DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020641/S-037

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Sangeeta Patel
Associate Director, CMC Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981-0915

Dear Ms. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated April 23, 2015, received April 24, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Claritin Grape Oral Solution (loratadine) 5 mg per 5 mL.

We acknowledge receipt of your amendment dated August 4, 2015.

This "Changes Being Effected" sNDA provides for new 6 fluid ounce and 8 fluid ounce package sizes with associated labeling. 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 the submitted stock keeping units (SKUs) identified in the table below by submission date, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Labeling SKU	Date of Submission
6 fluid ounce outer carton label	April 23, 2015
6 fluid ounce immediate container label	August 4, 2015
8 fluid ounce outer carton label	April 23, 2015
8 fluid ounce immediate container label	April 23, 2015
Tamper evident tape	April 23, 2015

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 20641/S-037.**" 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 Drug Products
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/

THERESA M MICHELE
10/21/2015