DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20704/S-34
NDA 21993/S-17

SUPPLEMENT APPROVAL

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

Dear Ms. Williams:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received August 28, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA NUMBER:	20704
SUPPLEMENT NUMBER:	34
PRODUCT NAME:	Claritin (loratadine) RediTabs 24 Hour orally disintegrating tablets, 10 mg

NDA NUMBER:	21993
SUPPLEMENT NUMBER:	17
PRODUCT NAME:	Claritin (loratadine) RediTabs 12 Hour orally disintegrating tablets, 5 mg

These "Prior Approval" sNDAs provide for the addition of three new hangtag type instantly redeemable coupons.

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 table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Item	Date
$2 hangtag coupon for 10-count or larger	08/28/2018
$3 hangtag coupon for 30-count only	08/28/2018
$4 hangtag coupon for 30-count only	08/28/2018

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 (April 2017, Revision 4).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20704/S-34"** and **"Final Printed labeling for approved NDA 21993/S-17**." 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

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
02/28/2019 07:33:00 PM