DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022578

NDA APPROVAL

McNeil Consumer Healthcare
Attention: Elizabeth H. Finn, Pharm.D.
Manager, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Dr. Finn:

Please refer to your new drug application NDA 022578 dated November 6, 2009, received November 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Zyrtec® Allergy (cetirizine HCl) orally disintegrating tablets, 10 mg.

We acknowledge receipt of your amendments dated December 22, 2009, February 24, March 2, 5, 11, and 17, April 2, June 9 and 10, and July 9, 12, and 29, 2010.

This new drug application provides for the use of Zyrtec® Allergy (cetirizine HCl) orally disintegrating tablets for the temporary relief of these symptoms due to hay fever or other upper respiratory allergies:

- Runny nose
- Sneezing
- Itchy, watery eyes
- Itching of the nose or throat

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

Submit final printed labeling as soon as available, but no more than 30 days after printing. The final printed labeling (FPL) must be identical to the enclosed labeling (6-count immediate container (blister card) submitted on July 12, 2010 and the 6-, 12-, 24-, and 66-count carton labels submitted on July 29, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 22578**." Approval of this submission 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.

We remind you to remove the "New Form" flag from the carton labels after 180 days of marketing.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

- We are waiving the pediatric study requirement for this application for ages 0 to less than 2 years because seasonal allergic rhinitis does not exist in children < 2 years of age. Children generally need to be exposed to allergens for at least two seasons before developing a seasonal allergy.

- We are also waiving the pediatric study requirement for ages 2 to less than 6 years because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group because other age-appropriate cetirizine formulations are approved for the same indication in children 2 to less than 6 years of age.

- For children from 6 to 17 years old, your product is appropriately labeled based on studies and extrapolation.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22578	ORIG-1	MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC	CETIRIZINE HCL ORALLY 10MG TABS

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
09/03/2010