DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020641/S-036

SUPPLEMENT APPROVAL

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

Dear Ms. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated December 15, 2014, received December 16, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin (loratadine) oral solution, 5 mg per 5 mL.

We also refer to our approval letter dated April 16, 2015 which contained the following eror: The labeling images in the attached labeling were incorrect.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 16, 2015, the date of the original approval letter.

We acknowledge receipt of your amendments dated December 23, 2014; March 9, March 11, April 6, and April 9, 2015.

This "Prior Approval" sNDA provides for:

- Reformulated Children's Claritin Allergy Grape oral solution
- Granted request to waive submission of evidence measuring the bioavailability and bioequivalence of the reformulated drug product
- Replaced existing dosage cup for all currently approved sizes
- 24-month expiry for all currently approved sizes
- Increased 1.5 fl oz bottle fill volume from 20 mL to 30 mL
- Replaced 20 mL product sample with new 1 fl oz (30 mL) product sample size
- Tightened the Loratadine Specification Acceptance Criteria in the drug product to (b) (4) %
- New source of (b) (4)
- Revised labeling to reflect these changes.

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. Submit FPL for Claritin (loratadine) oral solution, 5 mg per 5 mL, identical to the 1 fl oz (30 mL) and 4 fl oz (120 mL) immediate container (bottle) label and carton labeling and tamper evident tape labeling submitted on April 9, 2015. The 2 fl oz (60 mL) and 5 fl oz (150 mL) immediate container (bottle) labels and carton labeling will incorporate these changes and will be submitted as part of the FPL and must be identical to the enclosed labeling submitted April 9, 2015, except for differences in net contents of liquid measure, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. Please note that representative labeling is not acceptable for FPL.

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 020641/S-036**." 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/

SHERRY A STEWART
04/16/2015

THERESA M MICHELE
04/16/2015