DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-835/S-025

McNeil Consumer Healthcare
Division of McNeil-PPC, Inc.
Attention: Carolyn Zlogar
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Zlogar:

Please refer to your supplemental new drug application dated July 24, 2008, received July 25, 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec® (cetirizine hydrochloride) tablets, 5mg and 10mg.

This supplemental new drug application provides the following changes associated with the manufacture of and formulation for Zyrtec® tablets, 10 mg:

- McNeil Healthcare, LLC, located in Las Piedras, Puerto Rico, as an alternate manufacturing and testing site, and
- McNeil Consumer Healthcare, Fort Washington, Pennsylvania as a testing facility for stability studies.

This supplemental new drug application also provides for labeling changes to reflect the change in formulation (inactive ingredient listing), revision to the "country of origin" to reflect the source of the active ingredient, as well as other minor editorial changes.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text. Only the labels for the referenced count sizes are approved for use under this application. At this time, we are accepting the statement "Made in Belgium" on the labeling as the "country of origin" for the active ingredient for this product to be in compliance with U.S. Customs and Border Protection regulations.

The final printed labeling (FPL) must be identical to the enclosed labeling (the clamshell card for the 5- count Zyrtec® Allergy tablets 10mg (representative of the 5- and 14-count clamshell cards for Zyrtec® Allergy tablets 10mg and the 14-count carton label for Zyrtec® Hives Relief tablets 10mg) submitted on July 24, 2008, the clamshell card for the 30-count Zyrtec® Allergy tablets 10mg (representative of the 30- and 45-count clamshell cards, the 75-count clamshell card (containing one bottle of 45 tablets and one bottle of 30 tablets), and the 50-count pouch dispenser label for Zyrtec® Allergy tablets 10mg) submitted on July 24, 2008, the 1-count individual blister card for Zyrtec® Allergy tablets 10mg (representative of the 1-count individual blister card for the for Zyrtec® Allergy tablets 10mg and Zyrtec® Hives Relief tablets 10mg) submitted on July 24, 2008, the 1-count blister pouch for the for Zyrtec® Allergy tablets 10mg submitted on July 24, 2008, and the 30-count bottle label (representative of the 30- and 45-count bottle labels for the Zyrtec® Allergy tablets 10mg)

submitted on July 24, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66. FPL must be submitted for all the referenced count sizes. Representative labeling will not be acceptable in the FPL submission.

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 these submissions "**FPL for approved supplement NDA 19-835/S-025**." Approval of these submissions by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

At the time of next printing or within 180 days, whichever comes first, revise the tamper-evident statement for bottles to include the identifying tamper-evident feature, in accordance with 21 CFR 211.132(c)(i). This revision can be reported in the next annual report.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

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

11/25/2008 05:27:50 PM