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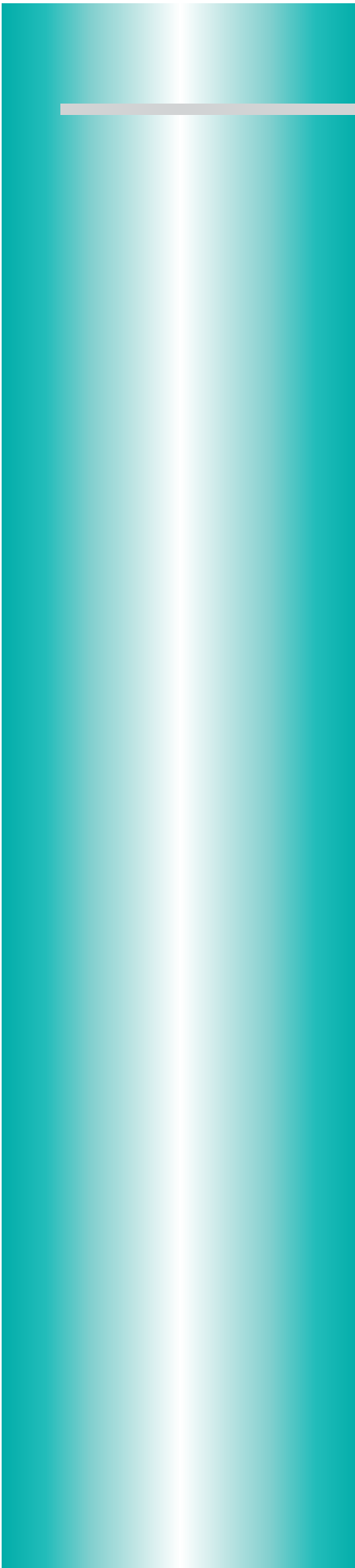


## RX-TO-OTC SWITCH: THE NEXT WAVE

Kline's newest edition in the  
Rx-to-OTC switch series



**KLINE & COMPANY, INC.**  
OVERLOOK AT GREAT NOTCH  
150 CLOVE ROAD  
PO BOX 410  
LITTLE FALLS, NJ 07424-0410  
(973) 435-6262  
[www.klinegroup.com](http://www.klinegroup.com)



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The Rx-to-OTC switch market has experienced a virtual standstill over the past few years; however, new switches are on the horizon. Recent switches, including Nizoral AD (Johnson & Johnson) and Lamisil AT (Novartis), were less significant than brands like Pepcid (Johnson & Johnson - Merck), Nicorette (Glaxo-SmithKline), and others. The new wave of switches is predicted to be larger in scale than the recent launches and will have a strong impact on the OTC market.

For existing OTC brands, switches can erode sales and market positions. Accurately predicting Rx-to-OTC switches and assessing their impact is crucial for maximizing business opportunities, minimizing threats, and successfully constructing long-term strategic plans. Kline's newly proposed study titled **RX-TO-OTC SWITCH: THE NEXT WAVE** includes highly objective, independent forecasts and assessments of future switches. For example, the predicted switch of Claritin (Schering-Plough) marks one of the largest switches in history and will have a significant impact on the existing OTC allergy drugs. The report provides subscribers with the following key deliverables:

- Assessment of future competitive Rx-to-OTC switch strategies
- Forecasts of major switches
- Projections for new OTC categories
- Examination of strategies that current OTC marketers can take to defend their brands

## TABLE OF CONTENTS

### 1. INTRODUCTION

### 2. EXECUTIVE SUMMARY

### 3. RECENT RX-TO-OTC SWITCHES

*This section provides a comprehensive overview of five recently switched brands with a detailed discussion of whether the switch was successful or not and supporting factors for each. The following factors are explored for Nicorette (GlaxoSmithKline), Rogaine (Pharmacia), NicoDerm CQ (Glaxo-SmithKline), Nizoral AD (Johnson & Johnson), and Lamisil AT (Novartis):*

- Rx-to-OTC switch method
- Sales analyses (as Rx and OTC)
- Market share and competitive environment
- Advertising and promotion
- Strengths and weaknesses
- Product strategy

### 4. POTENTIAL RX-TO-OTC SWITCHES

*For each therapeutic category listed in Table 1, the study examines the following:*

- Comparative analysis of the prescription and OTC markets
  - Category situation analyses
  - Demographics of target population
  - Incidence and prevalence of the disease state

- Strategic considerations for Rx to-OTC switch
  - Regulatory factors
  - Competitive pressures (patent expirations, generic threats, etc.)
  - Timing
  - Pricing considerations
  - Marketing issues
- Switch forecast
  - Brands that are likely to switch
  - Timing
  - Pricing
  - Implications to both prescription and OTC markets
  - Acceptance among professionals, consumers, and retailers

*For each brand listed in Table 1, the study examines the following:*

- Patent status
- Current prescription brand sales and share
- Rx-to-OTC switch expertise of the marketer
- Regulatory status
- OTC formulation considerations
- Potential OTC indications/claims
- Safety/efficacy
- Brand name awareness
- Direct-to-consumer spending
- Likelihood of switch/OTC market potential
- Pricing strategy
- Managed care influence

### 5. PHARMACISTS' PERCEPTIONS OF POTENTIAL SWITCHES

APPENDIX: Pharmacist Survey: Rx-to-OTC Switch

RX-TO-OTC SWITCH:  
THE NEXT WAVE

**Table 1**

**RX-TO-OTC SWITCH CANDIDATE S EXAMINED IN THE STUDY**

Class/brand	Company
<b>ALLERGY RELIEF PRODUCTS</b>	
Allegra	Aventis
Atrovent	Boehringer Ingelheim
Claritin	Schering-Plough
Flonase	GlaxoSmithKline
Nasonex	Schering-Plough
Vancenase	Schering-Plough
Zyrtec	Pfizer
<b>ANALGESICS/ARTHRITIC PAIN RELIEVERS</b>	
Bextra	Pfizer (Pharmacia)
Celebrex	Pfizer (Pharmacia)
Imitrex	GlaxoSmithKline
Vioxx	Merck
<b>ANTIFUNGALS</b>	
Spectazole	Johnson & Johnson
Sporanox	Johnson & Johnson
<b>ANTISEIZURE MEDICATIONS</b>	
Neurontin	Pfizer
<b>ASTHMA TREATMENTS</b>	
Accolate	AstraZeneca
Beconase	GlaxoSmithKline
Proventil	Schering-Plough
Singulair	Merck
Vanceril DS	Schering-Plough
Ventolin	GlaxoSmithKline
<b>CHOLESTEROL REDUCERS</b>	
Lescol	Novartis
Lipitor	Pfizer
Mevacor	Merck
Pravachol	Bristol-Myers Squibb
Zocor	Merck
<b>DIABETES TREATMENTS</b>	
Glucophage	Bristol-Myers Squibb
<b>INCONTINENCE PRODUCTS</b>	
Detrol	Pharmacia
Ditropan XL	Johnson & Johnson
<b>ORAL CONTRACEPTIVES</b>	
<b>OSTEOPOROSIS MEDICATIONS</b>	
Actonel	Aventis/Procter & Gamble
Evista	Eli Lilly
Fosamax	Merck
Miacalcin	Novartis
<b>PROTON PUMP INHIBITORS</b>	
Prilosec	AstraZeneca
Protonix	Wyeth
Prevacid	TAP
<b>SYSTEMIC VAGINAL YEAST INFECTION TREATMENTS</b>	
Diflucan	Pfizer

## BACKGROUND

Several recent developments may change the future process for switches. For the first time, a party other than the pharmaceutical companies has petitioned the FDA for switch approval.

In 1998, WellPoint Health Networks, one of the largest publicly held managed care companies, petitioned the FDA for OTC status for leading prescription non-sedating antihistamines Allegra, Claritin, and Zyrtec. In addition, both McNeil (Johnson & Johnson) and Whitehall-Robins (Wyeth) filed for applications to market generic forms of loratadine (Claritin) as an OTC product. In response, Schering-Plough has filed suit against McNeil and Wyeth and has subsequently filed a petition for OTC loratadine with the FDA.

The FDA has also opened the possibility of having a third class of OTC drugs available in the United States, as is the case in Canada. Because this would require some intervention by pharmacists, as the drugs would be stocked behind the counter, it opens up another area of possible switches, including the much talked-about cholesterol reducers.

Other classes of drugs with switch possibilities are emergency contraceptives (which are already sold without a prescription in Virginia and California), oral contraceptives, urinary tract analgesics and infection treatments, bladder treatments, and hormone replacement drugs.

## OBJECTIVE AND BENEFITS

The key objective of **RX-TO-OTC SWITCH: THE NEXT WAVE** is to provide subscribers with a detailed analysis of the historical and future switch market in the United States.

The report identifies strategies for success through a comprehensive analysis of past switches. Through a thorough assessment of prescription drug sales, DTC spending, and past strategies, the study supplies subscribers with key information for business planning. For marketers of OTC drugs, it examines key issues and implications that an Rx-to-OTC switch could have on the existing OTC business and identifies ways to successfully compete. For companies that are exploring switch strategies for their drugs, the report will provide a comprehensive overview of existing OTC market conditions, sales potential, and competitive assessment for the new switch.

## METHODOLOGY

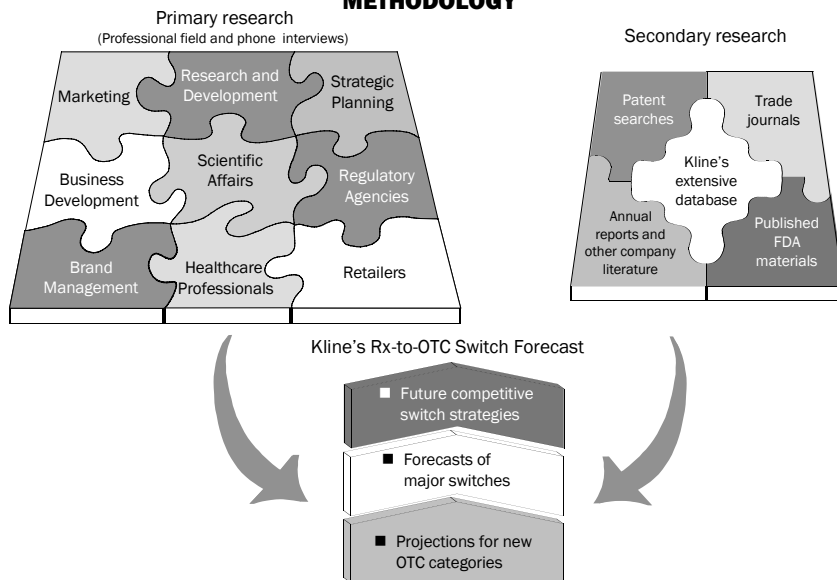
As the leading consultancy on Rx-to-OTC switches, Kline has developed a program based heavily on primary research (field and phone interviews) that has proven to be most effective and reliable in preparing switch forecasts.

**RX-TO-OTC SWITCH: THE NEXT WAVE** leverages our contacts in the industry and employs the use of primary research to capture insights and information available from a wide range of industry experts and opinion leaders. The field and phone interviews were conducted by Kline's professional staff. The functional areas targeted are shown in Figure 1.

In addition to primary research, the study draws on relevant secondary data, including regulatory information obtained from the FDA and patent searches. Other secondary resources are listed in Figure 1.

In forecasting Rx-to-OTC switches, a variety of factors are at play in each market that can impact the timing of switches. Competitive pressures, regulatory hurdles, and patent expirations each play significant roles in switch timing. Therefore, each brand and therapeutic category is analyzed on a case-by-case basis, and the forecast time horizon may differ for each.

**Figure 1**  
**METHODOLOGY**



## **KLINE'S CREDENTIALS**

Kline & Company is a leading international business research and consulting firm serving the pharmaceutical and related healthcare industries. Kline has been examining product switches and their impact on the OTC market for over 30 years through its **NONPRESCRIPTION DRUGS USA** annual survey and its series of **RX-TO-OTC SWITCH** studies. In addition, Kline has conducted numerous proprietary consulting assignments that have involved Rx-to-OTC switch forecasts of sales and competitive impacts on markets/brands in such categories as antifungal products, antacids, antihistamines, and feminine yeast infection remedies.

These custom analyses are further supported by our substantial database on this subject, gathered through the completion of several syndicated studies, including the following:

- **More Power for the Rx-to-OTC Switch: Volume I** (1991)
- **More Power for the Rx-to-OTC Switch: Volume II** (1995)
- **History and Impact of the Rx-to-OTC Switch** (1996)
- **Nonprescription Drugs USA** (annual service since 1979)
- **Nonprescription Drugs Canada** (biennial study)
- **Competitor Cost Structures 2001**

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## THE KLINE GROUP

### USA

**KLINE & COMPANY, INC.**  
OVERLOOK AT GREAT NOTCH  
150 CLOVE ROAD  
PO BOX 410  
LITTLE FALLS, NJ 07424-0410  
TEL: (973) 435-6262  
FAX: (973) 435-6291  
E-mail: [consult@klinegroup.com](mailto:consult@klinegroup.com)

### EUROPE

**KLINE EUROPE, S.A.**  
1 AVENUE GRIBAUMONT  
B-1150 BRUSSELS  
BELGIUM  
TEL: (32-2) 770-4740  
FAX: (32-2) 770-9440  
E-mail: [consult@kline-europe.com](mailto:consult@kline-europe.com)

### BRAZIL

**FACTOR DE SOLUÇÃO**  
AV. SÃO GABRIEL, 333 - CJ. 112  
ITAIM BIBI - SÃO PAULO - SP  
01435-001 BRAZIL  
TEL: (55-11) 30790829  
(55-11) 31672055  
(55-11) 30790792  
FAX: (55-11) 30796197  
E-mail: [srebello@factordesolucao.com.br](mailto:srebello@factordesolucao.com.br)

