DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19658/S-55
NDA 21952/S-18

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Mary E. Williams
Senior Associate Director, US Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Ms. Williams:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received July 6, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

- NDA 19658/S-55, Claritin (loratadine) tablets, 10 mg
- NDA 21952/S-18, Claritin Liqui-Gels (loratadine), capsules, 10 mg

These "Prior Approval" supplemental new drug applications provide for one full face instantly redeemable coupon (IRC) and six new hangtag IRCs for NDA 19658/S-55, and one full face IRC and five new hangtag IRCs for NDA 21952/S-18.

We have completed our review of these applications. 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: Labeling Submitted for Review of NDA 019658/S-55

Labeling Item	Submission Date
PDP coupon for $1 off 10-count or larger	07/06/18
Hangtag coupon for $1 off 10-count or larger	07/06/18
Hangtag coupon for $2 off 30-count or larger	07/06/18
Hangtag coupon for $3 off 30-count or larger	07/06/18
Hangtag coupon for $4 off 45-count or larger	07/06/18
Hangtag coupon for $5 off 70-count or larger	07/06/18
Hangtag coupon for $6 off 90-count only	07/06/18

Table 2: Labeling Submitted for Review of NDA 021952/S-18

Labeling Item	Submission Date
PDP coupon for $1 off 5-count or larger	07/06/18
Hangtag coupon for $1 off 10-count or larger	07/06/18
Hangtag coupon for $2 off 30-count or larger	07/06/18
Hangtag coupon for $3 off 30-count or larger	07/06/18
Hangtag coupon for $4 off 60-count only	07/06/18
Hangtag coupon for $5 off 60-count only	07/06/18

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 (April 2017, Revision 4).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19658/S-55**" and **"Final Printed Labeling for approved NDA 21952/-18."** 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 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 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:
Instantly Redeemable Coupons for NDA 19658/S-55 and NDA 21952/S-18

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/

THERESA M MICHELE
12/21/2018