NDA 21891/S-36

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Hans Knapp, PhD
US Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Dr. Knapp:

Please refer to your supplemental new drug application (sNDA) dated and received August 14, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin Chewables (loratadine) chewable tablets, 10 mg.

This "Prior Approval" supplemental new drug application provides for updates to the blister cards to comply with 21 CFR 201.10(i) and USP standards.

APPROVAL & LABELING

We have completed our review of this application. 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 table below.

Submitted Draft Labeling	Date Submitted
5 mg grape flavor 9-count blister card	8/14/2020
5 mg grape flavor 10-count blister card	8/14/2020
5 mg bubblegum flavor 10-count blister card	8/14/2020
10 mg cool mint flavor 2-count blister card	8/14/2020
10 mg cool mint flavor 4-count blister card	8/14/2020
10 mg grape flavor 10-count blister card	8/14/2020

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 21891/S-36**." 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 A. Stewart, PharmD, Senior Regulatory Project Manager, at 301-796-9618.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Container (blister) labels

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

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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
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