilast) in Canada and certain European countries. Additionally, the companies signed an exclusive distribution agreement for the commercialization of Daxas in the U.K.

Under the terms of the agreement, Nycomed received an undisclosed up-front fee from Merck and is eligible for certain regulatory and commercial milestone payments. The two companies co-promote the product in Germany, Italy Spain, Portugal and Canada. Merck has exclusive rights to the drug in the United Kingdom.

Daxas received marketing authorization in the European Union on July 6, 2010. The drug is indicated for the treatment of chronic-obstructive pulmonary disease, a life-threatening lung disease.

quick facts

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8152 Glattpark-Opfikon, Zurich
Switzerland
Phone: +41 44 555 10 00
Fax: +41 44 555 10 01
Website: www.nycomed.com
Year Established: 1874
No. of employees: 12,000

Some Key OTC Products:
Riopan for heartburn
Ibumetin for pain relief
Calcium D3 for osteoporosis

Perrigo Co.

Established in 1887, Perrigo is a leading global healthcare supplier. Perrigo develops, manufactures and distributes over-the-counter and generic prescription pharmaceuticals, nutritional products, infant formulas, active pharmaceutical in-

gredients, as well as pharm and medical diagnostic products. Perrigo is the world's largest store-brand manufacturer of over-the-counter pharmaceutical products and infant formula. Perrigo employs more than 7,500 people worldwide, with primary operations in the United States, Israel, Mexico and the United Kingdom.

The company reported net sales of $1.4 billion for the six-month period ended Dec. 25, 2010, compared with $1.1 billion for the same time frame ended in 2009. Research and development costs rose to a total of $42.3 million during the first half of fiscal 2010 from $39.4 million in the first six months of fiscal 2009. Net income for the first six months of fiscal 2010 totaled $164.5 million, compared with $112.7 million during fiscal 2009. Diluted earnings per share rose from $1.21 in the first half of fiscal 2009 to $1.76 for the same period in fiscal 2010.

Perrigo's Consumer Healthcare sales totaled $826.1 million for the first half of fiscal 2010, up from $797.8 million in the first half of fiscal 2009. The Consumer Healthcare segment is the world's largest store-brand manufacturer of over-the-counter pharmaceutical products. Perrigo is the market leader for consumer healthcare products in many of the regions where the company currently competes: the United States, United Kingdom and Mexico. Store-brand private-label OTC products represent about 30% of the total retail value of the categories in which Perrigo competes.

Perrigo received a favorable ruling in February 2010 in patent litigation involving **Guaifenesin Extended-Release Tablets** 600mg, a generic version of **Mucinex**. **Adams Respiratory** Therapeutics, holder of the New Drug Application and patent, sued perrigo over the product. The U.S. District Court for the Western District of Michigan ruled that Perrigo does not infringe the patent in the suit. The Abbreviated New Drug Application for Perrigo's product is awaiting FDA approval.

In March 2010, Perrigo acquired Orion Laboratories for $48.6 million in cash. Perrigo acquired about $600,000 of acquisition costs, which were expensed in operations in the third quarter of fiscal 2010. Orion is a leading supplier of over-the-counter store-brand pharmaceutical products in Australia and New Zealand, and manufactures and distributes pharmaceutical products supplied to hospitals in Australia.

During May 2010, Perrigo acquired exclusive U.S. store brand rights from **Tris Pharma** to sell and distribute **Dextromethorphan Polistirex Extended Release Suspension Cough Suppressant**, the generic version of **Delsym**. The product is indicated for 12-hour cough release, and has estimated annual sales of $125 million.

In June 2010, Perrigo acquired exclusive U.S. store brand rights to sell and distribute generic Allegra (fexofenadine HCl 180 mg and 60 mg) and Allegra-D12 (fexofenadine HCl 60 mg and pseudoephedrine 120 mg) products

FDA granted Perrigo final approval to manufacture and market OTC Cetirizine Cherry Syrup in July 2010. The product is marketed under store-brand labels and is comparable to McNeil Consumer Healthcare's Zyrtec Children's Allergy syrup. The Zyrtec brand reportedly recorded sales of $580 million for the 52-week period ended July 4, 2010.

Perrigo and **Stiefel** Research Australia Pty. Ltd., a GlaxoSmithKline company, reached a settlement agreement on Feb. 10, 2011, relating to **Minoxidil foam**. Under terms of the settlement, Perrigo will be able to launch a generic version of **Men's Rogaine Foam** in the United States on March 1, 2012, or earlier under certain circumstances. Men's Rogaine, which is used to regrow hair on the top of the scalp, has annual sales of roughly $60 million.

quick facts

515 Eastern Avenue
Allegan, Michigan 49010
United States
Phone: 269-673-8451
Website: www.perrigo.com
No. of employees: 7,700

Some Key OTC Products:
Phenylephrine HCl Tablets for nasal decongestion
Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate for cold symptom relief

Pfizer Inc.

Pfizer discovers, develops, manufactures, and markets leading prescription medicines for humans and animals. The New York-based corporation also markets many of the world's best-known consumer products, including Advil, **Dristan**, **Robitussin** and **Preparation H**.

Revenue for Pfizer during 2010 totaled $67.81 billion, increasing 36% from $50.01 billion in 2009. This increase is due to the inclusion of revenues from legacy Wyeth products of $18.1 billion, which favorably impacted revenue by 37%. Pfizer completed its acquisition of Wyeth on Oct. 15, 2009. Research and development expenses totaled $9.41 billion for 2010, compared with $7.85 billion for 2009. Net income decreased from $8.64 billion in 2009 to $8.26 billion during 2010. Diluted earnings per share also dropped between the two years, decreasing from $1.23 in 2009 to $1.02 in 2010.

Pfizer expects that it will lose exclusivity for **Lipitor** in the United States in November 2011, resulting in a substantial loss of its U.S. revenue from the product. Pfizer granted **Watson Laboratories** Inc. an exclusive right to sell the generic version of Lipitor in the United States, which is expected to begin in November. Pfizer will manufacture and sell the product to Watson. Lipitor revenue in emerging markets should not be materially affected by the loss of U.S. exclusivity.

Pfizer entered into various business transactions during 2010, including a definitive agreement to acquire **King Pharmaceuticals** Inc. as announced in October of that year. The announced purchase price for King Pharmaceuticals is $3.6 billion in cash, or $14.25 per share, without interest. During the first quarter of 2011, King Pharmaceuticals became a wholly owned subsidiary of Pfizer and the company's stock ceased trading on the NYSE. According to PharmaLive editors, this transaction was the ninth-largest among healthcare M&A deals during 2010.

During November 2010, Pfizer consummated its partnership with **Laboratorio Teuto Brasileiro** SA (Tueto), a Brazil-

ian generic company. Pfizer acquired a 40% equity stake in Teuto as well as two representatives on Teuto's board of directors. Under terms of the agreement, Pfizer made an up-front payment of $230 million. Teuto is eligible to receive a performance-based milestone payment from Pfizer during 2012. Pfizer retains an option to acquire the remaining 60% of the company beginning in 2014.

In February 2011, Pfizer entered into a definitive agreement to purchase Ferrosan's consumer healthcare business from Altor 2003 Fund GP Ltd. The consumer healthcare business includes dietary supplements and lifestyle products.

Ferrosan is an innovative and long-established consumer healthcare company based in Copenhagen, Denmark, with a portfolio of leading brands. They include Multi-Tabs, a popular multivitamin; Bifiform, a leading probiotic; Fri Flyt/Active Omega, an Omega 3 product; and Imedeen, a premium oral skin-care brand. All of these products are among the top-sellers in their respective categories.

"Ferrosan is an excellent strategic fit that strengthens our presence in dietary supplements with a new set of compelling brands and product pipeline," Mr. Sturman said.

Financial terms of the transaction, which is expected to close during the second quarter of 2011, were not disclosed.

Coinciding with the 2010 holiday season, Pfizer launched **Advil Congestion Relief** in November 2010. The product treats swelling due to nasal inflammation, often the true cause of congestion. Advil Congestion Relief is a unique combination of ibuprofen and phenylephrine that provides relief from sinus pressure, nasal swelling and congestion, and headache. The product is sold at all major retailers nationwide in the United States.

Pfizer announced a voluntary recall of one lot of **ThermaCare HeatWraps** in September 2010. The recall is a precautionary step after the company found a potential for a leak of the components contained in the wrap, which could cause skin injury such as irritation and burn.

The Pfizer board of directors elected Ian C. Read as its new president and CEO on Dec. 5, 2010. Mr. Read previously served as the head of the company's global biopharmaceutical operations and succeeded Jeffrey B. Kindler, who retired from Pfizer.

quick facts

235 East 42nd Street
New York, NY 10017
United States
Phone: 212-733-2323
Fax: 212-733-7851
Website: www.pfizer.com
Year established: 1849
No. of employees: 116,500

Some Key OTC Products:
Advil for pain relief
Dristan Nasal Spray for nasal congestion due to allergies
Robitussin cold symptom relief

The Procter & Gamble Co.

Procter & Gamble's business is focused on providing branded consumer goods. The Cincinnati company's products are sold in 180 countries through mass merchandisers, grocery stores, membership club stores, drug stores, and "high frequency" stores.

For the first six-month period ended Dec. 31, 2010, the company reported net sales of $41.5 billion, compared with $40.8 billion for the same period ended in 2009. Net earnings dropped from $4.7 billion in the first half of fiscal 2009 to $3.3 billion in the first half of fiscal 2010, Diluted earnings per share dropped as well, falling 26% to $1.11 in the first six months of fiscal 2010, from $1.49 in first-half fiscal 2009.

Net sales of P&G's healthcare segment increased 1% to $6.12 billion for the six-month period ended Dec. 31, 2010. This figure represented 14% of P&G's total sales for that period. The company increased global market share of its Oral Care category by about half a point. P&G's Personal Health Care volume grew in the low single digits behind shipments of **Vicks** in developing regions, as well as increased distribution of **PuR** in CEEMEA. This growth was partially offset by lower shipments of **Prilosec OTC** in North America.

In October 2010, P&G debuted **Crest Pro-Health Complete Rinse** with fluoride for tooth care. The product re-builds enamel, prevents cavities, cleans teeth and gums, and freshens breath.

P&G introduced a different Crest product in March 2010: the **Crest Pro-Health Sensitive Shield** toothpaste. Crest Pro-Health is the only leading toothpaste to protect against teeth sensitivity as well as cavities, gingivitis, tartar, plaque, fresh breath and whitening.

On June 24, 2010, P&G announced a voluntary recall of its **Vapospray 4-Hour Decongestant Nasal Spray**. The product was distributed nationwide in the United States. The company stated that the recall was a precautionary step after finding that the product formulation may not meet the expiration date on the package. This recall was not a result of consumer complaints.

quick facts

One Proctor & Gamble Plaza
Cincinnati, OH 45201
United States
Phone: 513-983-1100
Website: http://www.pg.com
Year established: 1837
No. of employees: 127,000

Some Key OTC Products:
Crest for dental care
Prilosec OTC for heartburn
Pepto-Bismol gastrointestinal relief

Reckitt Benckiser Plc.

Reckitt Benckiser (RB) manufactures and sells household and health-care products in over 180 countries.

RB reported net revenue of £8.4 billion ($12.9 billion) for fiscal-year 2010, an 8% increase from fiscal 2009 net revenue of £7.8 billion ($12.2 billion). Net income for fiscal 2010 totaled £1.7 billion ($2.6 billion), compared with £1.4 billion ($2.1 billion) in

fiscal 2009. Diluted earnings per share rose from £1.95 ($3.01) in fiscal 2009 to £2.27 ($3.51) in 2010.

RB manufactures several market leading products. **Nurofen** and **Gaviscon** are leading analgesic and gastrointestinal brands in Europe and Australia. **Stresils** in the No. 1 sore throat product globally. **Mucinex** is the leading cough brand in the United States.

During the first half of 2011, RB intends to launch **Nuromol**, a new ibuprofen-paracetamol combination tablet. The company uses a patented manufacturing process so that the active ingredients are released in a pre-determined way. This process will result in superior, longer-lasting pain relief.

In July 2010, RB commenced an offer to acquire all outstanding shares of **SSL** International. RB made an initial offer for SSL at £11.63 per share. As of Nov. 3, 2010, RB had received 204,173,628 SSL shares, representing 94.19% of the existing issued ordinary share capital of SSL.

SSL applied to the UK Listing Authority for the cancellation of the SSL shares on the official list and to the London Stock Exchange for the cancellation of admission to trading of SSL shares on the LSE's main market. The delisting took place on Nov. 29, 2010.

In December 2010, RB announced that it agreed to buy the Indian company **Paras** Pharmaceuticals Ltd. for £460 million. Paras' leading OTC portfolio includes **Moov**, the No. 2 topical analgesic pain ointment in India; **Krack**, the No. 2 medicated skin ointment for cracked heels; and several other leading brands. Paras also has a personal-care business led by its hair gel and deodorant brand **Set Wet**.

Commenting on the acquisition, Reckitt Benckiser CEO Bart Becht said, "The acquisition of Paras is another step forward in RB's growth strategy in consumer healthcare. It creates a material healthcare business in India, one of the most promising healthcare markets in the world, with the addition of a number of strong and leading brands."

In November 2010, RB appointed Liz Doherty as the company's chief financial officer. Ms. Doherty previously served a two-year stint as CFO of **Brambles** Industries Plc., a top 25 company on the Australian Stock Market. Ms. Doherty replaced Colin Day, who left the company in January 2011.

Rohto Pharmaceutical Co.

Founded in 1899, Rohto is a Japanese-based pharma company pledged to bring "Happy Surprises" through its products and services. Rohto has more than 4,500 employees across the globe.

The company reported net sales of ¥52.5 billion ($622.4 million) for the six-month period ended Sept. 30, 2010, slightly decreasing from ¥52.6 billion ($623.5 million) for the same period in 2009. Net income for the first half of fiscal 2010 totaled ¥3.6 billion ($42.7 million), compared with ¥3.1 billion ($36.7 million) in first-half fiscal 2009. Diluted net income per share rose to ¥30.5 (36 cents) for the first six months of fiscal 2010 from ¥26.25 (31 cents) during first-half fiscal 2009.

Rohto predicted that full-year fiscal 2010 sales sould be strong in Japan due in part to a prediction of elevated pollen levels in the spring. The company's international sales were expected to fall during the same time frame due to the global downturn and impact of exchange rates from the rapid rise of the yen.

Sales of eye-care products dropped 3.9% in the first six months of 2010 to ¥11.8 billion ($139.9 million). Skincare product sales for the same period totaled ¥30.9 billion ($366.3 million), a 2.1% increase for the same period in 2009. Internal medicines totaled ¥7.5 billion ($88.9 million) for the first half of fiscal 2010, decreasing from ¥7.7 billion for the same 2009 period.

quick facts

1-8-1, Tatsumi-nishi, Ikuno-ku
Osaka 544-8666
Japan
Phone: 81-6-6758-1231
Website: www.rohto.co.jp
Year established: 1899
No. of employees: 4,617

Some Key OTC Products:
Rohto V 11 for eye care
Dryaid Ex for dry eye
Alguard for hay fever

Sanofi-aventis (and Chattem)

Sanofi-aventis has became one of the leading players in the OTC arena through its acquisition of the consumer-products company Chattem. Sanofi-aventis reported 2010 net sales of €30.4 billion, increasing 3.7% from €29.3 billion in 2009. The Chattem acquisition represented a positive change of €297 million in sales for 2010. As a whole, sanofi-aventis Consumer Health Care sales totaled €2.2 billion, an increase of 55% over 2009. Sanofi-aventis attributes this increase to its acquisitions in this sector throughout the year, including Chattem.

Research and development costs for sanofi-aventis totaled €4.4 billion in 2010, compared with €4.6 billion in 2009. Net income rose 6.8% to €9.2 billion in 2010, up from €8.6 billion in 2009. Earnings per share also grew in 2010, totalling €7.06 for the year as opposed to €6.61 in 2009.

Chattem was founded in 1879 in Chattanooga, Tenn. The company has been a leader in consumer health care, marketing brands such as Gold Bond, Allegra and IcyHot.

Chattem underwent a major change when it was acquired by sanofi-aventis. The initial announcement came in December 2009, with sanofi-aventis an-

quick facts

Chattem Inc.
1715 West 28th St.
Chattanooga, TN 37409
United States
Phone: 423-821-4571
Website: www.chattem.com
Year established: 1879
No. of employees: 524

Some Key OTC Products:
Allegra for seasonal allergies
Gold Bond for irritated skin
IcyHot for pain relief
Aspercreme for pain relief

nouncing it had entered into a definitive agreement with Chattem to purchase the company for $93.50 per share, or approximately $1.9 billion.

The commencement of the tender offer through sanofi-aventis' wholly owned subsidiary **River Acquisition** Corp. took place on Jan. 11, 2010. The offer obtained antitrust clearance on Jan. 26, 2010, when the waiting period under the Hart-Scott Rodino Antitrust Improvement Act of 1976 expired.

The initial tender offer expired at midnight Eastern time on Feb. 8, 2010. At the time, 18,611,072 shares of Chattem common stock were tendered, representing 89.8% of shares on a fully diluted basis.

Sanofi-aventis wrapped up the acquisition in March 2010, announcing it had acquired 100% of Chattem. Now Chattem operates as a wholly owned subsidiary of sanofi-aventis. The acquisition strengthened sanofi-aventis' position in the U.S. consumer market, which represents 25% of the world market.

In January 2011, Chattem announced that FDA approved the Allegra (fexofenadine HCl) family of medicines for OTC use in adults and children older than 2 years. U.S. consumers could purchase the products without a prescription beginning in March 2011. Over 40 million American adults suffer from indoor and outdoor allergies. The Allegra family of medicines, which are indicated for the relief of symptoms associated with seasonal allergies, are available in drug, grocery, mass merchandiser and clubstores across the United States.

Santen Pharmaceutical Co.

Santen specializes in the R&D, manufacturing, and marketing of ophthalmic and anti-rheumatic pharmaceuticals to protect and improve people's eyesight and health. Santen was founded in 1890.

Net sales for the nine-month period ended Dec. 31, 2010, totaled ¥82.1 billion ($985.1 million), decreasing 4.9% from ¥86.3 billion ($1.04 billion) in the same period for 2009. Net income decreased 9.6% for the first three quarters of fiscal 2010 to ¥14.7 billion ($176.4 million). Net income per share for the same period totaled ¥172.24 ($2.07).

Santen's OTC pharmaceutical product sales totaled ¥4.1 billion ($49.2 million) for the first nine months of fiscal 2010, increasing 0.7% from ¥3.6 billion ($43.2 million) in the same period for 2009.

In April 2010, the Japanese Ministry of Health, Labour and Welfare granted approval for **Diquas** Ophthalmic Solution 3% (diquafosol tetrasodium) for the treatment of dry eye. Diquas was licensed from **Inspire Pharmaceutical** Inc. for certain ophthalmic uses. Diquas was launched in Japan during December 2010.

In May 2010, Santen exercised its option to license **Clinical Data** Inc.'s highly selective adenosine A2A agonist compound **ATL313** for the development of topical treatments for certain ophthalmic diseases, including glaucoma. Under terms of the agreement, Clinical Data was paid $2 million up front, followed by development, regulatory and commercial milestone payments subject to the fulfillment of certain conditions, as well as royalties on product sales. In return, Santen received a worldwide license to ATL313 and an option for an additional compound for the development and commercialization of treatments for certain ophthalmic diseases, including glaucoma.

In September 2010, Santen announced that it will transfer production and supply-chain management functions from its Osaka, Japan, plant to the Shiga plant in an effort to strengthen the company's global product-supply capability. The Osaka plant will be closed by March 2013, with the Shiga plant becoming a core production site for Santen's global health supply,

quick facts

9-19 Shimoshinjo 3-chome,
Higashiyodogawa-ku
Osaka 533-8651
Japan
Phone: 81-6-6321-7000
Fax: 81-6-6321-8400
Website: www.santen.co.jp
Year established: 1890
No. of employees: 2,756

Some Key OTC Products:
Sante for eye care
Diquas for dry eye

Taro Pharmaceutical Industries Ltd.

Taro is a research-based, international, specialty-pharma company that develops, manufactures and markets prescription and over-the-counter pharmaceutical products. Established during 1950, Taro's research programs and niche strategy have enabled it to attain gross margins that are among the highest in the specialty-pharma sector.

Taro's net sales for 2010 were $392.7 million, a 9.4% increase over 2009. Net income decreased 56.8% to $52.4 million in 2010, down from $121.3 million in 2010. R&D costs in 2010 totaled $36.2 million, increasing from 34.4 million in 2009. Diluted earnings per share decreased from $2.99 in 2009 to $1.27 in 2010.

In February 2010, Taro announced the discontinuation of manufacturing operations at the sterile manufacturing facility of its Irish subsidiary, **Taro Pharmaceuticals Ireland** Ltd., in Roscrea, Ireland. Taro said it was no longer in the best interest of the company to continue to incur losses from the facility or make the capital investments in order to achieve the level of efficiency found at Taro's other operating facilities. The closure of the facility was expected to impact 30 employees.

Also in February 2010, Taro received approval from the U.S. FDA for its ANDA for **Levetiracetam Tablets**, 250 mg, 500 mg, 750 mg and 1,000 mg. Levetiracetam Tablets, which are the bioequivalent to **Keppra** Tablets, is a prescription product indicated for the treatment of epilepsy.

The U.S. FDA approved Taro's ANDA for **Fluorouracil Topical Cream USP**, 5% in March 2010. The bioequivalent of Valeant Pharmaceuticals International's **Efudex**, Fluorouracil Topical Cream USP is a prescription product used for the topical treatment of multiple actinic or solar keratoses as well as superficial basal cell carcinomas.

During June 2010, **Granisetron Hydrochloride Tablets USP**, 1 mg, the bioequivalent of **Hoffman-La Roche**'s **Kytril**, was approved by U.S. regulators for the prevention of nausea and vomiting associated with chemotherapy and radiation treatment. Granisetron tablets had U.S. sales of $15 million in 2009.

The U.S. Patent and Trade Office issued patent 7,683,071 covering Taro's **T2007**, the sodium salt of diphenyl barbituric acid (DPB). The patent is for one of a class of non-sedating barbiturate compounds currently in development by the company. Taro began Phase I testing on T2007 in December 2009 for treating epilepsy.

Taro announced in September 2010 that the Levitt and Moros families had reached an agreement with **Sun Pharmaceutical** Industries Ltd. The agreement facilitates the immediate transfer of the families' interest in Taro to Sun in accordance with the previously agreed option entered into by the parties in 2007. Sun and the board of directors of Taro concurrently entered into an agreement in which the current members of the board resigned, and Sun appointees become directors of Taro effective immediately.

"We are gratified that the company's operational and financial turnaround leaves it on strong footing – and, we think, with a bright future ahead," said Barrie Levitt, M.D., Taro chairman, on behalf of the company's outgoing directors. "We are proud of what we have achieved in Taro's 60-year history, especially in the last three years, and we take heart at the significant value that has been created for our shareholders.

quick facts

14 Hakitor Street, P.O. Box 10347
Haifa Bay 26110
Israel
Phone: 972-4-847-5700
Website: www.taro.co.il
Year established: 1950
No. of employees: 1,149

Some Key Products:
Amiodarone HCl for ventricular arrhythmias
Clomipramine HCl for antidepression
Warfarin for anticoagulation

Unilever NV

Established during 1930, Unilever's portfolio includes more than 400 brands ranging from nutritionally balanced foods to indulgent ice creams, affordable soaps, luxurious shampoos and everyday household care products.

The company reported revenue of €44.3 billion ($58.8 billion) for its fiscal-year 2010, increasing from €39.8 billion ($52.8 billion) in fiscal 2009. Net profit for fiscal 2010 was €4.6 billion ($6.1 billion), of which €4.2 billion ($5.6 billion) was attributable to shareholders of Unilever. This represented an increase from €3.7 billion ($4.9 billion), of which €3.4 billion ($4.5 billion) was attributable to shareholders.

Unilever's diluted earnings per share rose from €1.17 ($1.55) in fiscal 2009 to €1.46 ($1.94) in 2010. Research and development costs also rose in fiscal 2010, totaling €928 million ($1.2 billion) compared with €891 million ($1.18 billion) in the previous term.

Personal care sales, which include the sales of skin and hair-care products, deodorants and antiperspirants, as well as oral care products, totaled €13.7 billion ($18.1 billion) in fiscal 2010. This amount represented an increase from €11.8 billion ($15.7 billion) generated during fiscal 2009.

Unilever announced in September 2010 that it entered into a definitive agreement to acquire U.S.-based **Alberto Culver** Co. for $3.7 billion. Alberto Culver shareholders voted in favor of the merger in December 2010. With this acquisition, Unilever is now considered the world's leading company in hair conditioning, second in shampoo, and the third largest in styling.

Paul Polman, CEO of Unilever, said: "We are delighted to be acquiring Alberto Culver. Their people have done an excellent job of building an impressive range of brands such as **TRESemmé**, **VO5**, **Nexxus**, **St. Ives** and **Simple**. These will complement Unilever's existing portfolio of iconic brands like **Dove**, **Clear** and **Sunsilk** in hair care and **Pond's** and **Vaseline** in skin and will help build on our strong global positions in both the hair care and skin care categories."

During November 2010, Unilever continued to strengthen the company's personal care segment through the acquisition of the **Sara Lee Personal Care and European Laundry** business. Under terms of the agreement, Unilever paid €1.2 billion in cash for Sarah Lee, whose brands generated annual sales in excess of €750 million during the year ended in June 2009.

In September 2010, Unilever entered into an agreement to access and **Apere Life Sciences**' Digital Biology platform. Terms of the transaction were not disclosed. The five-year initiative brings Unilever and Ampere scientists together to work on the core biology of aging.

Unilever underwent several management changes during 2010. In February, Tonia Lovell was named Steve Williams' replacement as chief legal officer of the company. Ms. Lovell previously served as the general counsel to the Unilever UK & Ireland business.

In March 2010, Unilever appointed Keith Weed as chief marketing and communications officer.

Also in March, Vindi Banga left the position of president, Global Foods, Home and Personal Care, after 33 years of service. Mr. Vanga was replaced by Dave Lewis, who previously served as executive VP of Unilever UK & Ireland.

quick facts

Weena 455, PO Box 760
3000 DK Rotterdam
The Netherlands
Phone: +31 10 217 4000
Fax: +31 10 217 4798
Website: www.unilever.com
Year established: 1930
No. of employees: 107,000

Some Key Products:
Vaseline for skin care
Sunsilk for hair care
Dove for skin care and hygiene

FDA OTC Approvals On The Market: By Action Date

Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
8/15/1950	CHLOR-TRIMETON	CHLORPHENIRAMINE MALEATE	TABLET, EXTENDED RELEASE; ORAL	12MG	SCHERING-PLOUGH
10/18/1963	DRIXORAL	DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	6MG;120MG	SCHERING-PLOUGH
10/18/1963	DISOPHROL	DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	6MG;120MG	SCHERING-PLOUGH
11/7/1968	NEOPAP	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	POLYMEDICA
1/30/1974	MONISTAT 7	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	JOHNSON AND JOHNSON
3/24/1976	GYNE-LOTRIMIN	CLOTRIMAZOLE	TABLET; VAGINAL	100MG	SCHERING-PLOUGH
9/17/1976	HIBICLENS	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	REGENT
2/9/1978	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	G AND W LABS
2/9/1978	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	G AND W LABS
2/9/1978	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	325MG	G AND W LABS
10/18/1978	UNISOM	DOXYLAMINE SUCCINATE	TABLET; ORAL	25MG	CHATTEM
11/8/1978	GYNE-LOTRIMIN	CLOTRIMAZOLE	CREAM; VAGINAL	1%	SCHERING-PLOUGH
1/15/1979	MYCELEX	CLOTRIMAZOLE	Solution; Topical	1%	BAYER HEALTHCARE
2/16/1979	MYCELEX-7	CLOTRIMAZOLE	CREAM; VAGINAL	1%	BAYER PHARMACEUTICALS
2/27/1979	MYCELEX-7	CLOTRIMAZOLE	TABLET; VAGINAL	100MG	BAYER PHARMACEUTICALS
4/22/1980	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	ACTAVIS MID ATLANTIC
4/22/1980	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	325MG	ACTAVIS MID ATLANTIC
4/22/1980	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	ACTAVIS MID ATLANTIC
4/22/1980	INFANTS' FEVERALL	ACETAMINOPHEN	SUPPOSITORY; RECTAL	80MG	ACTAVIS MID ATLANTIC
5/23/1980	HIBISTAT	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	0.5%	REGENT
10/30/1980	AFRINOL	PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	120MG	SCHERING-PLOUGH
3/31/1981	CHLOR-TRIMETON	CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	8MG;120MG	SCHERING-PLOUGH
3/15/1982	MONISTAT 7	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	JOHNSON AND JOHNSON
10/8/1982	DELSYM	DEXTROMETHORPHAN POLISTIREX	SUSPENSION, EXTENDED RELEASE; ORAL	EQ 30MG HBR/5ML	RECKITT BENCKISER
10/14/1982	IOSAT	POTASSIUM IODIDE	TABLET; ORAL	130MG	ANBEX
10/28/1982	HUMULIN R	INSULIN RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	LILLY
10/28/1982	HUMULIN R PEN	INSULIN RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	LILLY
10/28/1982	HUMULIN N	INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	LILLY
4/1/1983	TODAY	NONOXYNOL-9	SPONGE; VAGINAL	1GM	AZTIQ PHARMA
12/9/1983	GAVISCON	ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE	TABLET, CHEWABLE; ORAL	80MG;20MG	SANOFI-AVENTIS US
12/9/1983	GAVISCON	ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE	TABLET, CHEWABLE; ORAL	160MG;40MG	SANOFI-AVENTIS US
1/13/1984	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	GLAXOSMITHKLINE
1/13/1984	NICORETTE (MINT)	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	GLAXOSMITHKLINE
1/13/1984	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	GLAXOSMITHKLINE
5/18/1984	ADVIL	IBUPROFEN	TABLET; ORAL	200MG	WYETH CONS
5/18/1984	MOTRIN IB	IBUPROFEN	TABLET; ORAL	200MG	MCNEIL
5/18/1984	MOTRIN MIGRAINE PAIN	IBUPROFEN	TABLET; ORAL	200MG	MCNEIL
5/23/1984	EPINEPHRINE	EPINEPHRINE	AEROSOL, METERED; INHALATION	0.2MG/INH	ARMSTRONG PHARMS

Source: FDA.gov

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Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
12/24/1984	EXIDINE	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	XTTRIUM
12/24/1984	EXIDINE	CHLORHEXIDINE GLUCONATE	AEROSOL, METERED; TOPICAL	4%	XTTRIUM
10/18/1985	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	PAR PHARM
11/29/1985	E-Z SCRUB 201	POVIDONE-IODINE	SPONGE; TOPICAL	20%	BECTON, DICKINSON
12/17/1985	EXIDINE	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	2%	XTTRIUM
3/5/1986	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	WATSON LABS
5/30/1986	OCUCLEAR	OXYMETAZOLINE HYDROCHLORIDE	SOLUTION/DROPS; OPHTHALMIC	0.025%	SCHERING-PLOUGH
7/15/1986	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	OHM
7/22/1986	CIDA-STAT	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	2%	ECOLAB
7/22/1986	CHG SCRUB	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	ECOLAB
10/15/1986	PROFEN	IBUPROFEN	TABLET; ORAL	200MG	CONTRACT PHARMACAL
12/1/1986	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	PERRIGO NEW YORK
12/1/1986	IBUPROHM	IBUPROFEN	TABLET; ORAL	200MG	OHM LABS
1/7/1987	E-Z SCRUB 241	POVIDONE-IODINE	SPONGE; TOPICAL	10%	BECTON, DICKINSON
2/17/1987	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	AMNEAL PHARMS NY
4/1/1987	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	VINTAGE PHARMS
4/6/1987	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	PERRIGO NEW YORK
5/22/1987	DRIXORAL PLUS	ACETAMINOPHEN; DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	500MG;3MG;60MG	SCHERING-PLOUGH
9/4/1987	FOAMCOAT	ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE	TABLET, CHEWABLE; ORAL	80MG;20MG	GUARDIAN DRUG
9/10/1987	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	CONTRACT PHARMACAL
9/10/1987	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	CONTRACT PHARMACAL
10/2/1987	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	PAR PHARM
12/8/1987	TAB-PROFEN	IBUPROFEN	TABLET; ORAL	200MG	PERRIGO
12/8/1987	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	PERRIGO
12/17/1987	BRIAN CARE	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	SOAPCO
2/2/1988	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	VINTAGE PHARMS
3/1/1988	IMODIUM A-D	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	MCNEIL CONS
3/1/1988	IMODIUM A-D	LOPERAMIDE HYDROCHLORIDE	SUSPENSION; ORAL	1MG/7.5ML	MCNEIL CONS
5/23/1988	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	AMNEAL PHARMS NY
7/1/1988	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	CONTRACT PHARMACAL
8/11/1988	IBU-TAB 200	IBUPROFEN	TABLET; ORAL	200MG	ALRA
8/17/1988	ROGAINE (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	JOHNSON AND JOHNSON
8/17/1988	ROGAINE (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	JOHNSON AND JOHNSON
12/2/1988	PHARMASEAL SCRUB CARE	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	PHARMASEAL
3/31/1989	VISINE L.R.	OXYMETAZOLINE HYDROCHLORIDE	SOLUTION/DROPS; OPHTHALMIC	0.025%	JOHNSON AND JOHNSON
3/31/1989	POVIDONE IODINE	POVIDONE-IODINE	SOLUTION; TOPICAL	1%	ALLEGIANCE HLTHCARE
3/31/1989	BIOSCRUB	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	GRIFFEN
4/25/1989	HUMULIN 70/30	INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	30 UNITS/ML;70 UNITS/ML	LILLY
4/25/1989	HUMULIN 70/30 PEN	INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	30 UNITS/ML;70 UNITS/ML	LILLY

Source: FDA.gov

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9/19/1989	ADVIL COLD AND SINUS	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	WYETH CONS
10/24/1989	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	BECTON, DICKINSON
10/27/1989	LOTRIMIN AF	CLOTRIMAZOLE	Cream; Topical	1%	SCHERING-PLOUGH
10/27/1989	LOTRIMIN AF	CLOTRIMAZOLE	Lotion; Topical	1%	SCHERING-PLOUGH
10/27/1989	LOTRIMIN AF	CLOTRIMAZOLE	Solution; Topical	1%	SCHERING-PLOUGH
11/22/1989	IMODIUM A-D	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	MCNEIL CONS
5/2/1990	NIX	PERMETHRIN	LOTION; TOPICAL	1%	INSIGHT PHARMS
6/25/1991	NOVOLIN R	INSULIN RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	NOVO NORDISK INC
6/25/1991	NOVOLIN 70/30	INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	30 UNITS/ML;70 UNITS/ML	NOVO NORDISK INC
7/1/1991	NOVOLIN N	INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	NOVO NORDISK INC
10/31/1991	SUDAFED 12 HOUR	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	120MG	MCNEIL CONS
11/7/1991	NICODERM CQ	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	21MG/24HR	SANOFI-AVENTIS US
11/7/1991	NICODERM CQ	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	14MG/24HR	SANOFI-AVENTIS US
11/7/1991	NICODERM CQ	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	7MG/24HR	SANOFI-AVENTIS US
11/27/1991	HABITROL	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	7MG/24HR	NOVARTIS
11/27/1991	HABITROL	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	14MG/24HR	NOVARTIS
11/27/1991	HABITROL	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	21MG/24HR	NOVARTIS
1/21/1992	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	PERRIGO
3/27/1992	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	G AND W LABS
3/27/1992	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	325MG	G AND W LABS
4/30/1992	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	ROXANE
6/8/1992	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	GLAXOSMITHKLINE
6/8/1992	NICORETTE (MINT)	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	GLAXOSMITHKLINE
6/8/1992	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	GLAXOSMITHKLINE
8/21/1992	TAVIST-1	CLEMASTINE FUMARATE	TABLET; ORAL	1.34MG	NOVARTIS
9/3/1992	BRONCHO SALINE	SODIUM CHLORIDE	AEROSOL, METERED; INHALATION	0.9%	BLAIREX
12/7/1992	SHADE UVAGUARD	AVOBENZONE; OCTINOXATE; OXYBENZONE	LOTION; TOPICAL	3%;7.5%;3%	SCHERING-PLOUGH
12/10/1992	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	OHM LABS
12/15/1992	SUDAFED 24 HOUR	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	240MG	MCNEIL CONS
12/31/1992	SINE-AID IB	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	MCNEIL CONS
4/12/1993	CLARITIN	LORATADINE	TABLET; ORAL	10MG	SCHERING-PLOUGH
4/12/1993	CLARITIN HIVES RELIEF	LORATADINE	TABLET; ORAL	10MG	SCHERING-PLOUGH
4/26/1993	MONISTAT 7 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,100MG	JOHNSON AND JOHNSON
4/26/1993	GYNE-LOTRIMIN COMBINATION PACK	CLOTRIMAZOLE	CREAM, TABLET; TOPICAL, VAGINAL	1%,100MG	SCHERING-PLOUGH

Source: FDA.gov

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7/16/1993	CLOTRIMAZOLE	CLOTRIMAZOLE	CREAM; VAGINAL	1%	ACTAVIS MID ATLANTIC
7/30/1993	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	CONTRACT PHARMACAL
10/31/1993	CLEMASTINE FUMARATE	CLEMASTINE FUMARATE	TABLET; ORAL	1.34MG	SANDOZ
11/19/1993	MICONAZOLE NITRATE	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	ACTAVIS MID ATLANTIC
1/11/1994	ALEVE	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	BAYER
2/25/1994	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	CONTRACT PHARMACAL
3/30/1994	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	MCNEIL
6/8/1994	TYLENOL (CAPLET)	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	MCNEIL CONS
6/8/1994	TYLENOL (GELTAB)	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	MCNEIL CONS
6/8/1994	OPCON-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.02675%;0.315%	BAUSCH AND LOMB
6/8/1994	NAPHCON-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.025%;0.3%	ALCON
6/23/1994	MYCELEX-7 COMBINATION PACK	CLOTRIMAZOLE	CREAM, TABLET; TOPICAL, VAGINAL	1%,100MG	BAYER PHARMACEUTICALS
11/14/1994	CLARITIN-D	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	SCHERING-PLOUGH
4/20/1995	ADVIL LIQUI-GELS	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	WYETH CONS
4/20/1995	ADVIL MIGRAINE LIQUI-GELS	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	WYETH CONS
4/28/1995	PEPCID AC	FAMOTIDINE	TABLET; ORAL	10MG	MERCK SHARP DOHME
4/28/1995	PEPCID AC	FAMOTIDINE	TABLET; ORAL	20MG	MERCK SHARP DOHME
6/16/1995	CHILDREN'S MOTRIN	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	MCNEIL
6/19/1995	TAGAMET HB	CIMETIDINE	TABLET; ORAL	200MG	GLAXOSMITHKLINE
11/17/1995	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	HI TECH PHARMA
11/22/1995	CLEMASTINE FUMARATE	CLEMASTINE FUMARATE	TABLET; ORAL	1.34MG	PERRIGO
12/4/1995	CLOTRIMAZOLE	CLOTRIMAZOLE	CREAM; VAGINAL	1%	TARO
12/8/1995	ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	MCNEIL CONSUMER
12/8/1995	ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	MCNEIL CONSUMER
12/8/1995	ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	MCNEIL CONSUMER
12/8/1995	ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	MCNEIL CONSUMER
12/19/1995	ZANTAC 75	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	BOEHRINGER INGELHEIM
12/21/1995	FEMSTAT 3	BUTOCONAZOLE NITRATE	CREAM; VAGINAL	2%	BAYER
1/31/1996	VISINE-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.025%;0.3%	JOHNSON AND JOHNSON
2/22/1996	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	G AND W LABS
3/29/1996	MICONAZOLE 7	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	ACTAVIS MID ATLANTIC
4/5/1996	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	ACTAVIS MID ATLANTIC
4/16/1996	MONISTAT-3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,200MG	JOHNSON AND JOHNSON
5/9/1996	AXID AR	NIZATIDINE	TABLET; ORAL	75MG	WYETH CONS
6/10/1996	JUNIOR STRENGTH MOTRIN	IBUPROFEN	TABLET; ORAL	100MG	MCNEIL CONS
6/10/1996	CHILDREN'S MOTRIN	IBUPROFEN	SUSPENSION/DROPS; ORAL	40MG/ML	MCNEIL CONS
6/27/1996	CHILDREN'S ADVIL	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	WYETH CONS
6/27/1996	CHILDREN'S ADVIL-FLAVORED	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	WYETH CONS
7/29/1996	GYNE-LOTRIMIN 3	CLOTRIMAZOLE	TABLET; VAGINAL	200MG	SCHERING-PLOUGH

Source: FDA.gov

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7/29/1996	GYNE-LOTRIMIN 3 COMBINATION PACK	CLOTRIMAZOLE	CREAM, TABLET; TOPICAL, VAGINAL	1%,200MG	SCHERING-PLOUGH
8/23/1996	CLARITIN-D 24 HOUR	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	SCHERING-PLOUGH
8/26/1996	IVY BLOCK	BENTOQUATAM	LOTION; TOPICAL	5%	STAND HOMEOPATH
9/18/1996	DOXYLAMINE SUCCINATE	DOXYLAMINE SUCCINATE	TABLET; ORAL	25MG	PERRIGO
10/10/1996	CLARITIN	LORATADINE	SYRUP; ORAL	1MG/ML	SCHERING-PLOUGH
11/15/1996	CHILDREN'S MOTRIN	IBUPROFEN	TABLET, CHEWABLE; ORAL	50MG	MCNEIL CONS
11/15/1996	JUNIOR STRENGTH MOTRIN	IBUPROFEN	TABLET, CHEWABLE; ORAL	100MG	MCNEIL CONS
12/13/1996	JUNIOR STRENGTH ADVIL	IBUPROFEN	TABLET; ORAL	100MG	WYETH CONS
12/23/1996	CLARITIN REDITABS	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	SCHERING-PLOUGH
12/23/1996	CLARITIN HIVES RELIEF REDITAB	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	SCHERING-PLOUGH
12/24/1996	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	HI TECH PHARMA
12/24/1996	MINOXIDIL (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	HI TECH PHARMA
1/13/1997	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	TARO
1/13/1997	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	CONTRACT PHARMACAL
1/13/1997	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	SANDOZ
1/13/1997	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	PERRIGO
2/11/1997	VAGISTAT-1	TIOCONAZOLE	OINTMENT; VAGINAL	6.5%	NOVARTIS
2/27/1997	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	CONTRACT PHARMACAL
2/28/1997	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	WOCKHARDT
3/20/1997	MICONAZOLE NITRATE	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	PERRIGO
4/30/1997	MICONAZOLE NITRATE	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	G AND W LABS
5/15/1997	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	PERRIGO
6/26/1997	IMODIUM MULTI-SYMPTOM RELIEF	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET, CHEWABLE; ORAL	2MG;125MG	MCNEIL
7/11/1997	COLGATE TOTAL	SODIUM FLUORIDE; TRICLOSAN	PASTE; DENTAL	0.24%;0.3%	COLGATE PALMOLIVE
7/17/1997	M-ZOLE 7 DUAL PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,100MG	ACTAVIS MID ATLANTIC
7/24/1997	IMODIUM A-D EZ CHEWS	LOPERAMIDE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	2MG	MCNEIL
8/28/1997	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	WOCKHARDT
9/11/1997	DYNA-HEX	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	0.75%	XTTRIUM
10/10/1997	NIZORAL A-D	KETOCONAZOLE	SHAMPOO; TOPICAL	1%	MCNEIL CONS
10/20/1997	NICOTINE	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	14MG/24HR	AVEVA
10/20/1997	NICOTINE	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	21MG/24HR	AVEVA
10/20/1997	NICOTINE	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	7MG/24HR	AVEVA
11/14/1997	ROGAINE EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	JOHNSON AND JOHNSON
1/14/1998	EXCEDRIN (MIGRAINE)	ACETAMINOPHEN; ASPIRIN; CAFFEINE	TABLET; ORAL	250MG;250MG;65MG	NOVARTIS
1/30/1998	PEDIATRIC ADVIL	IBUPROFEN	SUSPENSION/DROPS; ORAL	100MG/2.5ML	WYETH CONS
3/30/1998	MONISTAT 3	MICONAZOLE NITRATE	CREAM; VAGINAL	4%	JOHNSON AND JOHNSON
4/29/1998	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	NOVEX
4/29/1998	MINOXIDIL (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	NOVEX
6/19/1998	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	CONTRACT PHARMACAL

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6/19/1998	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	CONTRACT PHARMACAL
7/6/1998	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	200MG	CONTRACT PHARMACAL
7/20/1998	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	CONTRACT PHARMACAL
7/28/1998	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	DR REDDYS LABS INC
9/24/1998	PEPCID AC	FAMOTIDINE	TABLET, CHEWABLE; ORAL	20MG	MERCK SHARP DOHME
10/29/1998	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	PERRIGO
11/24/1998	GYNE-LOTRIMIN 3	CLOTRIMAZOLE	CREAM; VAGINAL	2%	SCHERING-PLOUGH
12/16/1998	IBUPROFEN	IBUPROFEN	SUSPENSION/DROPS; ORAL	40MG/ML	PERRIGO
12/18/1998	CHILDREN'S ADVIL	IBUPROFEN	TABLET, CHEWABLE; ORAL	50MG	WYETH CONS
12/18/1998	JUNIOR STRENGTH ADVIL	IBUPROFEN	TABLET, CHEWABLE; ORAL	100MG	WYETH CONS
12/22/1998	CHILDREN'S IBUPROFEN	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	PERRIGO
2/26/1999	PSEUDOEPHEDRINE HYDROCHLORIDE	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	120MG	PERRIGO
3/1/1999	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	LNK
3/1/1999	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	LNK
3/9/1999	LAMISIL	TERBINAFINE HYDROCHLORIDE	CREAM; TOPICAL	1%	NOVARTIS
3/15/1999	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	WATSON LABS
3/19/1999	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	WATSON LABS
4/16/1999	M-ZOLE 3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,200MG	ACTAVIS MID ATLANTIC
4/20/1999	MICONAZOLE NITRATE COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,200MG	PERRIGO
4/22/1999	JUNIOR STRENGTH IBUPROFEN	IBUPROFEN	TABLET; ORAL	100MG	PERRIGO
4/30/1999	IBUPROFEN	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	ACTAVIS MID ATLANTIC
6/16/1999	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	IVAX SUB TEVA PHARMS
6/21/1999	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	CONTRACT PHARMACAL
7/2/1999	ZADITOR	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	NOVARTIS
7/28/1999	PLAN B	LEVONORGESTREL	TABLET; ORAL	0.75MG	DURAMED
7/29/1999	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	WATSON LABS
7/30/1999	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	PERRIGO
7/30/1999	MINOXIDIL (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	PERRIGO
8/5/1999	PEPCID AC (GELTAB)	FAMOTIDINE	TABLET; ORAL	10MG	MERCK SHARP DOHME
11/29/1999	ALEVE-D SINUS & COLD	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	200MG;120MG	BAYER
1/6/2000	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	PERRIGO
1/14/2000	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	WATSON LABS
1/14/2000	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	IVAX SUB TEVA PHARMS
1/14/2000	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	GENPHARM
2/25/2000	ACETAMINOPHEN	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	PERRIGO
3/7/2000	RID MOUSSE	PIPERONYL BUTOXIDE; PYRETHRINS	AEROSOL; TOPICAL	4%;EQ 0.33% BASE	PFIZER
3/17/2000	LAMISIL AT	TERBINAFINE HYDROCHLORIDE	SOLUTION; TOPICAL	1%	NOVARTIS
3/17/2000	LAMISIL AT	TERBINAFINE HYDROCHLORIDE	SPRAY; TOPICAL	1%	NOVARTIS
3/28/2000	PERMETHRIN	PERMETHRIN	LOTION; TOPICAL	1%	ACTAVIS MID ATLANTIC
3/28/2000	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	DR REDDYS LABS LTD
4/12/2000	TRIVAGIZOLE 3	CLOTRIMAZOLE	CREAM; VAGINAL	2%	TARO

Source: FDA.gov

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Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
5/4/2000	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	TORPHARM
7/14/2000	CHLORAPREP ONE-STEP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (3ML)	CAREFUSION
7/14/2000	CHLORAPREP WITH TINT	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (26ML)	CAREFUSION
7/14/2000	CHLORAPREP ONE-STEP FREPP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (1.5ML)	CAREFUSION
7/14/2000	CHLORAPREP ONE-STEP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (10.5ML)	CAREFUSION
7/14/2000	CHLORAPREP WITH TINT	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (10.5ML)	CAREFUSION
7/14/2000	CHLORAPREP ONE-STEP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (26ML)	CAREFUSION
7/14/2000	CHLORAPREP WITH TINT	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (3ML)	CAREFUSION
7/25/2000	ABREVA	DOCOSANOL	CREAM; TOPICAL	10%	GLAXOSMITHKLINE
8/1/2000	CHILDREN'S MOTRIN COLD	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	100MG/5ML;15MG/5ML	MCNEIL CONS
10/16/2000	PEPCID COMPLETE	CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE	TABLET, CHEWABLE; ORAL	800MG;10MG;165MG	MERCK SHARP DOHME
11/17/2000	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	ACTAVIS MID ATLANTIC
11/17/2000	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	AVACOR PRODS
11/30/2000	IMODIUM MULTI-SYMPTOM RELIEF	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET; ORAL	2MG;125MG	MCNEIL CONS
2/2/2001	MONISTAT 3 COMBINATION PACK (PREFILLED)	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%,4%	JOHNSON AND JOHNSON
2/2/2001	MONISTAT 3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%,4%	JOHNSON AND JOHNSON
3/1/2001	TAVIST ALLERGY/SINUS/ HEADACHE	ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	500MG;EQ 0.25MG BASE;30MG	NOVARTIS
4/17/2001	IBUPROHM COLD AND SINUS	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	OHM LABS
5/31/2001	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	TEVA
6/7/2001	AVAGARD	ALCOHOL; CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	61%;1%	3M
6/13/2001	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	PERRIGO
6/29/2001	MONISTAT 1 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,1.2GM	JOHNSON AND JOHNSON
7/3/2001	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	BAUSCH AND LOMB
7/26/2001	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	ACTAVIS MID ATLANTIC
7/26/2001	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	IVAX SUB TEVA PHARMS
8/10/2001	ZYRTEC-D 12 HOUR	CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	MCNEIL
8/17/2001	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	DR REDDYS LABS LTD
10/1/2001	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	NOVEX
11/20/2001	IBUPROFEN	IBUPROFEN	TABLET; ORAL	100MG	DR REDDYS LABS INC
11/21/2001	TIOCONAZOLE	TIOCONAZOLE	OINTMENT; VAGINAL	6.5%	PERRIGO
11/26/2001	ACETAMINOPHEN, ASPIRIN AND CAFFEINE	ACETAMINOPHEN; ASPIRIN; CAFFEINE	TABLET; ORAL	250MG;250MG;65MG	PERRIGO

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11/28/2001	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	WATSON LABS
12/7/2001	LOTRIMIN ULTRA	BUTENAFINE HYDROCHLORIDE	CREAM; TOPICAL	1%	SCHERING-PLOUGH
12/12/2001	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	PERRIGO
12/12/2001	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	DR REDDYS LA
12/20/2001	PERMETHRIN	PERMETHRIN	LOTION; TOPICAL	1%	PERRIGO NEW YORK
12/21/2001	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	GENPHARM
3/14/2002	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	PERRIGO
3/15/2002	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	PERRIGO NEW YORK
3/19/2002	ACETAMINOPHEN	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	OHM LABS
4/8/2002	IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	CONTRACT PHARMACAL
4/18/2002	CHILDREN'S ADVIL COLD	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	100MG/5ML;15MG/5ML	WYETH CONS
5/30/2002	ADVIL COLD AND SINUS	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT;30MG	WYETH CONS
7/12/2002	MUCINEX	GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	600MG	RECKITT BENCKISER
7/12/2002	MUCINEX	GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	1.2GM	RECKITT BENCKISER
8/30/2002	LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET, CHEWABLE; ORAL	2MG;125MG	PERRIGO
8/30/2002	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	PERRIGO
9/10/2002	THYROSAFE	POTASSIUM IODIDE	TABLET; ORAL	65MG	RECIP
10/7/2002	CHLORAPREP ONE-STEP SEPP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	2%;70% (0.67ML)	CAREFUSION
10/7/2002	CHLORAPREP SINGLE SWABSTICK	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	2%;70% (1.75ML)	CAREFUSION
10/18/2002	MIDOL LIQUID GELS	IBUPROFEN	CAPSULE; ORAL	200MG	BANNER PHARMACAPS
10/21/2002	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	SANDOZ
10/31/2002	COMMIT	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	GLAXOSMITHKLINE CONS
10/31/2002	COMMIT	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	GLAXOSMITHKLINE CONS
12/19/2002	ALAVERT	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	WYETH CONS
12/19/2002	ADVIL ALLERGY SINUS	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	2MG;200MG;30MG	WYETH CONS
1/21/2003	LORATADINE	LORATADINE	TABLET; ORAL	10MG	SANDOZ
1/30/2003	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	IMPAX LABS
2/10/2003	LORATADINE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	WYETH CONS
2/21/2003	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	WATSON LABS FLORIDA
2/28/2003	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	WOCKHARDT
6/10/2003	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	LNK
6/20/2003	PRILOSEC OTC	OMEPRAZOLE MAGNESIUM	TABLET, DELAYED RELEASE; ORAL	EQ 20MG BASE	ASTRAZENECA
8/18/2003	LORATADINE	LORATADINE	TABLET; ORAL	10MG	RANBAXY

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8/20/2003	LORATADINE	LORATADINE	TABLET; ORAL	10MG	MYLAN
8/22/2003	FAMOTIDINE	FAMOTIDINE	TABLET, CHEWABLE; ORAL	10MG	PERRIGO
9/29/2003	LORATADINE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	IMPAX LABS
11/3/2003	LORATADINE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	WATSON LABS FLORIDA
11/5/2003	IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	100MG/5ML;15MG/5ML	PERRIGO
11/7/2003	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	TEVA
11/26/2003	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	ADVENT PHARMS
1/7/2004	CHILDREN'S ELIXSURE	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	ALTERNA TCHP LLC
1/16/2004	IBUPROFEN	IBUPROFEN	TABLET, CHEWABLE; ORAL	50MG	PERRIGO
1/16/2004	IBUPROFEN	IBUPROFEN	TABLET, CHEWABLE; ORAL	100MG	PERRIGO
1/28/2004	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	WATSON LABS FLORIDA
2/24/2004	CHILDREN'S ADVIL ALLERGY SINUS	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	1MG/5ML; 100MG/5ML; 15MG/5ML	WYETH CONS
3/4/2004	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	IMPAX LABS
3/16/2004	CHILDREN'S ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	PFIZER
3/16/2004	CHILDREN'S ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	PFIZER
3/16/2004	CHILDREN'S ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	PFIZER
3/16/2004	CHILDREN'S ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	PFIZER
3/17/2004	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	EQ 200MG BASE;120MG	PERRIGO
3/26/2004	MICONAZOLE 7 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,100MG	G AND W LABS
3/30/2004	MICONAZOLE 3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%,4%	PERRIGO
4/29/2004	MUCINEX DM	DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	60MG;1.2GM	RECKITT BENCKISER
4/29/2004	MUCINEX DM	DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	30MG;600MG	RECKITT BENCKISER
6/17/2004	IBUPROFEN	IBUPROFEN	TABLET; ORAL	100MG	LNK
6/22/2004	MUCINEX D	GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	600MG;60MG	RECKITT BENCKISER
6/22/2004	MUCINEX D	GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	1.2GM;120MG	RECKITT BENCKISER
6/25/2004	LORATADINE	LORATADINE	TABLET; ORAL	10MG	PERRIGO
7/29/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	WATSON LABS
7/29/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	WATSON LABS
8/20/2004	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	PERRIGO
8/20/2004	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	WOCKHARDT
8/20/2004	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	RANBAXY
8/20/2004	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	TARO
8/24/2004	THEROXIDIL	MINOXIDIL	SOLUTION; TOPICAL	5%	HARMONY LABS

Source: FDA.gov

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8/27/2004	DOXYLAMINE SUCCINATE	DOXYLAMINE SUCCINATE	TABLET; ORAL	25MG	LNK
8/31/2004	ZANTAC 150	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	BOEHRINGER INGELHEIM
8/31/2004	ZANTAC 150	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	BOEHRINGER INGELHEIM
9/16/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	PERRIGO
9/16/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	PERRIGO
9/16/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	PERRIGO
9/16/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	PERRIGO
9/16/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	PERRIGO
9/16/2004	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	PERRIGO
9/22/2004	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	RANBAXY
10/5/2004	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	APOTEX INC
10/5/2004	LORATADINE	LORATADINE	SYRUP; ORAL	5MG/5ML	APOTEX INC
1/12/2005	THYROSHIELD	POTASSIUM IODIDE	SOLUTION; ORAL	65MG/ML	FLEMING
3/2/2005	MICONAZOLE 3	MICONAZOLE NITRATE	CREAM; VAGINAL	4%	TARO
3/7/2005	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	WOCKHARDT
3/18/2005	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	PERRIGO
4/25/2005	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	CLOTH; TOPICAL	2%	SAGE PRODS
6/3/2005	CHLORASCRUB SWAB	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	3.15%;70% (1ML)	SOLUMED
6/3/2005	CHLORASCRUB SWABSTICK	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	3.15%;70% (1.6ML)	SOLUMED
6/3/2005	CHLORASCRUB MAXI SWABSTICK	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	3.15%;70% (5.1ML)	SOLUMED
6/21/2005	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	PERRIGO R&D
8/4/2005	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	CAPSULE; ORAL	1MG	BANNER PHARMACAPS
8/4/2005	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	CAPSULE; ORAL	2MG	BANNER PHARMACAPS
9/28/2005	PSEUDOEPHEDRINE HYDROCHLORIDE	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	120MG	RANBAXY
10/4/2005	LORATADINE	LORATADINE	SUSPENSION; ORAL	1MG/ML	TARO
12/21/2005	ADVIL PM	DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN	CAPSULE; ORAL	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	WYETH CONS
12/21/2005	ADVIL PM	DIPHENHYDRAMINE CITRATE; IBUPROFEN	TABLET; ORAL	38MG;200MG	WYETH CONS
1/20/2006	MEN'S ROGAINE	MINOXIDIL	AEROSOL, FOAM; TOPICAL	5%	JOHNSON AND JOHNSON
1/31/2006	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	PERRIGO R&D
1/31/2006	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	PERRIGO R&D
2/14/2006	LORATADINE	LORATADINE	TABLET; ORAL	10MG	APOTEX INC
2/17/2006	NAPROXEN SODIUM	NAPROXEN SODIUM	CAPSULE; ORAL	EQ 200MG BASE	BANNER PHARMACAPS
2/24/2006	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	WOCKHARDT
5/9/2006	KETOTIFEN FUMARATE	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	APOTEX INC
6/29/2006	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	SILARX
7/21/2006	ANTHELIOS SX	AVOBENZONE; ECAMSULE; OCTOCRYLENE	CREAM; TOPICAL	2%;2%;10%	L'OREAL USA
7/24/2006	LAMISIL AT	TERBINAFINE	GEL; TOPICAL	1%	NOVARTIS
8/14/2006	IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	DR REDDYS LABS LTD
8/23/2006	CHILDREN'S CLARITIN	LORATADINE	TABLET, CHEWABLE; ORAL	5MG	SCHERING-PLOUGH

Source: FDA.gov

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9/6/2006	LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET; ORAL	2MG;125MG	RANBAXY
9/25/2006	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	PERRIGO
9/25/2006	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	DR REDDYS LABS LTD
9/27/2006	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	EQ 220MG BASE;120MG	DR REDDYS LABS INC
9/29/2006	DURAPREP	IODINE POVACRYLEX; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	EQ 0.7% IODINE;74% (6ML)	3M
9/29/2006	DURAPREP	IODINE POVACRYLEX; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	EQ 0.7% IODINE;74% (26ML)	3M
10/2/2006	CAPITAL SOLEIL 15	AVOBENZONE; ECAMSULE; OCTOCRYLENE	CREAM; TOPICAL	2%;3%;10%	L'OREAL USA
10/5/2006	ANTHELIOS 20	AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	CREAM; TOPICAL	2%;2%;10%;2%	L'OREAL USA
10/6/2006	MIRALAX	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	SCHERING-PLOUGH
10/30/2006	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	PERRIGO R&D
10/30/2006	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	PERRIGO R&D
12/1/2006	ALAWAY	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	BAUSCH AND LOMB
12/12/2006	CLARITIN REDITABS	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	5MG	SCHERING-PLOUGH
2/7/2007	ALLI	ORLISTAT	CAPSULE; ORAL	60MG	GLAXOSMITHKLINE CONS
4/11/2007	LORATADINE REDIDOSE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	RANBAXY
5/24/2007	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	PERRIGO R&D
5/24/2007	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	PERRIGO R&D
6/19/2007	THRIVE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	NOVARTIS
6/19/2007	THRIVE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	NOVARTIS
7/2/2007	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	CREAM; TOPICAL	1%	TARO
7/26/2007	KETOTIFEN FUMARATE	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	AKORN
8/31/2007	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	DR REDDYS LABS LTD
9/7/2007	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	QPHARMA
11/9/2007	THEROXIDIL	MINOXIDIL	SOLUTION; TOPICAL	2%	HARMONY LABS
11/16/2007	CHILDREN'S ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	MCNEIL CONSUMER
11/16/2007	CHILDREN'S ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	MCNEIL CONSUMER
11/26/2007	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	WOCKHARDT
12/4/2007	OMEPRAZOLE	OMEPRAZOLE	TABLET, DELAYED RELEASE; ORAL	20MG	DEXCEL PHARMA
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	CONTRACT PHARMA
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	CONTRACT PHARMA
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	MYLAN
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	MYLAN
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	MYLAN

Source: FDA.gov

FDA OTC Approvals On The Market: By Action Date

Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	MYLAN
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	RANBAXY
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	RANBAXY
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	RANBAXY
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	RANBAXY
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	CARACO
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	CARACO
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	CARACO
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	CARACO
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	SANDOZ
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	SANDOZ
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	APOTEX INC
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	APOTEX INC
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	PERRIGO R&D
12/27/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	PERRIGO R&D
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	PERRIGO R&D
12/27/2007	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	PERRIGO R&D
12/28/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	WOCKHARDT
12/28/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	WOCKHARDT
12/28/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	ACTAVIS ELIZABETH
12/28/2007	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	ACTAVIS ELIZABETH
1/11/2008	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	CARACO
1/11/2008	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	CARACO
1/11/2008	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	CARACO

Source: FDA.gov

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Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
1/11/2008	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	CARACO
1/15/2008	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	DR REDDYS LABS LTD
1/15/2008	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	DR REDDYS LABS LTD
1/15/2008	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	DR REDDYS LABS LTD
1/15/2008	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	DR REDDYS LABS LTD
2/6/2008	CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE	CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE	TABLET, CHEWABLE; ORAL	800MG;10MG;165MG	PERRIGO R&D
2/14/2008	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	SANDOZ
2/14/2008	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	SANDOZ
2/20/2008	SALONPAS	MENTHOL; METHYL SALICYLATE	PATCH; TOPICAL	3%;10%	HISAMITSU
2/25/2008	CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE	CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	IVAX SUB TEVA PHARMS
3/5/2008	CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE	CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	SANDOZ
3/31/2008	ANTHELIOS 40	AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	CREAM; TOPICAL	2%;3%;10%;5%	L'OREAL USA
3/31/2008	ANTHELIOS 40	AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	CREAM; TOPICAL	2%;3%;10%;5%	L'OREAL USA
4/9/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	PERRIGO R&D
4/9/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	PERRIGO R&D
4/22/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	TARO
4/22/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	TARO
4/23/2008	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	PERRIGO R&D
4/23/2008	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	PERRIGO R&D
4/24/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	RANBAXY
4/24/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	RANBAXY
6/16/2008	CLARITIN	LORATADINE	CAPSULE; ORAL	10MG	SCHERING-PLOUGH
7/31/2008	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	WOCKHARDT
9/2/2008	KETOTIFEN FUMARATE	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	ALCON
10/10/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	CYPRESS PHARM

Source: FDA.gov

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10/10/2008	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	CYPRESS PHARM
11/7/2008	LORATADINE	LORATADINE	TABLET; ORAL	10MG	MYLAN
12/16/2008	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	AMNEAL PHARMS NY
12/22/2008	IBUPROFEN AND DIPHENHYDRAMINE CITRATE	DIPHENHYDRAMINE CITRATE; IBUPROFEN	TABLET; ORAL	38MG;200MG	PERRIGO R&D
12/29/2008	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	WATSON LABS
12/29/2008	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	WATSON LABS
2/18/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	IVAX SUB TEVA PHARMS
2/18/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	IVAX SUB TEVA PHARMS
2/19/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	ORCHID HLTHCARE
2/19/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	ORCHID HLTHCARE
2/19/2009	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	ORCHID HLTHCARE
2/19/2009	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	ORCHID HLTHCARE
3/24/2009	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	BANNER PHARMACAPS
3/30/2009	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	DR REDDYS LABS LTD
3/30/2009	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	DR REDDYS LABS LTD
5/13/2009	CHLORPHENIRAMINE MALEATE	CHLORPHENIRAMINE MALEATE	TABLET, EXTENDED RELEASE; ORAL	12MG	AVANTHI INC
5/18/2009	PREVACID 24 HR	LANSOPRAZOLE	CAPSULE, DELAYED REL PELLETS; ORAL	15MG	NOVARTIS
5/18/2009	NICORETTE	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	GLAXOSMITHKLINE CONS
5/18/2009	NICORETTE	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	GLAXOSMITHKLINE CONS
6/5/2009	OMEPRAZOLE MAGNESIUM	OMEPRAZOLE MAGNESIUM	CAPSULE, DELAYED RELEASE; ORAL	EQ 20MG BASE	DR REDDYS LABS LTD
6/26/2009	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	UNICHEM
6/26/2009	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	UNICHEM
6/26/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	UNICHEM
6/26/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	UNICHEM
6/26/2009	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	MARKSANS PHARMA
7/8/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	WATSON LABS
7/8/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	WATSON LABS
7/8/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	WATSON LABS
7/8/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	WATSON LABS
7/8/2009	IBUPROFEN AND DIPHENHYDRAMINE CITRATE	DIPHENHYDRAMINE CITRATE; IBUPROFEN	TABLET; ORAL	38MG;200MG	DR REDDYS LABS LTD
7/10/2009	PLAN B ONE-STEP	LEVONORGESTREL	TABLET; ORAL	1.5MG	DURAMED
7/10/2009	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	DR REDDYS LABS LTD
7/10/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	PERRIGO R&D

Source: FDA.gov

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7/10/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	PERRIGO R&D
7/10/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	PERRIGO R&D
7/10/2009	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	PERRIGO R&D
7/22/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	TARO
7/22/2009	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	TARO
7/22/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	TARO
7/22/2009	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	TARO
7/23/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	5MG	BANNER PHARMACAPS
7/23/2009	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	10MG	BANNER PHARMACAPS
7/23/2009	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	5MG	BANNER PHARMACAPS
7/23/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	10MG	BANNER PHARMACAPS
8/26/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	UNIQUE PHARM LABS
8/26/2009	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	UNIQUE PHARM LABS
8/26/2009	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	UNIQUE PHARM LABS
8/26/2009	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	UNIQUE PHARM LABS
8/28/2009	LEVONORGESTREL	LEVONORGESTREL	TABLET; ORAL	0.75MG	WATSON LABS
8/31/2009	IBUPROFEN	IBUPROFEN	SUSPENSION/DROPS; ORAL	40MG/ML	TRIS PHARMA INC
10/6/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/PACKET	MYLAN
10/6/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	MYLAN
10/6/2009	GLYCOLAX	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/PACKET	KREMERS URBAN PHARMS
10/6/2009	GLYCOLAX	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	KREMERS URBAN PHARMS
10/6/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/PACKET	PERRIGO R&D
10/6/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	PERRIGO R&D
10/6/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	NOVEL LABS INC
10/7/2009	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	AMNEAL PHARMS
10/7/2009	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	AMNEAL PHARMS
10/7/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	NEXGEN PHARMA
10/15/2009	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	PADDOCK
11/17/2009	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	RANBAXY
11/17/2009	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	RANBAXY

Source: FDA.gov

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Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
11/18/2009	ACETAMINOPHEN	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	RANBAXY
11/25/2009	NEXCEDE	KETOPROFEN	FILM; ORAL	12.5MG	NOVARTIS
12/1/2009	ZEGERID OTC	OMEPRAZOLE; SODIUM BICARBONATE	CAPSULE; ORAL	20MG;1.1GM	SCHERING-PLOUGH
1/15/2010	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	4%	PERRIGO R&D
1/21/2010	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	AMNEAL PHARMS NY
1/21/2010	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	AMNEAL PHARMS NY
1/21/2010	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	AMNEAL PHARMS NY
1/21/2010	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	AMNEAL PHARMS NY
2/2/2010	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	AUROBINDO PHARMA
2/2/2010	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	AUROBINDO PHARMA
4/15/2010	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	TORRENT PHARMS LLC
4/15/2010	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	TORRENT PHARMS LLC
4/15/2010	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	TORRENT PHARMS LLC
4/15/2010	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	TORRENT PHARMS LLC
5/27/2010	ADVIL CONGESTION RELIEF	IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	TABLET; ORAL	200MG;10MG	WYETH CONS
6/2/2010	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,1.2GM	PERRIGO R&D
6/2/2010	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%	PERRIGO R&D
6/15/2010	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	CADISTA PHARMS
6/15/2010	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	CADISTA PHARMS
6/15/2010	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	CADISTA PHARMS
6/15/2010	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	CADISTA PHARMS
8/4/2010	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	WOCKHARDT
9/3/2010	ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	MCNEIL CONSUMER
9/27/2010	NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.02675%;0.315%	ALTAIRE PHARMS INC
11/22/2010	IBUPROFEN AND DIPHENHYDRAMINE	DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN	CAPSULE; ORAL	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	BANNER PHARMACAPS
12/10/2010	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	GRANULES INDIA
12/30/2010	LEVONORGESTREL	LEVONORGESTREL	TABLET; ORAL	0.75MG	PERRIGO R&D
12/30/2010	LEVONORGESTREL	LEVONORGESTREL	TABLET; ORAL	0.75MG	PERRIGO R&D

Source: FDA.gov

FDA OTC Approvals On The Market: By Action Date

Action Date	Drug Name	Active Ingredient	Form	Dosage	Sponsor Applicant
1/24/2011	ALLEGRA ALLERGY; ALLEGRA HIVES	FEXOFENADINE HYDROCHLORIDE	SUSPENSION; ORAL	30MG/5ML	SANOFI-AVENTIS US
2/1/2011	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	MARKSANS PHARMA
2/8/2011	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	MARKSANS PHARMA
—	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	APOTEX
—	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	APOTEX
—	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	ACTAVIS MID ATLANTIC
—	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	ACTAVIS MID ATLANTIC

Source: FDA.gov
Notes:
This listing contains over-the-counter human drugs currently approved by FDA for sale in the United States.
This listing does not include over-the-counter products approved for marketing by FDA through a process other than submission of a New Drug Application or Biologic License Application. Also excluded are dietary supplements, which do not require FDA approval to be sold in the United States.

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
3M	AVAGARD	ALCOHOL; CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	61%;1%	6/7/2001
3M	DURAPREP	IODINE POVACRYLEX; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	EQ 0.7% IODINE;74% (6ML)	9/29/2006
3M	DURAPREP	IODINE POVACRYLEX; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	EQ 0.7% IODINE;74% (26ML)	9/29/2006
ACTAVIS ELIZABETH	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/28/2007
ACTAVIS ELIZABETH	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/28/2007
ACTAVIS MID ATLANTIC	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	4/22/1980
ACTAVIS MID ATLANTIC	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	325MG	4/22/1980
ACTAVIS MID ATLANTIC	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	4/22/1980
ACTAVIS MID ATLANTIC	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	—
ACTAVIS MID ATLANTIC	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	—
ACTAVIS MID ATLANTIC	CLOTRIMAZOLE	CLOTRIMAZOLE	CREAM; VAGINAL	1%	7/16/1993
ACTAVIS MID ATLANTIC	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	7/26/2001
ACTAVIS MID ATLANTIC	IBUPROFEN	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	4/30/1999
ACTAVIS MID ATLANTIC	INFANTS' FEVERALL	ACETAMINOPHEN	SUPPOSITORY; RECTAL	80MG	4/22/1980
ACTAVIS MID ATLANTIC	MICONAZOLE 7	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	3/29/1996
ACTAVIS MID ATLANTIC	MICONAZOLE NITRATE	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	11/19/1993
ACTAVIS MID ATLANTIC	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	4/5/1996
ACTAVIS MID ATLANTIC	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	11/17/2000
ACTAVIS MID ATLANTIC	M-ZOLE 3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,200MG	4/16/1999

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
ACTAVIS MID ATLANTIC	M-ZOLE 7 DUAL PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,100MG	7/17/1997
ACTAVIS MID ATLANTIC	PERMETHRIN	PERMETHRIN	LOTION; TOPICAL	1%	3/28/2000
ADVENT PHARMS	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	11/26/2003
AKORN	KETOTIFEN FUMARATE	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	7/26/2007
ALCON	KETOTIFEN FUMARATE	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	9/2/2008
ALCON	NAPHCON-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.025%;0.3%	6/8/1994
ALLEGIANCE HLTHCARE	POVIDONE IODINE	POVIDONE-IODINE	SOLUTION; TOPICAL	1%	3/31/1989
ALRA	IBU-TAB 200	IBUPROFEN	TABLET; ORAL	200MG	8/11/1988
ALTAIRE PHARMS INC	NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.02675%;0.315%	9/27/2010
ALTERNA TCHP LLC	CHILDREN'S ELIXSURE	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	1/7/2004
AMNEAL PHARMS	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	10/7/2009
AMNEAL PHARMS	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	10/7/2009
AMNEAL PHARMS NY	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	1/21/2010
AMNEAL PHARMS NY	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	1/21/2010
AMNEAL PHARMS NY	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	1/21/2010
AMNEAL PHARMS NY	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	1/21/2010
AMNEAL PHARMS NY	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	2/17/1987
AMNEAL PHARMS NY	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	5/23/1988
AMNEAL PHARMS NY	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	12/16/2008
ANBEX	IOSAT	POTASSIUM IODIDE	TABLET; ORAL	130MG	10/14/1982
APOTEX	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	—
APOTEX	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	—
APOTEX INC	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
APOTEX INC	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
APOTEX INC	KETOTIFEN FUMARATE	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	5/9/2006
APOTEX INC	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	10/5/2004
APOTEX INC	LORATADINE	LORATADINE	SYRUP; ORAL	5MG/5ML	10/5/2004
APOTEX INC	LORATADINE	LORATADINE	TABLET; ORAL	10MG	2/14/2006
ARMSTRONG PHARMS	EPINEPHRINE	EPINEPHRINE	AEROSOL, METERED; INHALATION	0.2MG/INH	5/23/1984
ASTRAZENECA	PRILOSEC OTC	OMEPRAZOLE MAGNESIUM	TABLET, DELAYED RELEASE; ORAL	EQ 20MG BASE	6/20/2003

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
AUROBINDO PHARMA	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	2/2/2010
AUROBINDO PHARMA	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	2/2/2010
AVACOR PRODS	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	11/17/2000
AVANTHI INC	CHLORPHENIRAMINE MALEATE	CHLORPHENIRAMINE MALEATE	TABLET, EXTENDED RELEASE; ORAL	12MG	5/13/2009
AVEVA	NICOTINE	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	14MG/24HR	10/20/1997
AVEVA	NICOTINE	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	21MG/24HR	10/20/1997
AVEVA	NICOTINE	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	7MG/24HR	10/20/1997
AZTIQ PHARMA	TODAY	NONOXYNOL-9	SPONGE; VAGINAL	1GM	4/1/1983
BANNER PHARMACAPS	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	5MG	7/23/2009
BANNER PHARMACAPS	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	10MG	7/23/2009
BANNER PHARMACAPS	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	10MG	7/23/2009
BANNER PHARMACAPS	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	CAPSULE; ORAL	5MG	7/23/2009
BANNER PHARMACAPS	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	3/24/2009
BANNER PHARMACAPS	IBUPROFEN AND DIPHENHYDRAMINE	DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN	CAPSULE; ORAL	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	11/22/2010
BANNER PHARMACAPS	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	CAPSULE; ORAL	1MG	8/4/2005
BANNER PHARMACAPS	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	CAPSULE; ORAL	2MG	8/4/2005
BANNER PHARMACAPS	MIDOL LIQUID GELS	IBUPROFEN	CAPSULE; ORAL	200MG	10/18/2002
BANNER PHARMACAPS	NAPROXEN SODIUM	NAPROXEN SODIUM	CAPSULE; ORAL	EQ 200MG BASE	2/17/2006
BAUSCH AND LOMB	ALAWAY	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	12/1/2006
BAUSCH AND LOMB	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	7/3/2001
BAUSCH AND LOMB	OPCON-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.02675%;0.315%	6/8/1994
BAYER	ALEVE	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	1/11/1994
BAYER	ALEVE-D SINUS & COLD	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	200MG;120MG	11/29/1999
BAYER	FEMSTAT 3	BUTOCONAZOLE NITRATE	CREAM; VAGINAL	2%	12/21/1995
BAYER HLTHCARE	MYCELEX	CLOTRIMAZOLE	Solution; Topical	1%	1/15/1979
BAYER PHARMACEUTICALS	MYCELEX-7	CLOTRIMAZOLE	TABLET; VAGINAL	100MG	2/27/1979
BAYER PHARMACEUTICALS	MYCELEX-7	CLOTRIMAZOLE	CREAM; VAGINAL	1%	2/16/1979
BAYER PHARMACEUTICALS	MYCELEX-7 COMBINATION PACK	CLOTRIMAZOLE	CREAM, TABLET; TOPICAL, VAGINAL	1%,100MG	6/23/1994
BECTON, DICKINSON	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	10/24/1989
BECTON, DICKINSON	E-Z SCRUB 201	POVIDONE-IODINE	SPONGE; TOPICAL	20%	11/29/1985
BECTON, DICKINSON	E-Z SCRUB 241	POVIDONE-IODINE	SPONGE; TOPICAL	10%	1/7/1987

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
BLAIREX	BRONCHO SALINE	SODIUM CHLORIDE	AEROSOL, METERED; INHALATION	0.9%	9/3/1992
BOEHRINGER INGELHEIM	ZANTAC 150	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	8/31/2004
BOEHRINGER INGELHEIM	ZANTAC 150	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	8/31/2004
BOEHRINGER INGELHEIM	ZANTAC 75	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	12/19/1995
CADISTA PHARMS	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	6/15/2010
CADISTA PHARMS	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	6/15/2010
CADISTA PHARMS	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	6/15/2010
CADISTA PHARMS	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	6/15/2010
CARACO	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
CARACO	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
CARACO	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	1/11/2008
CARACO	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	1/11/2008
CARACO	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
CARACO	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
CARACO	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	1/11/2008
CARACO	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	1/11/2008
CAREFUSION	CHLORAPREP ONE-STEP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (3ML)	7/14/2000
CAREFUSION	CHLORAPREP ONE-STEP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (10.5ML)	7/14/2000
CAREFUSION	CHLORAPREP ONE-STEP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (26ML)	7/14/2000
CAREFUSION	CHLORAPREP ONE-STEP FREPP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (1.5ML)	7/14/2000
CAREFUSION	CHLORAPREP ONE-STEP SEPP	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	2%;70% (0.67ML)	10/7/2002
CAREFUSION	CHLORAPREP SINGLE SWABSTICK	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	2%;70% (1.75ML)	10/7/2002
CAREFUSION	CHLORAPREP WITH TINT	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (26ML)	7/14/2000
CAREFUSION	CHLORAPREP WITH TINT	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (10.5ML)	7/14/2000

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
CAREFUSION	CHLORAPREP WITH TINT	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70% (3ML)	7/14/2000
CHATTEM	UNISOM	DOXYLAMINE SUCCINATE	TABLET; ORAL	25MG	10/18/1978
COLGATE PALMOLIVE	COLGATE TOTAL	SODIUM FLUORIDE; TRICLOSAN	PASTE; DENTAL	0.24%;0.3%	7/11/1997
CONTRACT PHARMA	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
CONTRACT PHARMA	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
CONTRACT PHARMACAL	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	6/19/1998
CONTRACT PHARMACAL	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	6/19/1998
CONTRACT PHARMACAL	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	9/10/1987
CONTRACT PHARMACAL	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	9/10/1987
CONTRACT PHARMACAL	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	7/1/1988
CONTRACT PHARMACAL	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	2/25/1994
CONTRACT PHARMACAL	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	200MG	7/6/1998
CONTRACT PHARMACAL	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	7/20/1998
CONTRACT PHARMACAL	IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	4/8/2002
CONTRACT PHARMACAL	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	7/30/1993
CONTRACT PHARMACAL	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	1/13/1997
CONTRACT PHARMACAL	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	2/27/1997
CONTRACT PHARMACAL	PROFEN	IBUPROFEN	TABLET; ORAL	200MG	10/15/1986
CONTRACT PHARMACAL	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	6/21/1999
CYPRESS PHARM	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	10/10/2008
CYPRESS PHARM	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	10/10/2008
DEXCEL PHARMA	OMEPRAZOLE	OMEPRAZOLE	TABLET, DELAYED RELEASE; ORAL	20MG	12/4/2007
DR REDDYS LA	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	12/12/2001
DR REDDYS LABS INC	IBUPROFEN	IBUPROFEN	TABLET; ORAL	100MG	11/20/2001
DR REDDYS LABS INC	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	7/28/1998
DR REDDYS LABS INC	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	EQ 220MG BASE;120MG	9/27/2006
DR REDDYS LABS LTD	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	1/15/2008
DR REDDYS LABS LTD	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	1/15/2008
DR REDDYS LABS LTD	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	1/15/2008
DR REDDYS LABS LTD	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	1/15/2008
DR REDDYS LABS LTD	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	3/30/2009
DR REDDYS LABS LTD	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	3/30/2009
DR REDDYS LABS LTD	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	8/17/2001

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
DR REDDYS LABS LTD	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	9/25/2006
DR REDDYS LABS LTD	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	7/10/2009
DR REDDYS LABS LTD	IBUPROFEN AND DIPHENHYDRAMINE CITRATE	DIPHENHYDRAMINE CITRATE; IBUPROFEN	TABLET; ORAL	38MG;200MG	7/8/2009
DR REDDYS LABS LTD	IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	8/14/2006
DR REDDYS LABS LTD	OMEPRAZOLE MAGNESIUM	OMEPRAZOLE MAGNESIUM	CAPSULE, DELAYED RELEASE; ORAL	EQ 20MG BASE	6/5/2009
DR REDDYS LABS LTD	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	3/28/2000
DR REDDYS LABS LTD	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	8/31/2007
DURAMED	PLAN B	LEVONORGESTREL	TABLET; ORAL	0.75MG	7/28/1999
DURAMED	PLAN B ONE-STEP	LEVONORGESTREL	TABLET; ORAL	1.5MG	7/10/2009
ECOLAB	CHG SCRUB	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	7/22/1986
ECOLAB	CIDA-STAT	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	2%	7/22/1986
FLEMING	THYROSHIELD	POTASSIUM IODIDE	SOLUTION; ORAL	65MG/ML	1/12/2005
G AND W LABS	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	2/9/1978
G AND W LABS	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	2/9/1978
G AND W LABS	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	325MG	2/9/1978
G AND W LABS	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	3/27/1992
G AND W LABS	ACEPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	325MG	3/27/1992
G AND W LABS	MICONAZOLE 7 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,100MG	3/26/2004
G AND W LABS	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	2/22/1996
G AND W LABS	MICONAZOLE NITRATE	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	4/30/1997
GENPHARM	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	12/21/2001
GENPHARM	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	1/14/2000
GLAXOSMITHKLINE	ABREVA	DOCOSANOL	CREAM; TOPICAL	10%	7/25/2000
GLAXOSMITHKLINE	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	1/13/1984
GLAXOSMITHKLINE	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	1/13/1984
GLAXOSMITHKLINE	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	6/8/1992
GLAXOSMITHKLINE	NICORETTE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	6/8/1992
GLAXOSMITHKLINE	NICORETTE (MINT)	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	1/13/1984
GLAXOSMITHKLINE	NICORETTE (MINT)	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	6/8/1992
GLAXOSMITHKLINE	TAGAMET HB	CIMETIDINE	TABLET; ORAL	200MG	6/19/1995
GLAXOSMITHKLINE CONS	ALLI	ORLISTAT	CAPSULE; ORAL	60MG	2/7/2007
GLAXOSMITHKLINE CONS	COMMIT	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	10/31/2002
GLAXOSMITHKLINE CONS	COMMIT	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	10/31/2002
GLAXOSMITHKLINE CONS	NICORETTE	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	5/18/2009
GLAXOSMITHKLINE CONS	NICORETTE	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	5/18/2009
GRANULES INDIA	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	12/10/2010
GRIFFEN	BIOSCRUB	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	3/31/1989
GUARDIAN DRUG	FOAMCOAT	ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE	TABLET, CHEWABLE; ORAL	80MG;20MG	9/4/1987

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
HARMONY LABS	THEROXIDIL	MINOXIDIL	SOLUTION; TOPICAL	5%	8/24/2004
HARMONY LABS	THEROXIDIL	MINOXIDIL	SOLUTION; TOPICAL	2%	11/9/2007
HI TECH PHARMA	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	11/17/1995
HI TECH PHARMA	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	12/24/1996
HI TECH PHARMA	MINOXIDIL (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	12/24/1996
HISAMITSU	SALONPAS	MENTHOL; METHYL SALICYLATE	PATCH; TOPICAL	3%;10%	2/20/2008
IMPAX LABS	LORATADINE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	9/29/2003
IMPAX LABS	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	3/4/2004
IMPAX LABS	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	1/30/2003
INSIGHT PHARMS	NIX	PERMETHRIN	LOTION; TOPICAL	1%	5/2/1990
IVAX SUB TEVA PHARMS	CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE	CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	2/25/2008
IVAX SUB TEVA PHARMS	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	6/16/1999
IVAX SUB TEVA PHARMS	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	7/26/2001
IVAX SUB TEVA PHARMS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	2/18/2009
IVAX SUB TEVA PHARMS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	2/18/2009
IVAX SUB TEVA PHARMS	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	1/14/2000
JOHNSON AND JOHNSON	MEN'S ROGAINE	MINOXIDIL	AEROSOL, FOAM; TOPICAL	5%	1/20/2006
JOHNSON AND JOHNSON	MONISTAT 1 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,1.2GM	6/29/2001
JOHNSON AND JOHNSON	MONISTAT 3	MICONAZOLE NITRATE	CREAM; VAGINAL	4%	3/30/1998
JOHNSON AND JOHNSON	MONISTAT 3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%,4%	2/2/2001
JOHNSON AND JOHNSON	MONISTAT 3 COMBINATION PACK (PREFILLED)	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%,4%	2/2/2001
JOHNSON AND JOHNSON	MONISTAT 7	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	1/30/1974
JOHNSON AND JOHNSON	MONISTAT 7	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	3/15/1982
JOHNSON AND JOHNSON	MONISTAT 7 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,100MG	4/26/1993
JOHNSON AND JOHNSON	MONISTAT-3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,200MG	4/16/1996
JOHNSON AND JOHNSON	ROGAINE (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	8/17/1988
JOHNSON AND JOHNSON	ROGAINE (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	8/17/1988
JOHNSON AND JOHNSON	ROGAINE EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	11/14/1997
JOHNSON AND JOHNSON	VISINE L.R.	OXYMETAZOLINE HYDROCHLORIDE	SOLUTION/DROPS; OPHTHALMIC	0.025%	3/31/1989
JOHNSON AND JOHNSON	VISINE-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	SOLUTION/DROPS; OPHTHALMIC	0.025%;0.3%	1/31/1996
KREMERS URBAN PHARMS	GLYCOLAX	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/PACKET	10/6/2009
KREMERS URBAN PHARMS	GLYCOLAX	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/6/2009

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
LILLY	HUMULIN 70/30	INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	30 UNITS/ML;70 UNITS/ML	4/25/1989
LILLY	HUMULIN 70/30 PEN	INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	30 UNITS/ML;70 UNITS/ML	4/25/1989
LILLY	HUMULIN N	INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	10/28/1982
LILLY	HUMULIN R	INSULIN RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	10/28/1982
LILLY	HUMULIN R PEN	INSULIN RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	10/28/1982
LNK	DOXYLAMINE SUCCINATE	DOXYLAMINE SUCCINATE	TABLET; ORAL	25MG	8/27/2004
LNK	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	3/1/1999
LNK	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	3/1/1999
LNK	IBUPROFEN	IBUPROFEN	TABLET; ORAL	100MG	6/17/2004
LNK	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	6/10/2003
L'OREAL USA	ANTHELIOS 20	AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	CREAM; TOPICAL	2%;2%;10%;2%	10/5/2006
L'OREAL USA	ANTHELIOS 40	AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	CREAM; TOPICAL	2%;3%;10%;5%	3/31/2008
L'OREAL USA	ANTHELIOS 40	AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	CREAM; TOPICAL	2%;3%;10%;5%	3/31/2008
L'OREAL USA	ANTHELIOS SX	AVOBENZONE; ECAMSULE; OCTOCRYLENE	CREAM; TOPICAL	2%;2%;10%	7/21/2006
L'OREAL USA	CAPITAL SOLEIL 15	AVOBENZONE; ECAMSULE; OCTOCRYLENE	CREAM; TOPICAL	2%;3%;10%	10/2/2006
MARKSANS PHARMA	IBUPROFEN	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	6/26/2009
MARKSANS PHARMA	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	2/8/2011
MARKSANS PHARMA	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	2/1/2011
MCNEIL	CHILDREN'S MOTRIN	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	6/16/1995
MCNEIL	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	3/30/1994
MCNEIL	IMODIUM A-D EZ CHEWS	LOPERAMIDE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	2MG	7/24/1997
MCNEIL	IMODIUM MULTI-SYMPTOM RELIEF	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET, CHEWABLE; ORAL	2MG;125MG	6/26/1997
MCNEIL	MOTRIN IB	IBUPROFEN	TABLET; ORAL	200MG	5/18/1984
MCNEIL	MOTRIN MIGRAINE PAIN	IBUPROFEN	TABLET; ORAL	200MG	5/18/1984
MCNEIL	ZYRTEC-D 12 HOUR	CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	8/10/2001
MCNEIL CONS	CHILDREN'S MOTRIN	IBUPROFEN	TABLET, CHEWABLE; ORAL	50MG	11/15/1996
MCNEIL CONS	CHILDREN'S MOTRIN	IBUPROFEN	SUSPENSION/DROPS; ORAL	40MG/ML	6/10/1996
MCNEIL CONS	CHILDREN'S MOTRIN COLD	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	100MG/5ML;15MG/5ML	8/1/2000
MCNEIL CONS	IMODIUM A-D	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	3/1/1988

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
MCNEIL CONS	IMODIUM A-D	LOPERAMIDE HYDROCHLORIDE	SUSPENSION; ORAL	1MG/7.5ML	3/1/1988
MCNEIL CONS	IMODIUM A-D	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	11/22/1989
MCNEIL CONS	IMODIUM MULTI-SYMPTOM RELIEF	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET; ORAL	2MG;125MG	11/30/2000
MCNEIL CONS	JUNIOR STRENGTH MOTRIN	IBUPROFEN	TABLET, CHEWABLE; ORAL	100MG	11/15/1996
MCNEIL CONS	JUNIOR STRENGTH MOTRIN	IBUPROFEN	TABLET; ORAL	100MG	6/10/1996
MCNEIL CONS	NIZORAL A-D	KETOCONAZOLE	SHAMPOO; TOPICAL	1%	10/10/1997
MCNEIL CONS	SINE-AID IB	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	12/31/1992
MCNEIL CONS	SUDAFED 12 HOUR	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	120MG	10/31/1991
MCNEIL CONS	SUDAFED 24 HOUR	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	240MG	12/15/1992
MCNEIL CONS	TYLENOL (CAPLET)	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	6/8/1994
MCNEIL CONS	TYLENOL (GELTAB)	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	6/8/1994
MCNEIL CONSUMER	CHILDREN'S ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	11/16/2007
MCNEIL CONSUMER	CHILDREN'S ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	11/16/2007
MCNEIL CONSUMER	ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/8/1995
MCNEIL CONSUMER	ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/8/1995
MCNEIL CONSUMER	ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	9/3/2010
MCNEIL CONSUMER	ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/8/1995
MCNEIL CONSUMER	ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/8/1995
MERCK SHARP DOHME	PEPCID AC	FAMOTIDINE	TABLET; ORAL	10MG	4/28/1995
MERCK SHARP DOHME	PEPCID AC	FAMOTIDINE	TABLET; ORAL	20MG	4/28/1995
MERCK SHARP DOHME	PEPCID AC	FAMOTIDINE	TABLET, CHEWABLE; ORAL	20MG	9/24/1998
MERCK SHARP DOHME	PEPCID AC (GELTAB)	FAMOTIDINE	TABLET; ORAL	10MG	8/5/1999
MERCK SHARP DOHME	PEPCID COMPLETE	CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE	TABLET, CHEWABLE; ORAL	800MG;10MG;165MG	10/16/2000
MYLAN	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
MYLAN	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
MYLAN	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
MYLAN	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
MYLAN	LORATADINE	LORATADINE	TABLET; ORAL	10MG	11/7/2008
MYLAN	LORATADINE	LORATADINE	TABLET; ORAL	10MG	8/20/2003
MYLAN	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/PACKET	10/6/2009
MYLAN	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/6/2009

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
NEXGEN PHARMA	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/7/2009
NOVARTIS	EXCEDRIN (MIGRAINE)	ACETAMINOPHEN; ASPIRIN; CAFFEINE	TABLET; ORAL	250MG;250MG;65MG	1/14/1998
NOVARTIS	HABITROL	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	7MG/24HR	11/27/1991
NOVARTIS	HABITROL	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	14MG/24HR	11/27/1991
NOVARTIS	HABITROL	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	21MG/24HR	11/27/1991
NOVARTIS	LAMISIL	TERBINAFINE HYDROCHLORIDE	CREAM; TOPICAL	1%	3/9/1999
NOVARTIS	LAMISIL AT	TERBINAFINE HYDROCHLORIDE	SOLUTION; TOPICAL	1%	3/17/2000
NOVARTIS	LAMISIL AT	TERBINAFINE HYDROCHLORIDE	SPRAY; TOPICAL	1%	3/17/2000
NOVARTIS	LAMISIL AT	TERBINAFINE	GEL; TOPICAL	1%	7/24/2006
NOVARTIS	NEXCEDE	KETOPROFEN	FILM; ORAL	12.5MG	11/25/2009
NOVARTIS	PREVACID 24 HR	LANSOPRAZOLE	CAPSULE, DELAYED REL PELLETS; ORAL	15MG	5/18/2009
NOVARTIS	TAVIST ALLERGY/SINUS/ HEADACHE	ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	500MG;EQ 0.25MG BASE;30MG	3/1/2001
NOVARTIS	TAVIST-1	CLEMASTINE FUMARATE	TABLET; ORAL	1.34MG	8/21/1992
NOVARTIS	THRIVE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	6/19/2007
NOVARTIS	THRIVE	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	6/19/2007
NOVARTIS	VAGISTAT-1	TIOCONAZOLE	OINTMENT; VAGINAL	6.5%	2/11/1997
NOVARTIS	ZADITOR	KETOTIFEN FUMARATE	SOLUTION/DROPS; OPHTHALMIC	EQ 0.025% BASE	7/2/1999
NOVEL LABS INC	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/6/2009
NOVEX	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	4/29/1998
NOVEX	MINOXIDIL (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	4/29/1998
NOVEX	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	10/1/2001
NOVO NORDISK INC	NOVOLIN 70/30	INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	30 UNITS/ML;70 UNITS/ML	6/25/1991
NOVO NORDISK INC	NOVOLIN N	INSULIN SUSP ISOPHANE RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	7/1/1991
NOVO NORDISK INC	NOVOLIN R	INSULIN RECOMBINANT HUMAN	INJECTABLE; INJECTION	100 UNITS/ML	6/25/1991
OHM	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	7/15/1986
OHM LABS	ACETAMINOPHEN	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	3/19/2002
OHM LABS	IBUPROHM	IBUPROFEN	TABLET; ORAL	200MG	12/1/1986
OHM LABS	IBUPROHM COLD AND SINUS	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	4/17/2001
OHM LABS	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	12/10/1992
ORCHID HLTHCARE	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	2/19/2009
ORCHID HLTHCARE	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	2/19/2009
ORCHID HLTHCARE	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	2/19/2009

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
ORCHID HLTHCARE	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	2/19/2009
PADDOCK	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/15/2009
PAR PHARM	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	10/18/1985
PAR PHARM	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	10/2/1987
PERRIGO	ACETAMINOPHEN	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	2/25/2000
PERRIGO	ACETAMINOPHEN, ASPIRIN AND CAFFEINE	ACETAMINOPHEN; ASPIRIN; CAFFEINE	TABLET; ORAL	250MG;250MG;65MG	11/26/2001
PERRIGO	CHILDREN'S IBUPROFEN	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	12/22/1998
PERRIGO	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	10/29/1998
PERRIGO	CLEMASTINE FUMARATE	CLEMASTINE FUMARATE	TABLET; ORAL	1.34MG	11/22/1995
PERRIGO	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	12/12/2001
PERRIGO	DOXYLAMINE SUCCINATE	DOXYLAMINE SUCCINATE	TABLET; ORAL	25MG	9/18/1996
PERRIGO	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	3/18/2005
PERRIGO	FAMOTIDINE	FAMOTIDINE	TABLET, CHEWABLE; ORAL	10MG	8/22/2003
PERRIGO	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	9/25/2006
PERRIGO	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	12/8/1987
PERRIGO	IBUPROFEN	IBUPROFEN	SUSPENSION/DROPS; ORAL	40MG/ML	12/16/1998
PERRIGO	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	3/14/2002
PERRIGO	IBUPROFEN	IBUPROFEN	TABLET, CHEWABLE; ORAL	50MG	1/16/2004
PERRIGO	IBUPROFEN	IBUPROFEN	TABLET, CHEWABLE; ORAL	100MG	1/16/2004
PERRIGO	IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	100MG/5ML;15MG/5ML	11/5/2003
PERRIGO	JUNIOR STRENGTH IBUPROFEN	IBUPROFEN	TABLET; ORAL	100MG	4/22/1999
PERRIGO	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	1/21/1992
PERRIGO	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	TABLET; ORAL	2MG	1/6/2000
PERRIGO	LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET, CHEWABLE; ORAL	2MG;125MG	8/30/2002
PERRIGO	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	8/20/2004
PERRIGO	LORATADINE	LORATADINE	TABLET; ORAL	10MG	6/25/2004
PERRIGO	MICONAZOLE 3 COMBINATION PACK	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%,4%	3/30/2004
PERRIGO	MICONAZOLE NITRATE	MICONAZOLE NITRATE	SUPPOSITORY; VAGINAL	100MG	3/20/1997
PERRIGO	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	5/15/1997
PERRIGO	MICONAZOLE NITRATE COMBINATION PACK	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,200MG	4/20/1999
PERRIGO	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	7/30/1999
PERRIGO	MINOXIDIL (FOR WOMEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	7/30/1999
PERRIGO	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	6/13/2001
PERRIGO	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	1/13/1997
PERRIGO	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	EQ 200MG BASE;120MG	3/17/2004
PERRIGO	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	9/16/2004
PERRIGO	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	9/16/2004
PERRIGO	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	9/16/2004
PERRIGO	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	9/16/2004

Source: FDA.gov

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Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
PERRIGO	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	9/16/2004
PERRIGO	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	9/16/2004
PERRIGO	PSEUDOEPHEDRINE HYDROCHLORIDE	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	120MG	2/26/1999
PERRIGO	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	8/30/2002
PERRIGO	TAB-PROFEN	IBUPROFEN	TABLET; ORAL	200MG	12/8/1987
PERRIGO	TIOCONAZOLE	TIOCONAZOLE	OINTMENT; VAGINAL	6.5%	11/21/2001
PERRIGO NEW YORK	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	4/6/1987
PERRIGO NEW YORK	ACETAMINOPHEN	ACETAMINOPHEN	SUPPOSITORY; RECTAL	650MG	12/1/1986
PERRIGO NEW YORK	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	3/15/2002
PERRIGO NEW YORK	PERMETHRIN	PERMETHRIN	LOTION; TOPICAL	1%	12/20/2001
PERRIGO R&D	CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE	CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE	TABLET, CHEWABLE; ORAL	800MG;10MG;165MG	2/6/2008
PERRIGO R&D	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
PERRIGO R&D	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
PERRIGO R&D	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
PERRIGO R&D	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
PERRIGO R&D	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	4/9/2008
PERRIGO R&D	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	4/9/2008
PERRIGO R&D	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	6/21/2005
PERRIGO R&D	IBUPROFEN AND DIPHENHYDRAMINE CITRATE	DIPHENHYDRAMINE CITRATE; IBUPROFEN	TABLET; ORAL	38MG;200MG	12/22/2008
PERRIGO R&D	LEVONORGESTREL	LEVONORGESTREL	TABLET; ORAL	0.75MG	12/30/2010
PERRIGO R&D	LEVONORGESTREL	LEVONORGESTREL	TABLET; ORAL	0.75MG	12/30/2010
PERRIGO R&D	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	2%,1.2GM	6/2/2010
PERRIGO R&D	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; TOPICAL, VAGINAL	2%	6/2/2010
PERRIGO R&D	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	4%	1/15/2010
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	1/31/2006
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	1/31/2006
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	10/30/2006
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	10/30/2006
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	5/24/2007
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	5/24/2007
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	4/23/2008
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	4/23/2008
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	7/10/2009
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	7/10/2009
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 2MG BASE	7/10/2009
PERRIGO R&D	NICOTINE POLACRILEX	NICOTINE POLACRILEX	TROCHE/LOZENGE; ORAL	EQ 4MG BASE	7/10/2009
PERRIGO R&D	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/PACKET	10/6/2009

Source: FDA.gov

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Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
PERRIGO R&D	POLYETHYLENE GLYCOL 3350	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/6/2009
PFIZER	CHILDREN'S ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	3/16/2004
PFIZER	CHILDREN'S ZYRTEC ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	3/16/2004
PFIZER	CHILDREN'S ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	3/16/2004
PFIZER	CHILDREN'S ZYRTEC HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	3/16/2004
PFIZER	RID MOUSSE	PIPERONYL BUTOXIDE; PYRETHRINS	AEROSOL; TOPICAL	4%;EQ 0.33% BASE	3/7/2000
PHARMASEAL	PHARMASEAL SCRUB CARE	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	12/2/1988
POLYMEDICA	NEOPAP	ACETAMINOPHEN	SUPPOSITORY; RECTAL	120MG	11/7/1968
QPHARMA	CROMOLYN SODIUM	CROMOLYN SODIUM	SPRAY, METERED; NASAL	5.2MG/SPRAY	9/7/2007
RANBAXY	ACETAMINOPHEN	ACETAMINOPHEN	TABLET, EXTENDED RELEASE; ORAL	650MG	11/18/2009
RANBAXY	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
RANBAXY	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
RANBAXY	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
RANBAXY	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
RANBAXY	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	4/24/2008
RANBAXY	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	4/24/2008
RANBAXY	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	11/17/2009
RANBAXY	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	11/17/2009
RANBAXY	LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE	LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	TABLET; ORAL	2MG;125MG	9/6/2006
RANBAXY	LORATADINE	LORATADINE	TABLET; ORAL	10MG	8/18/2003
RANBAXY	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	8/20/2004
RANBAXY	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	9/22/2004
RANBAXY	LORATADINE REDIDOSE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	4/11/2007
RANBAXY	PSEUDOEPHEDRINE HYDROCHLORIDE	PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	120MG	9/28/2005
RECIP	THYROSAFE	POTASSIUM IODIDE	TABLET; ORAL	65MG	9/10/2002
RECKITT BENCKISER	DELSYM	DEXTROMETHORPHAN POLISTIREX	SUSPENSION, EXTENDED RELEASE; ORAL	EQ 30MG HBR/5ML	10/8/1982
RECKITT BENCKISER	MUCINEX	GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	600MG	7/12/2002
RECKITT BENCKISER	MUCINEX	GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	1.2GM	7/12/2002
RECKITT BENCKISER	MUCINEX D	GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	600MG;60MG	6/22/2004
RECKITT BENCKISER	MUCINEX D	GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	1.2GM;120MG	6/22/2004

Source: FDA.gov

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Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
RECKITT BENCKISER	MUCINEX DM	DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	60MG;1.2GM	4/29/2004
RECKITT BENCKISER	MUCINEX DM	DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN	TABLET, EXTENDED RELEASE; ORAL	30MG;600MG	4/29/2004
REGENT	HIBICLENS	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	9/17/1976
REGENT	HIBISTAT	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	0.5%	5/23/1980
ROXANE	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	4/30/1992
SAGE PRODS	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	CLOTH; TOPICAL	2%	4/25/2005
SANDOZ	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/27/2007
SANDOZ	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/27/2007
SANDOZ	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	5MG	2/14/2008
SANDOZ	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET, CHEWABLE; ORAL	10MG	2/14/2008
SANDOZ	CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE	CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	3/5/2008
SANDOZ	CLEMASTINE FUMARATE	CLEMASTINE FUMARATE	TABLET; ORAL	1.34MG	10/31/1993
SANDOZ	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	10/21/2002
SANDOZ	LORATADINE	LORATADINE	TABLET; ORAL	10MG	1/21/2003
SANDOZ	NAPROXEN SODIUM	NAPROXEN SODIUM	TABLET; ORAL	EQ 200MG BASE	1/13/1997
SANOFI-AVENTIS US	ALLEGRA ALLERGY; ALLEGRA HIVES	FEXOFENADINE HYDROCHLORIDE	SUSPENSION; ORAL	30MG/5ML	1/24/2011
SANOFI-AVENTIS US	GAVISCON	ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE	TABLET, CHEWABLE; ORAL	80MG;20MG	12/9/1983
SANOFI-AVENTIS US	GAVISCON	ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE	TABLET, CHEWABLE; ORAL	160MG;40MG	12/9/1983
SANOFI-AVENTIS US	NICODERM CQ	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	21MG/24HR	11/7/1991
SANOFI-AVENTIS US	NICODERM CQ	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	14MG/24HR	11/7/1991
SANOFI-AVENTIS US	NICODERM CQ	NICOTINE	FILM, EXTENDED RELEASE; TRANSDERMAL	7MG/24HR	11/7/1991
SCHERING-PLOUGH	AFRINOL	PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	120MG	10/30/1980
SCHERING-PLOUGH	CHILDREN'S CLARITIN	LORATADINE	TABLET, CHEWABLE; ORAL	5MG	8/23/2006
SCHERING-PLOUGH	CHLOR-TRIMETON	CHLORPHENIRAMINE MALEATE	TABLET, EXTENDED RELEASE; ORAL	12MG	8/15/1950
SCHERING-PLOUGH	CHLOR-TRIMETON	CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	8MG;120MG	3/31/1981
SCHERING-PLOUGH	CLARITIN	LORATADINE	TABLET; ORAL	10MG	4/12/1993
SCHERING-PLOUGH	CLARITIN	LORATADINE	SYRUP; ORAL	1MG/ML	10/10/1996
SCHERING-PLOUGH	CLARITIN	LORATADINE	CAPSULE; ORAL	10MG	6/16/2008
SCHERING-PLOUGH	CLARITIN HIVES RELIEF	LORATADINE	TABLET; ORAL	10MG	4/12/1993
SCHERING-PLOUGH	CLARITIN HIVES RELIEF REDITAB	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	12/23/1996

Source: FDA.gov

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Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
SCHERING-PLOUGH	CLARITIN REDITABS	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	12/23/1996
SCHERING-PLOUGH	CLARITIN REDITABS	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	5MG	12/12/2006
SCHERING-PLOUGH	CLARITIN-D	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	11/14/1994
SCHERING-PLOUGH	CLARITIN-D 24 HOUR	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	8/23/1996
SCHERING-PLOUGH	DISOPHROL	DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	6MG;120MG	10/18/1963
SCHERING-PLOUGH	DRIXORAL	DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	6MG;120MG	10/18/1963
SCHERING-PLOUGH	DRIXORAL PLUS	ACETAMINOPHEN; DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	500MG;3MG;60MG	5/22/1987
SCHERING-PLOUGH	GYNE-LOTRIMIN	CLOTRIMAZOLE	TABLET; VAGINAL	100MG	3/24/1976
SCHERING-PLOUGH	GYNE-LOTRIMIN	CLOTRIMAZOLE	CREAM; VAGINAL	1%	11/8/1978
SCHERING-PLOUGH	GYNE-LOTRIMIN 3	CLOTRIMAZOLE	TABLET; VAGINAL	200MG	7/29/1996
SCHERING-PLOUGH	GYNE-LOTRIMIN 3	CLOTRIMAZOLE	CREAM; VAGINAL	2%	11/24/1998
SCHERING-PLOUGH	GYNE-LOTRIMIN 3 COMBINATION PACK	CLOTRIMAZOLE	CREAM, TABLET; TOPICAL, VAGINAL	1%,200MG	7/29/1996
SCHERING-PLOUGH	GYNE-LOTRIMIN COMBINATION PACK	CLOTRIMAZOLE	CREAM, TABLET; TOPICAL, VAGINAL	1%,100MG	4/26/1993
SCHERING-PLOUGH	LOTRIMIN AF	CLOTRIMAZOLE	Cream; Topical	1%	10/27/1989
SCHERING-PLOUGH	LOTRIMIN AF	CLOTRIMAZOLE	Lotion; Topical	1%	10/27/1989
SCHERING-PLOUGH	LOTRIMIN AF	CLOTRIMAZOLE	Solution; Topical	1%	10/27/1989
SCHERING-PLOUGH	LOTRIMIN ULTRA	BUTENAFINE HYDROCHLORIDE	CREAM; TOPICAL	1%	12/7/2001
SCHERING-PLOUGH	MIRALAX	POLYETHYLENE GLYCOL 3350	FOR SOLUTION; ORAL	17GM/SCOOPFUL	10/6/2006
SCHERING-PLOUGH	OCUCLEAR	OXYMETAZOLINE HYDROCHLORIDE	SOLUTION/DROPS; OPHTHALMIC	0.025%	5/30/1986
SCHERING-PLOUGH	SHADE UVAGUARD	AVOBENZONE; OCTINOXATE; OXYBENZONE	LOTION; TOPICAL	3%;7.5%;3%	12/7/1992
SCHERING-PLOUGH	ZEGERID OTC	OMEPRAZOLE; SODIUM BICARBONATE	CAPSULE; ORAL	20MG;1.1GM	12/1/2009
SILARX	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	6/29/2006
SOAPCO	BRIAN CARE	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	12/17/1987
SOLUMED	CHLORASCRUB MAXI SWABSTICK	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	3.15%;70% (5.1ML)	6/3/2005
SOLUMED	CHLORASCRUB SWAB	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	3.15%;70% (1ML)	6/3/2005
SOLUMED	CHLORASCRUB SWABSTICK	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	3.15%;70% (1.6ML)	6/3/2005
STAND HOMEOPATH	IVY BLOCK	BENTOQUATAM	LOTION; TOPICAL	5%	8/26/1996
TARO	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	7/22/2009

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
TARO	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	7/22/2009
TARO	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	7/22/2009
TARO	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	7/22/2009
TARO	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	4/22/2008
TARO	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML	4/22/2008
TARO	CLOTRIMAZOLE	CLOTRIMAZOLE	CREAM; VAGINAL	1%	12/4/1995
TARO	LORATADINE	LORATADINE	SUSPENSION; ORAL	1MG/ML	10/4/2005
TARO	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	8/20/2004
TARO	MICONAZOLE 3	MICONAZOLE NITRATE	CREAM; VAGINAL	4%	3/2/2005
TARO	MICONAZOLE NITRATE	MICONAZOLE NITRATE	CREAM; VAGINAL	2%	1/13/1997
TARO	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	CREAM; TOPICAL	1%	7/2/2007
TARO	TRIVAGIZOLE 3	CLOTRIMAZOLE	CREAM; VAGINAL	2%	4/12/2000
TEVA	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	5/31/2001
TEVA	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	11/7/2003
TORPHARM	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	5/4/2000
TORRENT PHARMS LLC	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	4/15/2010
TORRENT PHARMS LLC	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	4/15/2010
TORRENT PHARMS LLC	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	4/15/2010
TORRENT PHARMS LLC	CETIRIZINE HYDROCHLORIDE HIVES RELIEF	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	4/15/2010
TRIS PHARMA INC	IBUPROFEN	IBUPROFEN	SUSPENSION/DROPS; ORAL	40MG/ML	8/31/2009
UNICHEM	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	6/26/2009
UNICHEM	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	6/26/2009
UNICHEM	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	6/26/2009
UNICHEM	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	6/26/2009
UNIQUE PHARM LABS	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	8/26/2009
UNIQUE PHARM LABS	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	8/26/2009
UNIQUE PHARM LABS	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	8/26/2009
UNIQUE PHARM LABS	CETIRIZINE HYDROCHLORIDE HIVES	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	8/26/2009
VINTAGE PHARMS	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	4/1/1987
VINTAGE PHARMS	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	2/2/1988

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
WATSON LABS	CIMETIDINE	CIMETIDINE	TABLET; ORAL	200MG	7/29/1999
WATSON LABS	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	11/28/2001
WATSON LABS	IBUPROFEN	IBUPROFEN	TABLET; ORAL	200MG	3/5/1986
WATSON LABS	LEVONORGESTREL	LEVONORGESTREL	TABLET; ORAL	0.75MG	8/28/2009
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	3/15/1999
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	3/19/1999
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	7/29/2004
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	7/29/2004
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	12/29/2008
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	12/29/2008
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	7/8/2009
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	7/8/2009
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 2MG BASE	7/8/2009
WATSON LABS	NICOTINE POLACRILEX	NICOTINE POLACRILEX	GUM, CHEWING; BUCCAL	EQ 4MG BASE	7/8/2009
WATSON LABS	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	1/14/2000
WATSON LABS FLORIDA	LORATADINE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	11/3/2003
WATSON LABS FLORIDA	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	10MG;240MG	2/21/2003
WATSON LABS FLORIDA	LORATADINE AND PSEUDOEPHEDRINE SULFATE	LORATADINE; PSEUDOEPHEDRINE SULFATE	TABLET, EXTENDED RELEASE; ORAL	5MG;120MG	1/28/2004
WOCKHARDT	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	5MG	12/28/2007
WOCKHARDT	CETIRIZINE HYDROCHLORIDE ALLERGY	CETIRIZINE HYDROCHLORIDE	TABLET; ORAL	10MG	12/28/2007
WOCKHARDT	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	10MG	3/7/2005
WOCKHARDT	FAMOTIDINE	FAMOTIDINE	TABLET; ORAL	20MG	8/4/2010
WOCKHARDT	LOPERAMIDE HYDROCHLORIDE	LOPERAMIDE HYDROCHLORIDE	SOLUTION; ORAL	1MG/5ML	8/28/1997
WOCKHARDT	LORATADINE	LORATADINE	SYRUP; ORAL	1MG/ML	8/20/2004
WOCKHARDT	MINOXIDIL (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	2%	2/28/1997
WOCKHARDT	MINOXIDIL EXTRA STRENGTH (FOR MEN)	MINOXIDIL	SOLUTION; TOPICAL	5%	2/28/2003
WOCKHARDT	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	2/24/2006
WOCKHARDT	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 150MG BASE	11/26/2007
WOCKHARDT	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	TABLET; ORAL	EQ 75MG BASE	7/31/2008
WYETH CONS	ADVIL	IBUPROFEN	TABLET; ORAL	200MG	5/18/1984
WYETH CONS	ADVIL ALLERGY SINUS	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	2MG;200MG;30MG	12/19/2002
WYETH CONS	ADVIL COLD AND SINUS	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	TABLET; ORAL	200MG;30MG	9/19/1989
WYETH CONS	ADVIL COLD AND SINUS	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT;30MG	5/30/2002
WYETH CONS	ADVIL CONGESTION RELIEF	IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	TABLET; ORAL	200MG;10MG	5/27/2010

Source: FDA.gov

FDA OTC Approvals On The Market: By Company

Sponsor Applicant	Drug Name	Active Ingredient	Form	Dosage	Action Date
WYETH CONS	ADVIL LIQUI-GELS	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	4/20/1995
WYETH CONS	ADVIL MIGRAINE LIQUI-GELS	IBUPROFEN	CAPSULE; ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	4/20/1995
WYETH CONS	ADVIL PM	DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN	CAPSULE; ORAL	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	12/21/2005
WYETH CONS	ADVIL PM	DIPHENHYDRAMINE CITRATE; IBUPROFEN	TABLET; ORAL	38MG;200MG	12/21/2005
WYETH CONS	ALAVERT	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	12/19/2002
WYETH CONS	AXID AR	NIZATIDINE	TABLET; ORAL	75MG	5/9/1996
WYETH CONS	CHILDREN'S ADVIL	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	6/27/1996
WYETH CONS	CHILDREN'S ADVIL	IBUPROFEN	TABLET, CHEWABLE; ORAL	50MG	12/18/1998
WYETH CONS	CHILDREN'S ADVIL ALLERGY SINUS	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	1MG/5ML; 100MG/5ML; 15MG/5ML	2/24/2004
WYETH CONS	CHILDREN'S ADVIL COLD	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	SUSPENSION; ORAL	100MG/5ML;15MG/5ML	4/18/2002
WYETH CONS	CHILDREN'S ADVIL-FLAVORED	IBUPROFEN	SUSPENSION; ORAL	100MG/5ML	6/27/1996
WYETH CONS	JUNIOR STRENGTH ADVIL	IBUPROFEN	TABLET; ORAL	100MG	12/13/1996
WYETH CONS	JUNIOR STRENGTH ADVIL	IBUPROFEN	TABLET, CHEWABLE; ORAL	100MG	12/18/1998
WYETH CONS	LORATADINE	LORATADINE	TABLET, ORALLY DISINTEGRATING; ORAL	10MG	2/10/2003
WYETH CONS	PEDIATRIC ADVIL	IBUPROFEN	SUSPENSION/DROPS; ORAL	100MG/2.5ML	1/30/1998
XTTRIUM	DYNA-HEX	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	0.75%	9/11/1997
XTTRIUM	EXIDINE	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	12/24/1984
XTTRIUM	EXIDINE	CHLORHEXIDINE GLUCONATE	AEROSOL, METERED; TOPICAL	4%	12/24/1984
XTTRIUM	EXIDINE	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	2%	12/17/1985

Notes:
This listing contains over-the-counter human drugs currently approved by FDA for sale in the United States.
This listing does not include over-the-counter products approved for marketing by FDA through a process other than submission of a New Drug Application or Biologic License Application. Also excluded are dietary supplements, which do not require FDA approval to be sold in the United States.

Source: FDA.gov

Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975

Ingredient	Adult Dosage	Product Category	Date Of OTC Approval	Product Examples
brompheniramine maleate	4 mg/4-6 hours (oral)	antihistamine	September 9, 1976	Dimetapp
chlorpheniramine maleate	4 mg/4-6 hours (oral)	antihistamine	September 9, 1976	Chlor-Trimeton, Coridicin HBP, Triaminic Cold & Allergy
oxmetazoline hydrochloride	0.05% aqueous solution (topical)	nasal decongestant	September 9, 1976	Afrin, Neo-Synephrine-12 Hour
pseudoephedrine hydrochloride	60 mg/4 or 4-6 hours (oral) 240 mg max./24 hours	nasal decongestant	September 9, 1976	Sudafed
pseudoephedrine sulfate	60 mg/4 or 4-6 hours (oral)	nasal decongestant	September 9, 1976	Drixoral
xylometazoline hydrochloride	0.01% aqueous solution (topical)	nasal decongestant	September 9, 1976	Natru-Vent
doxylamine succinate (NDA)	25 mg single dose only (oral)	sleep aid	October 18, 1978	Unisom
hydrocortisone	0.25 to 0.50% (topical)	antipruritic (anti-itch)	December 4, 1979+	Cortaid, Lanacort

Source: Consumer Healthcare Products Association

Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975

Ingredient	Adult Dosage	Product Category	Date Of OTC Approval	Product Examples
hydrocortisone acetate	0.25 to 0.50% (topical)	antipruritic (anti-itch)	December 4, 1979+	Bactine
acidulated phosphate fluoride rinse	0.02% fluoride in aqueous solution	dental rinse	March 28, 1980	
sodium fluoride rinse	0.05% aqueous solution (topical)	dental rinse	March 28, 1980	Fluorigard
stannous fluoride gel	0.4% gel (topical)	anticaries gel	March 28, 1980	GelKam Gel
stannous fluoride rinse	0.1% aqueous solution (topical)	dental rinse	March 28, 1980	
ephedrine sulfate	0.1 to 1.25% (topical)	anorectal/vasoconstrictor	May 27, 1980	Pazo Ointment
epinephrine hydrochloride	0.005 to 0.01% (topical)	anorectal/vasoconstrictor	May 27, 1980	
phenylephrine hydrochloride	0.25% (topical)	anorectal/vasoconstrictor	May 27, 1980	
chlorpheniramine maleate (NDA)	12 mg/12 hours (oral timed-release)	antihistamine	July 23, 1981	Triaminic 12
phenylpropanolamine hydrochloride (NDA)	75 mg/12 hours (oral timed-release)	nasal decongestant	July 23, 1981	
diphenhydramine hydrochloride (NDA)	25 mg/4 hours (oral)	antitussive	August 7, 1981	Benylin
haloprogin	1.0% (topical)	antifungal	March 23, 1982	
miconazole nitrate	2.0% (topical)	antifungal	March 23, 1982	Micatin
diphenhydramine hydrochloride	50 mg single dose only (oral)	sleep aid	April 23, 1982	Sominex 2
diphenhydramine monocitrate	76 mg single dose only (oral)	sleep aid	April 23, 1982	Excedrin PM
dyclonine hydrochloride	0.05 to 0.1% solution or suspension, 1 to 3 mg as lozenge	oral anesthetic	May 25, 1982	Sucrets Maximum Strength
dexbrompheniramine maleate (NDA)	6 mg/12 hours (oral timed-release)	antihistamine	September 3, 1982	Drixoral
pseudoephedrine sulfate (NDA)	120 mg/12 hours (oral timed-release)	nasal decongestant	September 3, 1982	Afrinol Repetabs
triprolidine hydrochloride	2.5 mg/4-6 hours	antihistamine	November 26, 1982	Actifed Capsules
ibuprofen (NDA)	200 mg/4-6 hours (oral)	internal analgesic/ antipyretic	May 18, 1984	Advil, Nuprin
dexbrompheniramine maleate	2 mg/4-6 hours (oral)	antihistamine	January 15, 1985	
diphenhydramine hydrochloride	25-50 mg/4-6 hours (oral)	antihistamine	January 15, 1985	Benadryl
pseudoephedrine hydrochloride (NDA)	120 mg/12 hours (oral timed-release)	nasal decongestant	June 17, 1985	
triprolidine hydrochloride (NDA)	5 mg/12 hours	antihistamine	June 17, 1985	Actifed 12-hour Capsules
oxymetazoline hydrochloride (NDA)	0.025% solution/drops (topical)	ocular vasoconstrictor	May 30, 1986	Ocuclear
pyrantel pamoate	11 mg/kg of body weight maximum dose 1 g (oral)	anthelmintic	August 1, 1986	Pin-X
povidone iodine sponge (NDA)	10% (new dosage form)	antimicrobial	January 7, 1987	E-Z Scrub 241
diphenhydramine hydrochloride	25-50 mg/4-6 hours (oral)	antiemetic	April 30, 1987	
dexbrompheniramine maleate (NDA)	3 mg/6-8 hours (oral)	antihistamine	May 22, 1987	Drixoral Plus
chlophedianol hydrochloride	25 mg/6-8 hours (oral)	antitussive	August 12, 1987	
doxylamine succinate	7.5 mg - 12.5 mg./4-6 hours (oral)	antihistamine	August 24, 1987	Nyquil
loperamide (NDA)	4 mg, then 2 mg, 8 mg/day (oral)	antidiarrheal	March 3, 1988	Imodium A-D (Johnson & Johnson)

Source: Consumer Healthcare Products Association

Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975

Ingredient	Adult Dosage	Product Category	Date Of OTC Approval	Product Examples
hydrogenated soybean oil and lecithin	12.4 g powder in 2-3 oz. water 20 minutes before gall bladder x-rays	cholecystokinetic	February 28, 1989	Liposperse (Merck)
ibuprofen, pseudoephedrine HCl (NDA)*	200 mg ibuprofen, 30 mg pseudoephedrine HCl	analgesic/decongestant	September 19, 1989	Advil Cold and Sinus (Wyeth)
clotrimazole (NDA)	1% lotion and cream/2 times daily	antifungal	October 23, 1989	Lotrimin AF (Schering)
permethrin (NDA)	1% cream rinse	pediculicide (head lice)	May 5, 1990	Nix (Warner-Lambert)
clotrimazole (NDA)	1% cream & 100 mg inserts	anticandidal	November 30, 1990	Gyne-Lotrimin (Schering), Mycelex-7 (Miles)
miconazole nitrate	2.0% cream and 100 mg inserts	anticandidal	March 13, 1991	Monistat 7 (Ortho)
hydrocortisone+	Above 0.50% to 1.0%	antipruritic (anti-itch)	August 30, 1991	
hydrocortisone acetate+	Above 0.50% to 1.0%	antipruritic (anti-itch)	August 30, 1991	
clemastine fumarate (NDA)	1.34 mg/12 hours	antihistamine	August 21, 1992	Tavist-1 (Novartis)
clemastine fumarate (in combination with phenylpropanolamine HCl (NDA)	1.34 mg/12 hours	antihistamine/ decongestant	August 21, 1992	Tavist-D (Novartis)
dexchlorpheniramine maleate	2 mg/4-6 hours (oral)	antihistamine	December 9, 1992	(last monograph switch)
naproxen sodium (NDA)	220 mg/4-6 hours (oral)	internal analgesic/ antipyretic	January 11, 1994	Aleve (Bayer)
pheniramine maleate with naphazoline HCl (NDA)	0.3%; 0.025% in solution	ophthalmic antihistamine/ decongestant	June 8, 1994	Naphcon A (Alcon), Opcon A (Bausch & Lomb) Ocuhist (Akorn)
antazoline phosphate with naphazoline HCl (NDA)	0.5%; 0.05% in solution	ophthalmic antihistamine/ decongestant	July 11, 1994	Vasocon A (Ciba)
famotidine (NDA)	10 mg, up to 20 mg/day	acid reducer	April 28, 1995	Pepcid AC (J&J·Merck)
ibuprofen suspension 100mg/5ml for pediatric use (NDA)	7.5 mg/kg up to 4 times a day	internal analgesic/antipyretic	June 16, 1995	Children's Motrin (McNeil Consumer)
cimetidine (NDA)	200 mg up to twice per day	acid reducer	June 19, 1995	Tagamet HB (GlaxoSmithKline)
ketoprofen (NDA)	12.5 mg every 4 to 6 hours	internal analgesic	October 6, 1995	Orudis KT (Wyeth), Actron (Bayer)
ranitidine (NDA)	75 mg up to twice per day	acid reducer	December 19, 1995	Zantac 75 (McNeil)
butoconazole nitrate (NDA)	2.0% cream and applicators (3 days)	anticandidal	December 26, 1995	Femstat 3 (Procter & Gamble)
minoxidil (NDA)	2.0% topical solution	hair grower	February 9, 1996	Rogaine (McNeil)
nicotine polacrilex (NDA)	2 mg and 4 mg gum	smoking cessation	February 9, 1996	Nicorette (GlaxoSmithKline)
nizatidine (NDA)	75 mg up to twice daily	acid reducer	May 9, 1996	AXID AR (Wyeth)
miconazole nitrate (NDA)	2.0% cream and 200-mg inserts	anticandidal	April 16, 1996	Monistat 3 (Ortho)
nicotine transdermal system (NDA)	15 mg. patch	smoking cessation	July 3, 1996	Nicotrol (McNeil Consumer)
clotrimazole (NDA)*	1% cream & 200 mg inserts	anticandidal	July 29, 1996	Gyne-Lotrimin 3 (Schering-Plough)
nicotine transdermal system (NDA)	21, 14, & 7 mg patch	smoking cessation	August 2, 1996	Nicoderm CQ (GlaxoSmithKline Beecham) Habitrol (Novartis) (Nov. 12, 1999)
bentoquatam (NDA)*	5% lotion	poison ivy protection	August 26, 1996	Ivy Block (EnviroDerm)
cromolyn sodium (NDA)	4% nasal solution	allergy prevention & treatment	January 6, 1997	Nasalcrom (McNeil Consumer)
tioconazole (NDA)	6.5% vaginal ointment	anticandidal	February 11, 1997	Vagistat-1 (Bristol-Myers Squibb), Monistat 1 (McNeil)
loperamide/simethicone (NDA)*	2 mg loperamide, 125 mg simethicone	antidiarrheal/antigas	June 26, 1997	Imodium Advanced (McNeil Consumer)

Source: Consumer Healthcare Products Association

Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975

Ingredient	Adult Dosage	Product Category	Date Of OTC Approval	Product Examples
triclosan (dentifrice) (NDA)*	0.30% triclosan/0.243% fluoride	antigingivitis	July 11, 1997	Total (Colgate-Palmolive)
ketoconazole (NDA)	1% shampoo	dandruff shampoo	October 10, 1997	Nizoral (Johnson & Johnson Consumer Products)
minoxidil (NDA)*	5.0% topical solution	hair grower	November 17, 1997	Rogaine Extra Strength for Men (Johnson & Johnson)
aspirin /caffeine / acetaminophen (NDA)**	250 mg/65 mg/250 mg	migraine	January 14, 1998	Excedrin Migraine (Novartis)
miconazole nitrate (NDA)*	4.0% cream	anticandidal	March 30, 1998	Monistat 3 (Advanced Care Products)
terbinafine hydrochloride (NDA)	1.0% cream	antifungal	March 9, 1999	Lamisil AT (Novartis)
cimetidine suspension (NDA)*	Suspension	acid reducer	July 9, 1999	Tagamet HB 200 (GlaxoSmithKline)
naproxen Na, pseudoephedrine HCl (NDA)*	220 mg naproxen Na, 120 mg pseudoephedrine HCl	analgesic/decongestant	November 29, 1999	Aleve Cold & Sinus (Bayer Consumer Care)
ibuprofen (NDA)**	200 mg	migraine	February 25, 2000	Motrin Migraine Pain (McNeil Consumer Healthcare)
ibuprofen (NDA)**	200 mg	migraine	March 16, 2000	Advil Migraine Liqui-Gels (Wyeth)
docosanol (NDA)*	10% cream	cold sore/fever blister	July 25, 2000	Abreva Cream (Avanir Pharmaceuticals)
famotidine, calcium carbonate, magnesium hydroxide (NDA)*	10 mg famotidine, 800 mg calcium carbonate, 165 mg magnesium hydroxide	heartburn, acid indigestion	October 17, 2000	Pepcid Complete (J&J/ Merck)
butenafine hydrochloride (NDA)	1.0% cream	athlete's foot, jock itch, ringworm	December 7, 2001	Lotrimin Ultra (Schering-Plough)
ibuprofen, pseudoephedrine HCl, suspension for pediatric use (NDA)*	100 mg ibuprofen, 15 mg pseudo-ephedrine HCl/5 ml; 5 or 10 ml up to 4 times a day	analgesic/decongestant	April 18, 2002	Children's Advil Cold (Wyeth)
guaifenesin extended-release tablet (NDA)	600 or 1200 mg once or twice a day	expectorant	July 12, 2002	Mucinex (Adams Respiratory Therapeutics)
nicotine polacrilex troche/ lozenge (NDA)*	2 mg and 4 mg	smoking cessation	October 31, 2002	Commit (GlaxoSmithKline)
loratadine (NDA)	10 mg/day	antihistamine	November 27, 2002	Claritin Tablets, Claritin RediTabs, Claritin Syrup (Schering-Plough)
loratadine, pseudoephededrine sulfate (NDA)	10 mg loratadine, 240 mg pseudo- ephedrine sulfate Daily	antihistamine/ decongestant	November 27, 2002	Claritin-D 12 Hour Extended Release Tablets, Claritin-D 24 Hour Extended Release Tablets (Schering-Plough)
omeprazole magnesium (NDA)	20 mg/day	acid reducer to treat frequent heartburn	June 20, 2003	Prilosec OTC (Procter & Gamble)
loratadine (NDA)**	10 mg/day	hives relief	November 15, 2003	Claritin hives relief (Schering-Plough)
diphenhydramine citrate & ibuprofen (NDA)*; diphenhydramine HCl & ibuprofen potassium (NDA)*	400 mg ibuprofen and 78 mg diphenhydramine citrate or 50 mg diphenhydramine HCl at bedtime	analgesic sleep-aid	December 21, 2005	Advil PM (Wyeth)
ecamsule (combined with avobenzone and octocrylene (NDA)*	2% ecamsule; 2% avobenzone; 10% octocrylene	sunscreen	July 21, 2006	Anthelios SX (L'Oreal)
levonorgestrel (NDA)	Two 0.75-mg tablets, with the second one taken 12 hours after the first	contraceptive	August 24, 2006	Plan B (Duramed)
polyethylene glycol 3350 (NDA)	17 g (scoopful) of powder per day in 8 oz. of water	laxative	October 6, 2006	MiraLAX (Schering-Plough)
ketotifen (NDA)	0.025% ophthalmic solution	antihistamine eye drops	October 19, 2006	Zaditor (Novartis)
orlistat (NDA)	60 mg; 180 mg daily max.	weight loss aid	February 7, 2007	alli (GlaxoSmithKline)

Source: Consumer Healthcare Products Association

Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975

Ingredient	Adult Dosage	Product Category	Date Of OTC Approval	Product Examples
cetirizine HCl & pseudoephedrine HCl (NDA)	5 mg cetirizine and 120 mg pseudoephedrine	antihistamine/decongestant	November 9, 2007	Zyrtec-D (McNeil)
cetirizine HCl (NDA)	1 mg/ml (children's syrup), 5 mg and 10 mg (tablets and chewable tablets)	antihistamine, hives relief	November 16, 2007	Zyrtec (McNeil)
lansoprazole (NDA)	15 mg/day	acid reducer to treat frequent heartburn	May 18, 2009	Prevacid 24 HR (Novartis)
levonorgestrel (NDA)	1.5 mg	contraceptive	July 10, 2009	Plan B One Step (Duramed)
omeprazole and sodium bicarbonate (NDA)	20 mg omeprazole and 1100 mg sodium bicarbonate	acid reducer to treat frequent heartburn	December 1, 2009	Zegerid OTC (Schering-Plough)
ibuprofen and phenylephrine HCl (NDA)	200 mg ibuprofen and 10 mg phenylephrine HCl	analgesic/decongestant	May 27, 2010	Advil Congestion Relief (Pfizer)
fexofenadine hydrochloride (NDA)	30 mg; 60 mg; 180 mg 30 mg/5 mL	antihistamine	January 24, 2011	Allegra (Chattem)
fexofenadine hydrochloride and pseudoephedrine HCl (NDA)	60 mg; 120 mg	antihistamine/decongestant	January 24, 2011	Allegra D 12-Hour (Chattem)
fexofenadine hydrochloride and pseudoephedrine HCl (NDA)	180 mg; 240 mg	antihistamine/decongestant	January 24, 2011	Allegra D 24-Hour (Chattem)

Notes:
List is updated through Feb. 7, 2011
+ FDA approval for OTC marketing is on an interim basis pending adoption of a Final Monograph
** New OTC NDA – Not previously Rx*
***New OTC indication, product previously OTC*

Source: Consumer Healthcare Products Association

OTC Product U.S. Patent Data: By Company

3M HEALTH CARE INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
ALCOHOL; CHLORHEXIDINE GLUCONATE - 61%;1%	AVAGARD	SOLUTION; TOPICAL	5897031	June 21, 2016			
ALCOHOL; CHLORHEXIDINE GLUCONATE - 61%;1%	AVAGARD	SOLUTION; TOPICAL	6090395	June 22, 2015			
ALCOHOL; CHLORHEXIDINE GLUCONATE - 61%;1%	AVAGARD	SOLUTION; TOPICAL	6534069	June 22, 2015			
ALCOHOL; CHLORHEXIDINE GLUCONATE - 61%;1%	AVAGARD	SOLUTION; TOPICAL	6623744	June 23, 2015	U-1008		
ALCOHOL; CHLORHEXIDINE GLUCONATE - 61%;1%	AVAGARD	SOLUTION; TOPICAL	7081246	August 3, 2016			
ALCOHOL; CHLORHEXIDINE GLUCONATE - 61%;1%	AVAGARD	SOLUTION; TOPICAL	7566460	June 22, 2015	U-1008		
IODINE POVACRYLEX; ISOPROPYL ALCOHOL - EQ 0.7% IODINE;74% (26ML)	DURAPREP	SPONGE; TOPICAL				NC	September 29, 2009
IODINE POVACRYLEX; ISOPROPYL ALCOHOL - EQ 0.7% IODINE;74% (6ML)	DURAPREP	SPONGE; TOPICAL				NC	September 29, 2009

Source: eKnowledgeBase

ASTRAZENECA LP

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	PRILOSEC OTC	TABLET, DELAYED RELEASE; ORAL	5690960	November 25, 2014			
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	PRILOSEC OTC	TABLET, DELAYED RELEASE; ORAL	5753265	June 7, 2015			
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	PRILOSEC OTC	TABLET, DELAYED RELEASE; ORAL	5817338	October 6, 2015			
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	PRILOSEC OTC	TABLET, DELAYED RELEASE; ORAL	5900424	May 4, 2016			
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	PRILOSEC OTC	TABLET, DELAYED RELEASE; ORAL	6403616	November 15, 2019			
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	PRILOSEC OTC	TABLET, DELAYED RELEASE; ORAL	6428810	November 3, 2019			

BANNER PHARMACAPS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
IBUPROFEN - 200MG	MIDOL LIQUID GELS	CAPSULE; ORAL	6251426	June 25, 2018			

BOEHRINGER INGELHEIM PHARMACEUTICALS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
RANITIDINE HYDROCHLORIDE - EQ 150MG BASE	ZANTAC 150	TABLET; ORAL	5098715	December 20, 2010			

CAREFUSION 213 LLC

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (0.67ML)	CHLORAPREP ONE-STEP SEPP	SWAB; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (1.5ML)	CHLORAPREP ONE-STEP FREPP	SPONGE; TOPICAL	5538353	August 25, 2015			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (1.5ML)	CHLORAPREP ONE-STEP FREPP	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (1.5ML)	CHLORAPREP ONE-STEP FREPP	SPONGE; TOPICAL	5752363	April 22, 2017			

Source: eKnowledgeBase

CAREFUSION 213 LLC

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (1.5ML)	CHLORAPREP ONE-STEP FREPP	SPONGE; TOPICAL	5772346	April 22, 2017			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (1.5ML)	CHLORAPREP ONE-STEP FREPP	SPONGE; TOPICAL	D386849	November 25, 2011			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (1.5ML)	CHLORAPREP ONE-STEP FREPP	SPONGE; TOPICAL	D396911	August 11, 2012			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	6536975	November 10, 2020			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6536975	November 10, 2020			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6729786	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6991393	January 31, 2024			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (10.5ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	7241065	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6729786	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6991393	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	6991394	January 31, 2024			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6991394	January 31, 2024			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	7182536	December 30, 2023			

CAREFUSION 213 LLC

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	7182536	December 30, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (26ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	7241065	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	5690958	September 30, 2016			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP ONE-STEP	SPONGE; TOPICAL	6536975	November 10, 2020			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6536975	November 10, 2020			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6729786	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	6991393	March 14, 2023			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 2%;70% (3ML)	CHLORAPREP WITH TINT	SPONGE; TOPICAL	7241065	March 14, 2023			

DR. REDDY'S LABORATORIES LTD.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
OMEPRAZOLE MAGNESIUM - EQ 20MG BASE	OMEPRAZOLE MAGNESIUM	CAPSULE, DELAYED RELEASE; ORAL				PC	June 7, 2010

DURAMED PHARMACEUTICALS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
LEVONORGESTREL - 0.75MG	PLAN B	TABLET; ORAL				NP	August 24, 2009
LEVONORGESTREL - 1.5MG	PLAN B ONE-STEP	TABLET; ORAL				NP	July 10, 2012

GLAXOSMITHKLINE CONSUMER HEALTHCARE

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
NICOTINE POLACRILEX - EQ 2MG BASE	COMMIT	TROCHE/ LOZENGE; ORAL	5110605	August 21, 2010			

Source: eKnowledgeBase

GLAXOSMITHKLINE CONSUMER HEALTHCARE

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
NICOTINE POLACRILEX - EQ 2MG BASE	NICORETTE	TROCHE/ LOZENGE; ORAL	5110605	August 21, 2010			
NICOTINE POLACRILEX - EQ 4MG BASE	COMMIT	TROCHE/ LOZENGE; ORAL	5110605	August 21, 2010			
NICOTINE POLACRILEX - EQ 4MG BASE	NICORETTE	TROCHE/ LOZENGE; ORAL	5110605	August 21, 2010			
ORLISTAT - 60MG	ALLI	CAPSULE; ORAL	6004996	January 6, 2018		NP	February 7, 2010

GLAXOSMITHKLINE INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
DOCOSANOL - 10%	ABREVA	CREAM; TOPICAL	4874794	April 28, 2014	U-815		
DOCOSANOL - 10%	ABREVA	CREAM; TOPICAL	5534554	December 13, 2013	U-815		

HISAMITSU PHARMACEUTICAL CO. INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
MENTHOL; METHYL SALICYLATE - 3%;10%	SALONPAS	PATCH; TOPICAL				NDF	February 20, 2011
MENTHOL; METHYL SALICYLATE - 3%;10%	SALONPAS	PATCH; TOPICAL				NC	February 20, 2011

JOHNSON & JOHNSON GROUP OF CONSUMER COMPANIES

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
MINOXIDIL - 5%	MEN'S ROGAINE	AEROSOL, FOAM; TOPICAL	6946120	April 20, 2019	U-702		

JOHNSON & JOHNSON HEALTHCARE PRODUCTS

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
MICONAZOLE NITRATE - 2%,1.2GM	MONISTAT 1 COMBINATION PACK	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	5514698	March 21, 2014			
MICONAZOLE NITRATE - 2%,1.2GM	MONISTAT 1 COMBINATION PACK	CREAM, SUPPOSITORY; TOPICAL, VAGINAL	6153635	November 28, 2020			

Source: eKnowledgeBase

LES ENTREPRISES SOLUMED INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - 3.15%;70% (5.1ML)	CHLOR-ASCRUB MAXI SWABSTICK	SWAB; TOPICAL	D468424	January 7, 2017			

L'OREAL USA PRODUCTS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
AVOBENZONE; ECAMSULE; OCTOCRYLENE - 2%;2%;10%	ANTHELIOS SX	CREAM; TOPICAL	5587150	December 24, 2013	U-752	NC	July 21, 2009
AVOBENZONE; ECAMSULE; OCTOCRYLENE - 2%;3%;10%	CAPITAL SOLEIL 15	CREAM; TOPICAL				NP	October 2, 2009
AVOBENZONE; ECAMSULE; OCTOCRYLENE - 2%;3%;10%	CAPITAL SOLEIL 15	CREAM; TOPICAL				NC	July 21, 2009
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - 2%;2%;10%;2%	ANTHELIOS 20	CREAM; TOPICAL				NC	October 5, 2009
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - 2%;3%;10%;5%	ANTHELIOS 40	CREAM; TOPICAL				NC	October 5, 2009
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - 2%;3%;10%;5%	ANTHELIOS 40	CREAM; TOPICAL				NP	March 31, 2011
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - 2%;3%;10%;5%	ANTHELIOS 40	CREAM; TOPICAL				NP	October 29, 2012

MCNEIL CONSUMER PRODUCTS CO., A DIV. OF MCNEILAB INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - 5MG;120MG	ZYRTEC-D 12 HOUR	TABLET, EXTENDED RELEASE; ORAL	6469009	July 13, 2019	U-295		
CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - 5MG;120MG	ZYRTEC-D 12 HOUR	TABLET, EXTENDED RELEASE; ORAL	6489329	April 8, 2016			
CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - 5MG;120MG	ZYRTEC-D 12 HOUR	TABLET, EXTENDED RELEASE; ORAL	7014867	June 10, 2022			
CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - 5MG;120MG	ZYRTEC-D 12 HOUR	TABLET, EXTENDED RELEASE; ORAL	7226614	June 10, 2022	U-295		
IBUPROFEN - 100MG/5ML	CHILDREN'S MOTRIN	SUSPENSION; ORAL	5374659	December 20, 2011			
IBUPROFEN - 100MG/5ML	CHILDREN'S MOTRIN	SUSPENSION; ORAL	5374659*PED	June 20, 2012			

Source: eKnowledgeBase

MCNEIL CONSUMER PRODUCTS CO., A DIV. OF MCNEILAB INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
LOPERAMIDE HYDROCHLORIDE - 2MG	IMODIUM A-D EZ CHEWS	TABLET, CHEWABLE; ORAL	5489436	February 6, 2013			
LOPERAMIDE HYDROCHLORIDE - 2MG	IMODIUM A-D EZ CHEWS	TABLET, CHEWABLE; ORAL	6814978	August 26, 2021			
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - 2MG;125MG	IMODIUM MULTI-SYMPTOM RELIEF	TABLET, CHEWABLE; ORAL	5248505	July 28, 2010			
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - 2MG;125MG	IMODIUM MULTI-SYMPTOM RELIEF	TABLET, CHEWABLE; ORAL	5489436	February 6, 2013			
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - 2MG;125MG	IMODIUM MULTI-SYMPTOM RELIEF	TABLET, CHEWABLE; ORAL	5612054	September 28, 2010			
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - 2MG;125MG	IMODIUM MULTI-SYMPTOM RELIEF	TABLET, CHEWABLE; ORAL	5679376	October 21, 2014			
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - 2MG;125MG	IMODIUM MULTI-SYMPTOM RELIEF	TABLET, CHEWABLE; ORAL	5716641	May 21, 2012	U-226		

MCNEIL CONSUMER HEALTHCARE

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
IBUPROFEN - 100MG	JUNIOR STRENGTH MOTRIN	TABLET, CHEWABLE; ORAL	5215755*PED	December 1, 2010			
IBUPROFEN - 40MG/ML	CHILDREN'S MOTRIN	SUSPENSION/ DROPS; ORAL	5374659	December 20, 2011			
IBUPROFEN - 40MG/ML	CHILDREN'S MOTRIN	SUSPENSION/ DROPS; ORAL	5374659*PED	June 20, 2012			
IBUPROFEN - 50MG	CHILDREN'S MOTRIN	TABLET, CHEWABLE; ORAL	5215755*PED	December 1, 2010			
IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE - 100MG/5ML;15MG/5ML	CHILDREN'S MOTRIN COLD	SUSPENSION; ORAL	6211246	June 10, 2019			
KETOCONAZOLE - 1%	NIZORAL A-D	SHAMPOO; TOPICAL	5456851	April 7, 2014			
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - 2MG;125MG	IMODIUM MULTI-SYMPTOM RELIEF	TABLET; ORAL	6103260	July 17, 2017			

Source: eKnowledgeBase

MERCK SHARP & DOHME CORP.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	5075114*PED	November 23, 2010			
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	5229137	May 16, 2012	U-349		
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	5229137*PED	November 16, 2012			
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	5989588	September 30, 2015	U-349		
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	5989588*PED	March 30, 2016	U-349		
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	6814978	August 26, 2021			
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - 800MG;10MG;165MG	PEPCID COMPLETE	TABLET, CHEWABLE; ORAL	6814978*PED	February 26, 2022			
FAMOTIDINE - 10MG	PEPCID AC	TABLET; ORAL	5854267	December 29, 2015	U-267		
FAMOTIDINE - 10MG	PEPCID AC (GELTAB)	TABLET; ORAL	5854267	December 29, 2015	U-368		
FAMOTIDINE - 10MG	PEPCID AC	TABLET; ORAL	5854267*PED	June 29, 2016	U-267		
FAMOTIDINE - 10MG	PEPCID AC (GELTAB)	TABLET; ORAL	5854267*PED	June 29, 2016	U-368		
FAMOTIDINE - 20MG	PEPCID AC	TABLET, CHEWABLE; ORAL	5075114*PED	November 23, 2010			
FAMOTIDINE - 20MG	PEPCID AC	TABLET, CHEWABLE; ORAL	6814978	August 26, 2021			
FAMOTIDINE - 20MG	PEPCID AC	TABLET, CHEWABLE; ORAL	6814978*PED	February 26, 2022			

NOVARTIS CONSUMER HEALTH INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
ACETAMINOPHEN; ASPIRIN; CAFFEINE - 250MG;250MG;65MG	EXCEDRIN (MIGRAINE)	TABLET; ORAL	5972916	July 14, 2017	U-296		
LANSOPRAZOLE - 15MG	PREVACID 24 HR	CAPSULE, DELAYED REL PELLETS; ORAL				NP	May 18, 2012
TERBINAFINE - 1%	LAMISIL AT	GEL; TOPICAL	5681849	October 28, 2014			
TERBINAFINE - 1%	LAMISIL AT	GEL; TOPICAL	5681849*PED	April 28, 2015			
TERBINAFINE - 1%	LAMISIL AT	GEL; TOPICAL	5856355	May 18, 2012	U-504		
TERBINAFINE - 1%	LAMISIL AT	GEL; TOPICAL	5856355	May 18, 2012	U-540		
TERBINAFINE - 1%	LAMISIL AT	GEL; TOPICAL	5856355*PED	November 18, 2012			

Source: eKnowledgeBase

NOVARTIS CONSUMER HEALTH INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
TERBINAFINE HYDROCHLORIDE - 1%	LAMISIL AT	SOLUTION; TOPICAL	5681849	October 28, 2014			
TERBINAFINE HYDROCHLORIDE - 1%	LAMISIL AT	SPRAY; TOPICAL	5681849	October 28, 2014			
TERBINAFINE HYDROCHLORIDE - 1%	LAMISIL AT	SOLUTION; TOPICAL	5681849*PED	April 28, 2015			
TERBINAFINE HYDROCHLORIDE - 1%	LAMISIL AT	SPRAY; TOPICAL	5681849*PED	April 28, 2015			

PERRIGO R&D CO.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
MICONAZOLE NITRATE - 2%,1.2GM	MICONAZOLE NITRATE	CREAM, SUPPOSITORY; TOPICAL, VAGINAL				PC	December 24, 2010

PFIZER INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CETIRIZINE HYDROCHLORIDE - 10MG	CHILDREN'S ZYRTEC ALLERGY	TABLET, CHEWABLE; ORAL	6455533	July 2, 2018	U-295		
CETIRIZINE HYDROCHLORIDE - 10MG	CHILDREN'S ZYRTEC HIVES RELIEF	TABLET, CHEWABLE; ORAL	6455533	July 2, 2018	U-295		
CETIRIZINE HYDROCHLORIDE - 5MG	CHILDREN'S ZYRTEC ALLERGY	TABLET, CHEWABLE; ORAL	6455533	July 2, 2018	U-295		
CETIRIZINE HYDROCHLORIDE - 5MG	CHILDREN'S ZYRTEC HIVES RELIEF	TABLET, CHEWABLE; ORAL	6455533	July 2, 2018	U-295		

RECKITT BENCKISER INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN - 30MG;600MG	MUCINEX DM	TABLET, EXTENDED RELEASE; ORAL	6372252	April 28, 2020			
DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN - 30MG;600MG	MUCINEX DM	TABLET, EXTENDED RELEASE; ORAL	6955821	April 28, 2020	U-685		
DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN - 30MG;600MG	MUCINEX DM	TABLET, EXTENDED RELEASE; ORAL	7838032	April 28, 2020			
DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN - 60MG;1.2GM	MUCINEX DM	TABLET, EXTENDED RELEASE; ORAL	6372252	April 28, 2020			

Source: eKnowledgeBase

RECKITT BENCKISER INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN - 60MG;1.2GM	MUCINEX DM	TABLET, EXTENDED RELEASE; ORAL	6955821	April 28, 2020	U-685		
DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN - 60MG;1.2GM	MUCINEX DM	TABLET, EXTENDED RELEASE; ORAL	7838032	April 28, 2020			
DEXTROMETHORPHAN POLISTIREX - EQ 30MG HBR/5ML	DELSYM	SUSPENSION, EXTENDED RELEASE; ORAL	5980882	April 16, 2017			
GUAIFENESIN - 1.2GM	MUCINEX	TABLET, EXTENDED RELEASE; ORAL	6372252	April 28, 2020	U-489		
GUAIFENESIN - 1.2GM	MUCINEX	TABLET, EXTENDED RELEASE; ORAL	6955821	April 28, 2020	U-489		
GUAIFENESIN - 1.2GM	MUCINEX	TABLET, EXTENDED RELEASE; ORAL	7838032	April 28, 2020			
GUAIFENESIN - 600MG	MUCINEX	TABLET, EXTENDED RELEASE; ORAL	6372252	April 28, 2020	U-489		
GUAIFENESIN - 600MG	MUCINEX	TABLET, EXTENDED RELEASE; ORAL	6955821	April 28, 2020	U-489		
GUAIFENESIN - 600MG	MUCINEX	TABLET, EXTENDED RELEASE; ORAL	7838032	April 28, 2020			
GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE - 1.2GM;120MG	MUCINEX D	TABLET, EXTENDED RELEASE; ORAL	6372252	April 28, 2020			
GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE - 1.2GM;120MG	MUCINEX D	TABLET, EXTENDED RELEASE; ORAL	6955821	April 28, 2020	U-686		
GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE - 1.2GM;120MG	MUCINEX D	TABLET, EXTENDED RELEASE; ORAL	7838032	April 28, 2020			
GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE - 600MG;60MG	MUCINEX D	TABLET, EXTENDED RELEASE; ORAL	6372252	April 28, 2020			
GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE - 600MG;60MG	MUCINEX D	TABLET, EXTENDED RELEASE; ORAL	6955821	April 28, 2020	U-686		
GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE - 600MG;60MG	MUCINEX D	TABLET, EXTENDED RELEASE; ORAL	7838032	April 28, 2020			

SAGE PRODUCTS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CHLORHEXIDINE GLUCONATE - 2%	CHLOR-HEXIDINE GLUCONATE	CLOTH; TOPICAL	7066916	February 17, 2024	U-737		

Source: eKnowledgeBase

SAGE PRODUCTS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
CHLORHEXIDINE GLUCONATE - 2%	CHLOR-HEXIDINE GLUCONATE	CLOTH; TOPICAL	7427574	April 25, 2026			
CHLORHEXIDINE GLUCONATE - 2%	CHLOR-HEXIDINE GLUCONATE	CLOTH; TOPICAL	7595021	May 12, 2023	U-1022		

SANOFI-AVENTIS U.S. LLC

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
NICOTINE - 14MG/24HR	NICODERM CQ	FILM, EXTENDED RELEASE; TRANSDERMAL	5508038	April 16, 2013			
NICOTINE - 21MG/24HR	NICODERM CQ	FILM, EXTENDED RELEASE; TRANSDERMAL	5508038	April 16, 2013			
NICOTINE - 7MG/24HR	NICODERM CQ	FILM, EXTENDED RELEASE; TRANSDERMAL	5508038	April 16, 2013			

SCHERING-PLOUGH HEALTHCARE PRODUCTS INC.

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
LORATADINE - 1MG/ML	CLARITIN	SYRUP; ORAL	6132758	June 1, 2018			
LORATADINE; PSEUDOEPHEDRINE SULFATE - 10MG;240MG	CLARITIN-D 24 HOUR	TABLET, EXTENDED RELEASE; ORAL	5314697	October 23, 2012			
OMEPRAZOLE; SODIUM BICARBONATE - 20MG;1.1GM	ZEGERID OTC	CAPSULE; ORAL	6489346	July 15, 2016	U-1025		
OMEPRAZOLE; SODIUM BICARBONATE - 20MG;1.1GM	ZEGERID OTC	CAPSULE; ORAL	6645988	July 15, 2016			
OMEPRAZOLE; SODIUM BICARBONATE - 20MG;1.1GM	ZEGERID OTC	CAPSULE; ORAL	6699885	July 15, 2016			
OMEPRAZOLE; SODIUM BICARBONATE - 20MG;1.1GM	ZEGERID OTC	CAPSULE; ORAL	7399772	July 15, 2016	U-1025		
POLYETHYLENE GLYCOL 3350 - 17GM/SCOOPFUL	MIRALAX	FOR SOLUTION; ORAL				NP	Oct 6, 2009

WYETH CONSUMER HEALTHCARE

Ingredient - Strength	Trade Name	Dosage	Patent Number	Patent Expire Date	Patent Use Code	Marketing Exclusivity Code	Marketing Exclusivity Expiration Date
IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE - 200MG;10MG	ADVIL CONGESTION RELIEF	TABLET; ORAL	5087454	July 30, 2010			

Source: eKnowledgeBase

OTC Class I Devices – General Controls – 510(k)

Product Name	Product Code	Regulation Number	Medical Specialty
Cleanser, Denture, Over The Counter	EFT	872.3520	Dental
Container, Specimen, Urine, Drugs Of Abuse, Over The Counter	MPQ	864.3260	Pathology
Lipoprotein, High Density, Hdl, Over The Counter	NAQ	862.1175	Clinical Chemistry
Test, Cholesterol, Total, Over The Counter	NFX	862.1175	Clinical Chemistry
Test, Follicle Stimulating Hormone (Fsh), Over The Counter	NGA	862.1300	Clinical Chemistry
Test, Lactic Acid, Over The Counter	NGD	862.1450	Clinical Chemistry
Test, Luteinizing Hormone (Lh), Over The Counter	NGE	862.1485	Clinical Chemistry
Test, Nitrite, Urinary, Non-Quantitative, Over The Counter	NGJ	862.1510	Clinical Chemistry
Test, Triglycerides, Over The Counter	NGO	862.1705	Clinical Chemistry
Cushion, Pad, Denture, Wax Impregnated Cotton, Over The Counter	NKJ	872.3540	Dental

OTC Class II Devices – General Controls and Special Controls – 510(k)

Product Name	Product Code	Regulation Number	Medical Specialty
Over The Counter Denture Repair Kit	EBO	872.3570	Dental
Reliner, Denture, Over The Counter	EBP	872.3560	Dental
Pad, Denture, Over The Counter	EHR	872.3540	Dental
Cushion, Denture, Over The Counter	EHS	872.3540	Dental
Kit, Test, Pregnancy, Hcg, Over The Counter	LCX	862.1155	Clinical Chemistry
System, Test, Blood Glucose, Over The Counter	NBW	862.1345	Clinical Chemistry
Test, Amphetamine, Over The Counter	NFT	862.3100	Clinical Toxicology
Test, Benzodiazepine, Over The Counter	NFV	862.3170	Clinical Toxicology
Test, Cannabinoid, Over The Counter	NFW	862.3870	Clinical Toxicology
Test, Cocaine And Cocaine Metabolites, Over The Counter	NFY	862.3250	Clinical Toxicology
Test, Creatinine, Over The Counter	NFZ	862.1225	Clinical Chemistry
Test, Glycosylated Hemoglobin, Over The Counter	NGB	864.7470	Hematology
Test, Methamphetamine, Over The Counter	NGG	862.3610	Clinical Toxicology
Test, Morphine, Over The Counter	NGI	862.3640	Clinical Toxicology
Test, Occult Blood, Over The Counter	NGK	864.6550	Hematology
Test, Opiates, Over The Counter	NGL	862.3650	Clinical Toxicology
Light Based Over The Counter Wrinkle Reduction	OHS	878.4810	General and Plastic Surgery
Light Based Over-The-Counter Hair Removal	OHT	878.4810	General and Plastic Surgery

OTC Unclassified Devices – 510(k)

Product Name	Product Code	Regulation Number	Medical Specialty
Kit, Test, Multiple, Drugs Of Abuse, Over The Counter	MVO		

Source: MDRWeb.com