NDA 020641/S-048

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Amrita Raman
Associate Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981-0915

Dear Amrita Raman:

Please refer to your supplemental new drug application (sNDA) dated and received on August 18, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin (loratadine) oral solution, 1 mg/mL.

We acknowledge receipt of your amendment dated October 4, 2023, which constituted a complete response to our October 5, 2022, action letter.

This Prior Approval sNDA provides for a loratadine 5 mg/5 mL oral solution product in a new cooling honey flavor in a 1 oz/30 mL sample size stock keeping unit (sku), a 2.7 oz/80 mL retail size sku, and an 8 oz/240 mL retail size sku.

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.

We note that you have committed in your submission received on April 19, 2024, that you intend to use boldface type for the Statement of Identity (SOI) in all carton and bottle labeling presented in sNDA 020641/S-048.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling (with revision listed above), 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 (with revision listed above) described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Dates submitted
1 oz outer container (sample)	2/9/2024
1 oz immediate container (bottle) (sample)	10/4/2023
2.7 oz outer container	2/9/2024
2.7 oz immediate container (bottle)	10/4/2023
8 oz outer container	2/9/2024
8 oz immediate container (bottle)	10/4/2023
Tamper-evident seal	6/6/2022
1 fl oz dosing cup	1/10/2024
80-240 mL dosing cup	1/10/2024

Please submit these labeling 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 "**Product Correspondence – Final Printed Carton and Container Labeling for approved NDA 020641/S-048**." Approval of this submission by FDA is not required before the labeling is used.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly

stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[1].

If you have any questions, contact Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656 or Phong.Pham@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Carton and Container Labeling

[1] https://www.uspnf.com/

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/

MARTHA K LENHART
05/22/2024 01:38:25 PM