DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21891/S-26

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Danielle Larino
Associate Director, Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Ms. Larino:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 18, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Claritin (loratadine) chewable tablet, 5 mg.

This "Prior Approval" supplemental new drug application provides for new 40-count packages of grape and bubblegum flavored Children's Claritin (loratadine) chewable tablets, 5 mg.

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, with the minor editorial revisions listed below:

We refer to your clarifying email response dated January 4, 2018, to our recent information request regarding required bolding of the statement of identity.

We observe that although the statement of identity may be bolded, the bolded font weight characteristics appear to vary.

This variation may be a factor of font family style differences or actual variation in the PDF unrelated to the final printed labeling. Such differences may account for the bold weight variation we observe in our copies of the electronic PDF labels. We note that most, but not all, standard font families include a standard bold face type.

Adjust the statement of identity graphic characteristic (i.e., bolding) to be consistent in bolding font style weight. Submit these typeface adjustments in your final printed labeling.

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 described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Labeling Item	Date Submitted
40-count (grape flavor) outer container (carton)	09/18/2017
40-count (bubblegum flavor) outer container (carton)	09/18/2017
10-count immediate container (blister mat)	09/18/2017

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21891/S-26**." 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
02/15/2018