NDA 021891/S-043

SUPPLEMENT APPROVAL

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

Dear Ms. Raman:

Please refer to your supplemental new drug application (sNDA) dated and received on July 1, 2022, and your amendments 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 new packaging sizes, 70-count (30-ct plus 40-ct) and 80-count (2 x 40-ct), as well as labeling updates to previously approved grape and bubblegum flavor cartons, blister cards, pouch, pouch dispensing bin, and backer cards.

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 with the agreed-upon revision listed below:

For enclosed labeling that has not been revised as of the date of this letter, make the following revision, in accordance with your commitment in the amendment to this supplement dated December 13, 2022:

For ALL Outer Carton Labeling:

- Add the "Made In (variable)" country of origin statement that is printed during final packaging production, with India inserted into the variable placeholder as indicated:

  • 10 count carton, grape flavor – bottom panel
  • 10 count carton, bubblegum flavor – bottom panel
  • 20 count carton, grape flavor – bottom panel
  • 20 count carton, bubblegum flavor – bottom panel
  • 30 count carton, grape flavor – bottom panel

- 30 count carton, grape flavor, no UPC, new – side panel
- 30 count carton, bubblegum flavor – bottom panel
- 36 count carton, grape flavor, no UPC – side panel
- 40 count carton, grape flavor – bottom panel
- 40 count carton, grape flavor, no UPC, new – side panel
- 40 count carton, bubblegum flavor – bottom panel
- 40 count carton, variety pack (grape & bubblegum flavors) – bottom panel
- 60 count carton, variety pack (grape & bubblegum flavors) – bottom panel
- 60 count carton, grape flavor – bottom panel

LABELING

Submit final printed labeling (FPL), with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must include the labeling listed in the table below, with the agreed upon revision, 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)	12/21/22
2-count pouch (grape flavor), 50-pouch dispenser	12/21/22
10-count blister (grape flavor)	12/21/22
10-count blister (grape flavor), variety pack	12/21/22
10-count blister (bubblegum flavor)	12/21/22
10-count blister (bubblegum flavor), variety pack	12/21/22
10-count carton (grape flavor)	12/21/22
10-count carton (bubblegum flavor)	12/21/22
20-count carton (grape flavor)	12/21/22
20-count carton (bubblegum flavor)	12/21/22
30-count carton (grape flavor)	12/21/22
30-count carton (grape flavor), no UPC	12/21/22
30-count carton (bubblegum flavor)	12/21/22
36-count carton (grape flavor), no UPC	12/21/22
40-count carton (grape flavor)	12/21/22
40-count carton (grape flavor), no UPC	12/21/22
40-count carton (bubblegum flavor)	12/21/22
40-count carton, variety pack (grape & bubblegum flavors)	12/21/22
60-count carton, variety pack (grape & bubblegum flavors)	12/21/22
60-count carton (grape flavor)	12/21/22
70-count (30-ct + 40-ct) backer card (grape flavor)	12/21/22
72-count (36-ct + 36-ct) backer card (grape flavor)	12/21/22
80-count (2 x 40-count) backer card (grape flavor)	12/21/22

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-043**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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

[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

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).

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 Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656 or email at 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
Office of New 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
12/27/2022 03:24:14 PM