DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022155/S-009

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare
Attention: Rebecca P. Martinez, M.S.
Manager, Regulatory Affairs
7050 Camp Hill Road, Mail Stop 111
Fort Washington, PA 19034-2299

Dear Ms. Martinez:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 27, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Zyrtec Allergy (cetirizine hydrochloride) syrup, 1mg/mL.

We acknowledge receipt of your amendments dated January 23 and March 28, 2014.

This "Prior Approval" sNDA provides for 1) updates to the Drug Facts Label to reflect recommendations included in the May 2011 Guidance for Industry – Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products and 2) additional labeling revisions such as a revised NDC number, reformatted company name and address, and addition of a phone number for collect calls.

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling for Children's Zyrtec Allergy (cetirizine hydrochloride) 1mg/mL submitted on March 28, 2014 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

- Grape, Dye-Free, Sugar-Free Syrup: 4 fl oz outer carton and immediate container labels
- Bubble Gum, Dye-Free, Sugar-Free Syrup: 4 fl oz outer carton and immediate container labels

Even though no revisions were made to the 15 mL (sample) grape, dye-free, sugar-free; 2oz, 15 mL (sample) bubble gum, dye-free, sugar-free; and 2 oz, 4 oz, 15 mL (sample) grape, non-sugar free, submit labels 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 FPL 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-009**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
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/

THERESA M MICHELE
05/16/2014