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RESEARCH**

APPLICATION NUMBER:

22-155

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-155

McNeil Consumer Healthcare
Attention: Robert Kohler
Senior Director, Global Regulatory Affairs
U.S. Agent for Pfizer, Inc.
201 Tabor Road
Morris Plains, NJ 07950

Dear Mr. Kohler:

Please refer to your January 15, 2007 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Zyrtec (cetirizine HCl) Allergy syrup 1 mg/mL and Children's Zyrtec (cetirizine HCl) Hives Relief syrup 1 mg/mL.

We acknowledge receipt of your submissions dated March 2, May 15 (2), June 6, July 19 and 25, September 26, October 11, and November 8, 2007.

This new drug application provides for the nonprescription use of Children's Zyrtec (cetirizine HCl) Allergy syrup for the temporary relief of symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, itching of the nose or throat in adults and children 2 years of age and older, and for the nonprescription use of Children's Zyrtec (cetirizine HCl) Hives Relief syrup for the relief of itching due to hives (urticaria) in adults and children 6 years of age and older.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the draft labeling (4 oz. bottle and carton "Hives Relief" labeling submitted October 11, 2007 and 4 oz. bottle and carton, twin pack retail carton, 15 mL sample bottle, 12-count sample tray "Allergy" labeling, "Allergy" dosing cup and "Hives" dosing cup submitted on November 8, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 22-155." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the word "NEW!" from the principal display panel (PDP) after 180 days of marketing.

We have determined that your application does not trigger the Pediatric Research Equity Act (PREA).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

[See appended electronic signature page]

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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/s/

Andrea Segal
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