NDA 21891/S-32

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 28, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin (loratadine) chewable tablet, 10 mg.

We acknowledge receipt of your resubmission dated July 3, 2019, in response to our April 29, 2019 refusal-to-file letter.

This "Prior Approval" supplemental new drug application provides for a new loratadine 10 mg chewable tablet drug product formulation with cool mint flavor and associated labeling.

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 enclosed labeling submitted on July 3, 2019, as described below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. We remind you to remove the "New Cool Mint 10 mg Chewable" flag from the upper left corner of the principal display panel 6 months after marketing.

Submitted Labeling
2-count outer container (pouch)
4-count outer container (carton)
4-count outer container (sample carton)
8-count outer container (carton)
24-count outer container (carton)
56-count outer container (carton)
64-count outer container (carton)
2-count outer container (backer card)
2-count immediate container (blister)
4-count immediate container (blister)
8-count immediate container (blister)
Coupon ($3) for inside outer container (carton)
Coupon ($4) for inside outer container (carton)
Coupon ($5) for inside outer container (carton)
Instantly redeemable coupon ($1) hangtag type for outer container (carton)
Instantly redeemable coupon ($2) hangtag type for outer container (carton)
Instantly redeemable coupon ($3) hangtag type for outer container (carton)
Instantly redeemable coupon ($4) hangtag type for outer container (carton)

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 Labeling for approved NDA 21891/S-32**." Approval of this submission by FDA is not required before the labeling is used.

[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.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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).

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

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

---

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
11/07/2019 08:37:40 AM