DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21891/S-29

**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 July 24, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin (loratadine) chewable tablet, 5 mg.

This "Prior Approval" supplemental new drug application provides for the addition of a new Claritin (loratadine) chewable tablet,10 mg drug product and Bayer Healthcare LLC, Myerstown, PA as the site of manufacture and quality control testing for the Claritin (loratadine) chewable tablet, 10 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 and with the revisions listed below.

This approval is based on, in part, the commitment from Bayer Healthcare L.L.C. to revise all labeling in this supplement such that all labeling is compliant with 21 CFR 201.61(b). Specifically, the sponsor agreed to move the descriptive term "Chewables" so that it does interfere with the proprietary name or the statement of identity. This commitment was made in an email dated November 20, 2018 and by formal submission to the NDA. The revised labeling will be submitted as final printed labeling.

## LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Except for the required revision to the labeling in which the descriptor "Chewables" must be moved or removed such that the label becomes compliant with 21 CFR 201.61(b), FPL must be identical to the draft labeling, described in Table 1 below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

**Table 1: Reviewed Labeling**

| Labeling Item | Date Submitted |
|---|---|
| 10-count outer container (carton) | 11/16/2018 |
| 30-count outer container (carton) | 11/16/2018 |
| 10-count immediate container (blister) | 07/24/2018 |

The final printed labeling 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 (April 2017, Revision 4)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21891/S-29.**" 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.

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:
Draft Carton and Container Labeling

---

**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

---

/s/

---

THERESA M MICHELE
11/21/2018