



NDA 19670/S-34
NDA 20470/S-47

SUPPLEMENT APPROVAL

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

Dear Ms. Larino:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received February 2, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 19670/S-34 Claritin-D 12 Hour (loratadine 5mg/pseudoephedrine sulfate 120 mg) tablets, extended release
- NDA 20470/S-47: Claritin-D 24 Hour (loratadine 10 mg/pseudoephedrine sulfate 240 mg) tablets, extended release

These “Prior Approval” sNDAs provide for the addition of in-pack coupons (IPCs).

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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

**Table 1: NDA 019670/S-034 Claritin D 12 Hour
Final Printed Labeling**

Labeling Item	Date Submitted
In-pack coupon (version 1) \$2 coupon will accompany 10-count	02/02/2018
In-pack coupon (version 2) \$3 coupon will accompany 20-, 30-count	02/02/2018

**Table 2: NDA 020704/S-044 Claritin D 24 Hour
Final Printed Labeling**

Labeling Item	Date Submitted
In-pack coupon (version 1) \$2 coupon will accompany 10-count	02/02/2018
In-pack coupon (version 2) \$3 coupon will accompany 15-count	02/02/2018

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate these submissions “**Final Printed Labeling for approved NDA 19670/S-34 and Final Printed labeling for approved NDA 20470/S-47.**” Approval of these submissions 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 FPL, the content of labeling (Drug Facts) should be submitted in SPL format as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for approved NDAs (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:
In-Pack Coupons (IPCs)

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/

KAREN M MAHONEY
07/31/2018
Signing for Theresa Michele.