DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019835/S-032

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc.
Attention: Elizabeth H. Finn, Pharm.D.
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Dr. Finn:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 15, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyrtec (cetirizine HCl) tablets, 5 mg and 10 mg.

We acknowledge receipt of your amendment dated and received July 6, 2012.

This "Prior Approval" supplemental new drug application provides for the addition of a "6yrs & older" sticker to the outer container labeling of the below specified Zyrtec Allergy 10 mg stock keeping units (SKUs).

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the "6yrs & older" stickers for the 5-, 14-, 30-,40 (30 +10), 45- and 60 (45 +15)-count carton (clamshell) and the 7- and 14-count carton labels submitted on March 15, 2012 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 10 mg 5-, 14-, 30-,40 (30 +10), 45- and 60 (45 +15)-count outer carton (clamshell) and the 7- and 14- count outer carton labels for Zyrtec Allergy 10 mg, you should submit the outer cartons and outer carton (clamshell) as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 019835/S-032**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Jade Pham, Regulatory Project Manager, at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Andrea Leonard Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Labeling

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

/s/

ANDREA LEONARD SEGAL
09/10/2012