DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-155/S-002

McNeil Consumer Healthcare
Division of McNeil-PPC, Inc.
Attention: Larry Litle
Director, Chemistry, Manufacturing and Controls Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Mr. Litle:

Please refer to your supplemental new drug application dated April 9, 2008, received April 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Zyrtec Allergy (cetirizine 5 mg/5 mL) syrup and Children's Zyrtec Hives Relief (cetirizine 5 mg/5 mL) syrup.

This supplemental new drug application provides for the following changes:

- The addition of [redacted] as an alternate manufacturing, packaging and analytical testing site
- Change in the order of addition of ingredients
- Adjustment of process temperature
- Use of alternate materials transfer equipment for ingredient addition
- Use of [redacted] equipment of the same design and operating principle as that currently approved
- Introduction of a new 2 fl. oz. bottle size for Children's Zyrtec Allergy syrup
- Change to the cap liner for all sizes (15 mL, 2 fl. oz. and 4 fl. oz.)

We have completed our review of this supplemental new drug application. This supplement 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 (2.0 fl. oz. carton and container labels for Children's Zyrtec Allergy syrup submitted April 9, 2008), 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 22-155/S-002**." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your statement that minor editorial changes made in the pregnancy warning and the Poison Control toll-free number will also be incorporated in the labeling for the approved 15 mL and 4 fl. oz. package sizes of the Children's Zyrtec Allergy syrup and will 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the 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}

Joel Schiffenbauer, M.D.
Deputy 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/

Joel Schiffenbauer

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