DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019658/S-044

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Consumer Care
Attention: Joanna Fleming
Sr. Specialist, Regulatory Affairs
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981-0915

Dear Ms. Fleming

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 7, 2015 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin (loratadine) tablets, 10 mg.

This "Prior Approval" sNDA provides for changes to the cartons, window box cartons, backer cards, and dump bins as follows: removes the NDC number, adds the Bayer wordmark and cross, updates the Bayer trademark, and revises the legal entity and distributor information. The blistercards, bottle labels, and single pouches are also updated to reflect Bayer's ownership. Provision is also made for use of in-pack coupons and instant redeemable coupons (IRCs) with specific package count sizes as delineated below.

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 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 for the stock keeping units (SKUs) identified below by submission date, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

18 June 2015 Outer container labels:

- 5-count
- 5-count (hanger)
- 10-count
- 20-count
- 30-count (window box)
- 40-count (bonus window box))

- 45-count (window box)
- 60-count (bonus window box)
- 70-count (window box)
- 80-count (bonus window box)
- Two 45-count (backer card)
- 90-count (backer card)
- 105-count (90 + 15 bonus backer card)
- 105-count (45 + 60 bonus backer card)
- 25-count bin
- 50-count bin
- 50-count bin (sample)
- 70-count (window box; IRC applied)

18 June 2015 Immediate container labels:

- 5-count blister card
- 10-count blister card
- 30-count bottle
- 40-count bottle (bonus)
- 45-count bottle
- 60-count bottle (bonus)
- 60-count bottle
- 70-count bottle
- 80-count bottle (bonus)
- 90-count bottle
- 1-count pouch
- 1-count pouch (sample)

18 June 2015 Coupons:

- $5 IRC [front (70-count PDP) and back ($5 IRC)]
- Version 1 - $3 coupon (10-count carton)
- Version 2 - $2/$3/$5 coupon (30-count window box, 30 + 10 bonus window box)
- Version 3 - $3/$5 coupon (45-count window box, 45 + 15 bonus window box)

08 October 2015 Outer container labels:

- 30-count (window box; IRC applied)
- 45-count (bonus window box; IRC applied)

08 October 2015 Coupons:

- $2 IRC [front (30-count PDP) and back ($2 IRC)]
- $3 IRC [front (45-count PDP) and back ($3 IRC)]

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 019658 /S-044**." 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 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, 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(s) 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 an approved NDA (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

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
12/18/2015