

NDA 021891/S-047

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 November 21, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin Chewables (loratadine) chewable tablets, 10 mg, grape flavored.

This “Prior Approval” supplemental new drug application provides for new count sizes and updated labeling as follows:

- 40 count carton (no UPC);
- 50 count carton (no UPC);
- 60 count carton (no UPC);
- 80 count backer card with 2 x 40 count cartons;
- 90 count backer card with one 40 count carton and one 50 count carton;
- 100 count backer card with 2 x 50 count cartons.

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 in the “Drug Facts” format (21 CFR 201.66), where applicable, and identical to the following:

Submitted Draft Labeling	Dates submitted
40-count carton (No UPC)	11/14/2025
50-count carton (No UPC)	11/14/2025
60-count carton (No UPC)	11/14/2025
80-count backer card (2 x 40-count cartons)	4/27/2026
90-count backer card (1 x 40-count carton and 1 x 50-count carton)	4/27/2026
100-count backer card (2 x 50-count cartons)	4/27/2026

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 021891/S-047.**” 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*. 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).

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>

If you have any questions, contact Tam Dinh, PharmD, Regulatory Project Manager, at 240-402-6284 or Tam.Dinh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Carton and 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
05/20/2026 08:49:51 AM