DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020641/S-032

SUPPLEMENT APPROVAL

MSD Consumer Care, Inc.
Attention: Sangeeta Patel
Senior Specialist, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated October 31, 2012, received November 2, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin (loratadine) oral solution, 5 mg/5 mL.

This "Prior Approval" supplemental new drug application proposes to introduce a new physician sample size of 20 mL.

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 and with the minor editorial revisions listed below.

1. The standard abbreviation for milliliter is "mL". In the net quantity of contents statement on the carton and bottle labels, correct the "ml" to "mL" in the final printed labeling.
2. The bullet size at 3.5 point type size does not meet the specifications listed in 21 CFR 201.66(d)(4). The bullets should be changed to 5 point type size. This change should be made in the final printed labeling.
3. Consider revising the abbreviation for teaspoon from "TSP" to "tsp" on the carton and bottle labels and dosing cup. See ***Guidance for Industry – Dosage Delivery Devices for Orally Ingested Liquid Drug Products (May 2011)***.

LABELING

Submit final printed labeling, with the revisions listed above, 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 Claritin 0.67 fl. oz. (20 mL) carton and immediate container (bottle) label submitted on October 31, 2012, with the editorial revisions noted above and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling 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 020641/S-032**." 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.

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy 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/

JOEL SCHIFFENBAUER
02/28/2013