



NDA 021891/S-044

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Amrita Raman
Associate Director, Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Amrita Raman:

Please refer to your supplemental new drug application (sNDA) dated and received on September 15, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin Chewables (loratadine) tablets, 5 mg.

This Prior Approval sNDA provides for:

- addition of a “DYE FREE” graphic flag and deletion of dyes from the Inactive Ingredients section of the Drug Facts Label for both grape and bubble gum flavored products
- updates to the dosage form imagery for the grape flavored tablet to reflect a change in imprint

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.

CARTON AND CONTAINER LABELING

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

Submitted Draft Labeling	Date(s) Submitted
2-count pouch (grape flavor)	6/25/24
2-count pouch (grape flavor), 50-pouch dispenser	5/1/24

10-count carton (grape flavor)	5/1/24
10-count carton (bubblegum flavor)	5/1/24
20-count carton (grape flavor)	5/1/24
20-count carton (bubblegum flavor)	5/1/24
30-count carton (grape flavor)	5/1/24
30-count carton (bubblegum flavor)	5/1/24
40-count carton (grape flavor), vertical PDP	5/1/24
40-count carton (grape flavor), horizontal PDP, with UPC	6/25/24
40-count carton (grape flavor), horizontal PDP, no UPC, new	6/25/24
40-count carton (bubblegum flavor)	5/1/24
40-count carton, variety pack (grape & bubblegum flavors)	5/1/24
60-count carton, variety pack (grape & bubblegum flavors)	5/1/24
60-count carton (grape flavor)	5/1/24
80-count (2 x 40-count) backer card (grape flavor)	9/15/23

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 021891/S-044.**” 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.

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}

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

ENCLOSURE(S):

- 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
07/11/2024 02:50:50 PM