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APPLICATION NUMBER:

21-150/S007

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-150/S-007

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 10, 2007 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec-D (cetirizine HCl 5 mg/ pseudoephedrine HCl 120 mg) tablets.

We acknowledge receipt of your submissions dated April 27, May 4, July 11, August 23, October 12 and 30, and November 6, 2007.

This supplemental new drug application provides for the nonprescription use of Zyrtec-D (cetirizine HCl/pseudoephedrine HCl) 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, and nasal congestion in adults and children 12 years of age and older.

We have completed our review of this supplemental 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 (1-count sample blister packet and 12-count carton labeling submitted November 6, 2007 and 1-count individual blister, 24-count FDM and Club cartons, and 50-count packet dispenser labeling submitted on October 30, 2007, except that the labeling for these SKUs must include the revised "Uses" sections as submitted in the representative labeling on November 6, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66. We remind you of your correspondence dated November 6, 2007, in which you certified that the labeling for all SKUs submitted on October 30, 2007 would be revised to follow the "Uses" section of the representative 12-count carton and 1-count sample blister packet labeling submitted on November 6, 2007.

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 supplement NDA 21-150/S-007.**" 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