NDA 21891/S-33

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Danielle Larino
US 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 April 3, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Claritin Chewables (loratadine) chewable tablets, 5 mg.

This "Prior Approval" supplemental new drug application provides for two new packaging configurations for blisters, a 36-count stock keeping unit (SKU) and a 72-count SKU consisting of two 36-count SKUs on a backer card held in place with a clear plastic overlay. The 36-count SKU consists of four 9-count blister cards (9 blister cells instead of 10) in a carton based on the 5 mg chewable tablet 10-count blister card.

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

Labeling	Date Submitted
72-count outer container (backer card)	04/03/2019
36-count outer container (carton)	04/03/2019
9-count immediate container (blister card)	04/03/2019

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-33**". 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.[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*.

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

[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.

[2] 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/

THERESA M MICHELE
10/03/2019 09:51:31 AM