NDA 21891/S-34

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 February 11, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin Chewables (loratadine) chewable tablet, 10 mg.

This "Prior Approval" supplemental new drug application provides for labeling an 80-count (cool mint flavor) configuration, consisting of two 40-count cartons (cool mint flavor) each carton containing five 8-count blister cards, and each carton attached to a backer card held in place with a clear plastic overlay.

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

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*.[1] For administrative purposes, designate this submission "**Final Printed**

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Labeling for approved NDA 21891/S-34." Approval of this submission by FDA is not required before the labeling is used.

Submitted Draft Labeling	Date Submitted
40-count outer container (carton, 10 mg, cool mint)	5/15/2020
80-count backer card (front and back, 10 mg, cool mint)	5/15/2020
8-count immediate container (blister card, 10 mg, cool mint)	5/15/2020

ADDITIONAL COMMENTS

We acknowledge your submission dated June 23, 2020, wherein you committed to submit the changes listed in our April 6, 2020 request for information to the remaining approved blister card labels under this NDA in a prior approval supplement in third quarter 2020. We expect the corrected labels to be implemented once the current supply of printed labels is exhausted.

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.[2] 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).

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

If you have any questions, call Dr. Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- 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/

NUSHIN F TODD
08/07/2020 02:32:07 PM