DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-155/S-005

McNeil Consumer Healthcare
Attention: Terry Chan
Senior Associate, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Mr. Chan:

Please refer to your supplemental new drug application dated November 6, 2008, received November 7, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Zyrtec® Allergy and Children's Zyrtec® Hives Relief (1 mg/ mL cetirizine HCl) syrup.

We acknowledge receipt of your submission dated November 6, 2008.

This supplemental new drug application provides for:

1. A new grape flavored, sugar-free, dye-free formulation of Children's Zyrtec® Allergy and Children's Zyrtec® Hives Relief syrup.
2. The addition of a (b) (4) batch size, and the manufacturing process change from a (b) (4)

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 submitted labeling (carton (with Drug Facts) and container labels for the 15 mL and 4 fl oz package sizes for the Children's Zyrtec® Allergy and the 4 fl oz package size for the Children's Zyrtec® Hives Relief grape sugar-free dye-free flavor syrup submitted, on November 6, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66 where applicable.

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-005**." Approval of this submission by FDA is not required before the labeling is used.

We recommend that you include a "New Sugar-Free, Dye Free!" flag on the principal display panel of each SKU for the first six months of marketing. We remind you to remove the flag from the principal display panel after six months of marketing.

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
Suite 12B05
5600 Fishers Lane
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

Enclosure

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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