DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-835/S-022

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 supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine HCl) Allergy tablets 5 mg and 10 mg and Zyrtec (cetirizine HCl) Hives Relief tablets 5 mg and 10 mg.

We acknowledge receipt of your submissions dated March 28, May 15 and 31, July 10 and 31, October 9, and November 6, 2007.

This supplemental application provides for the nonprescription use of Zyrtec (cetirizine HCl) Allergy tablets 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 6 years of age and older, and for the nonprescription use of Zyrtec (cetirizine HCl) Hives Relief tablets 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 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 individual blister card [5 and 10 mg], 14-count carton [5 and 10 mg], "Hives Relief" labeling submitted October 9, 2007 and 5-, 14-, 30-, 45- and 75-count clamshell [10 mg], 14-count clamshell [5 mg], 30- and 45-count bottle [10 mg], 1-count individual blister card [5 and 10 mg], 1-count blister pouch [10 mg], 50-count pouch dispenser [10 mg] "Allergy" labeling submitted on November 6, 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 supplement NDA 19-835/S-022**." 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Andrea Segal

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