

EXHIBIT -3

U.S. Food and Drug Administration

FDA News

FOR IMMEDIATE RELEASE
P02-51
November 27, 2002

Media Inquiries: 301-827-6242
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FDA Approves OTC Claritin

FDA has approved Claritin (loratadine) as an over-the-counter (OTC) allergy drug product. Previously available only as a prescription drug, Claritin is approved for seasonal allergic rhinitis -- a condition that causes runny nose, nasal congestion, sneezing, and itchy nose, throat, eyes, and ears.

"By making it easier to get this widely-used drug, today's action will enable many people to get less-sedating, effective relief for their allergy symptoms more quickly and at a lower cost," said Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs. "This approval reflects FDA's commitment to bringing prescription drugs to the over-the-counter market when they can be safely used without a prescription."

Claritin's approval for OTC marketing was based on FDA's criteria for determining appropriate drugs for OTC use - namely that the drug in question treats a condition that consumers can diagnose and manage themselves; that the drug is sufficiently safe for use by consumers without direct prescriber supervision; and that the drug's label explains potential adverse effects and conditions of use with clear and understandable directions. When drugs move from prescription to OTC status the price typically declines.

Today's action also marks a milestone in FDA's work with the National Transportation Safety Board to improve public awareness of the concerns about possible impairment caused by certain prescription and OTC drug products that cause drowsiness. Because OTC antihistamines already on the market may cause drowsiness, the FDA requires them to carry warnings about using them while driving or operating machinery. This new approval offers many consumers a potentially safer alternative to currently-available OTC drugs that may contribute to driving impairment.

Approximately 10 to 30 percent of adults in the United States suffer from seasonal allergy symptoms. In April 1993, Claritin was approved as one of the first new generation antihistamines developed to be less sedating than traditional antihistamines.

Claritin is manufactured by Schering-Plough based in Kenilworth, N.J.

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Office of Public Affairs
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Search results from the "OB_OTC" table for query on "020641."

Active Ingredient: LORATADINE
Dosage Form;Route: SYRUP; ORAL
Proprietary Name: CLARITIN
Applicant: SCHERING
Strength: 1MG/ML
Application Number: 020641
Product Number: 002
Approval Date: Nov 27, 2002
Reference Listed Drug: Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: LORATADINE
Dosage Form;Route: SYRUP; ORAL
Proprietary Name: CLARITIN HIVES RELIEF
Applicant: SCHERING
Strength: 1MG/ML
Application Number: 020641
Product Number: 003
Approval Date: Nov 19, 2003
Reference Listed Drug: Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: [View](#)

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Patent Data Last Updated: February 03, 2005

Patent and Exclusivity Search Results from query on Appl No 020641 Product 003 in the OB_OTC list.

For Hives Relief

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

[Note: Title I of the 1984 Amendments does not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug and Cosmetic Act (antibiotic products). Drug products of this category will not have patents listed.]

Exclusivity Data

There is no unexpired exclusivity for this product.

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Patent Data Last Updated: February 03, 2005

Search results from the "OB_OTC" table for query on "019658."

Active Ingredient: LORATADINE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: CLARITIN
Applicant: SCHERING
Strength: 10MG
Application Number: 019658
Product Number: 002
Approval Date: Nov 27, 2002
Reference Listed Drug: Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: LORATADINE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: CLARITIN HIVES RELIEF
Applicant: SCHERING
Strength: 10MG
Application Number: 019658
Product Number: 003
Approval Date: Nov 19, 2003
Reference Listed Drug: Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: [View](#)

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Patent Data Last Updated: February 03, 2005

Patent and Exclusivity Search Results from query on Appl No 019658 Product 003 in the OB_OTC list.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

[Note: Title I of the 1984 Amendments does not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug and Cosmetic Act (antibiotic products). Drug products of this category will not have patents listed.]

Exclusivity Data

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