



NDA 019835/S-29

SUPPLEMENT APPROVAL

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

Dear Dr. Finn:

Please refer to your Supplemental New Drug Application (sNDA) dated July 26, 2011, received July 26, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyrtec[®] (cetirizine HCl) tablet, 10 mg.

We acknowledge receipt of your amendments dated October 11 and November 18, 2011.

This “Prior Approval” supplemental new drug application provides for three bonus package sizes of Zyrtec[®] Allergy 10 mg tablets in the following count sizes: 40-count (30 + 10 free tablets), 60-count (45 + 15 free tablets), and 120-count (100 + 20 free tablets).

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.

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 following enclosed labeling submitted on July 26 and November 18, 2011, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable. FPL must be submitted for all the representative count sizes. Representative labeling will not be acceptable in the FPL submission.

- 40-count immediate container (bottle) label
 - Representative of 60 count immediate container (bottle) label
- 50- and 70-count immediate container (bottle) labels
- 40- count carton labels (front and back card)
 - Representative of 60-count carton labels (front and back card)
- 120-count carton labels (front and back card)
- “Bonus Pack” sticker

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-029.**” 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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

Carton and Container Labeling

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
01/26/2012