DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-835/S-028 **SUPPLEMENT APPROVAL**

McNeil Consumer Healthcare
Attention: Hina Harlow
Associate Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Harlow:

Please refer to your supplemental new drug application (sNDA) dated August 26, 2009, received August 27, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine hydrochloride 5 mg) Tablets.

We acknowledge receipt of your amendments dated September 15, 2009, October 20, 2009, November 23, 2009, February 22, 2010 and February 24, 2010.

This Prior Approval supplemental new drug application proposes to add the following descriptors to the principal display panel: "Flexible Dosing" and "New lower dose".

Your August 26, 2009 submissions notified us that the submitted carton labeling is intended to serve as a representative package size for the 18-count and 36-count package sizes of the 5 mg tablet. Any changes approved for this representative carton will be incorporated onto the carton label of the 18-count and 36-count package sizes, which are identical to the submitted carton labeling with the exception of the count size.

We remind you of your letter of commitment received February 24, 2010 in which you agree to make the following labeling revisions prior to introduction of this labeling to the marketplace :

- Revise the "Lower Dose" flag to state "Lower Strength"
- For the dosing direction in the "orange" banner:
  - Relocate the "65 and older" direction to be within the banner
  - Revise the complete dosing directions within the banner to be the same font, size and color, which includes "65 and older" direction
- Remove the side panels "dosing direction banner"

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 and with the editorial revisions listed above.

Submit final printed labeling, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Except for the revisions listed above, the final printed labeling (FPL) must be identical to the enclosed labeling (Zyrtec 18-count and 36-count cartons labels submitted on February 22, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the immediate container label (blister card) for the Zyrtec (cetirizine hydrochloride 5 mg) Tablet 18-count and 36-count package sizes, we request that you submit immediate container label (blister card) as part of the FPL for this supplement to maintain a record of the complete labeling for these count sizes and packaging configurations.

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 (October 2005). 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 19-835/S-028**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division.

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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 Michelle Poindexter, Regulatory Project Manager, at (301) 796-4795.

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

Enclosure:

Letter of commitment
Carton Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19835	SUPPL-28	MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC	ZYRTEC

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
02/26/2010