NDA 021891/S-038

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Hans Knapp
Director, Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NY 07981-0915

Dear Dr. Knapp:

Please refer to your supplemental new drug application (sNDA) dated and received on October 6, 2020, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Claritin® Chewables loratadine (5mg) chewable tablets. This Prior Approval supplemental new drug application provides for the introduction of two new carton configurations containing the following:

- 40-count variety pack with 2 blister cards of 10-count bubblegum, and 2 blister cards of 10-count grape flavor in a single carton, and

- 60-count variety pack with 3 blister cards of 10-count bubblegum flavor, and 3 blister cards of 10-count grape flavor in single carton.

APPROVAL & 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 enclosed agreed-upon 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 following table:

Submitted Draft Labeling	Date Submitted
grape flavor, bubblegum flavor – 40-count variety pack carton	3/11/2021
grape flavor, bubblegum flavor – 60-count variety pack carton	3/11/2021
bubblegum flavor – 10-count blister card	10/6/2020
grape flavor – 10-count blister card	10/6/2020

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021891/S-038**." 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 FDA.gov.[1] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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.

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

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director (Acting)
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container (blister) 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/

NUSHIN F TODD
04/02/2021 11:10:36 AM