DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021891/S-018

SUPPLEMENT APPROVAL

MSD Consumer Care,
Attention: Danielle Shanley
Specialist, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Shanley:

Please refer to your Supplemental New Drug Application (sNDA) dated January 24, 2014, received January 27, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin® (loratadine) chewable tablet, 5 mg.

We acknowledge receipt of your amendments dated May 28, July 2, and July 17, 2014.

This "Prior Approval" sNDA provides for changes to the principal display panel (PDP) including:

- Removal of the red "Allergy" flag
- Repositioning the word "Chewables" to the center of the PDP below the proprietary name
- Addition of a red banner to the left side of the PDP
- Repositioning the net contents statement to the right of the PDP

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling for Claritin (loratadine) chewable tablets, 5 mg:

- 10-count carton (representative of the 20-, 30- and 50-count cartons), 2-count pouch, 50 x 2-count sample bin and 50-count blister card submitted on May 28, 2014
- 20-count + 5-ct consumer sampling carton submitted on July 17, 2014

We remind you that representative labeling is not acceptable in the FPL, therefore, submit the 20-, 30- and 50-count outer carton labels as part of the FPL.

In addition, if you plan to re-introduce a discontinued SKU for marketing, submit the labeling as a prior approval supplement.

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 021891/S-018**." 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 Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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
07/25/2014