



NDA 022155/S-007

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 on December 2, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Zyrtec (cetirizine HCL) Allergy Syrup.

This "Prior Approval" supplemental new drug application provided for the following:

- A. An instant redeemable coupon (IRC) to be applied to the Principal Display Panel of 4 oz. package sizes of Children's Zyrtec Allergy Syrup

We also acknowledge receipt of your amendment dated March 28, 2012.

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 Instant Redeemable Coupon – Allergy Grape Dye Free- Sugar Free Syrup- 4fl oz and the Allergy Bubble Gum Dye Free-Sugar Free Syrup- 4 fl oz labels submitted on March 28, 2012.

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 022155/S-007.**" 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

Enclosures:

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/

ANDREA LEONARD SEGAL
05/22/2012