NDA 213872

NDA APPROVAL

Bayer Healthcare, LLC
Attention: Cherise Adair
Rx to OTC Switch Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Ms. Adair:

Please refer to your new drug application dated and received August 20, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Astepro Allergy (azelastine hydrochloride) nasal spray, 205.5 mcg per spray and Children's Astepro Allergy (azelastine hydrochloride) nasal spray, 205.5 mcg per spray.

This new drug application provides for the use of Astepro Allergy (azelastine hydrochloride) nasal spray, 205.5 mcg per spray and Children's Astepro Allergy (azelastine hydrochloride) nasal spray, 205.5 mcg per spray for the temporary relief of these symptoms due to hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, and itchy nose.

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 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.

Submitted Draft Labeling	Date submitted
22 sprays outer carton	6/4/21
22 sprays immediate container	6/4/21
22 sprays sample outer carton	6/4/21
60 sprays outer carton	6/4/21
60 sprays immediate container	6/4/21

120 sprays outer carton	6/4/21
120 sprays immediate container	6/4/21
200 sprays outer carton	6/4/21
200 sprays immediate container	6/4/21
Children's 60 spray outer carton	6/4/21
Children's 60 spray immediate container	6/4/21
Children's 120 spray outer carton	6/4/21
Children's 120 spray immediate container	6/4/21
Twin pack (2 x 120 sprays) outer carton	6/4/21
Club pack (3 x 120 sprays) front and back cards	6/4/21
Tamper evident seal	8/20/20
User guide leaflet	6/4/21
User guide tri-fold	6/4/21

The final printed labeling should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 213872**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. 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.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 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.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

4103-1: Conduct an extended antimicrobial effectiveness test (AET) to demonstrate that the formulation meets USP <51> acceptance criteria over a 50-day in-use period.

Final Report Submission: 12/31/2021

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, PharmD, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director (Acting)
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling

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/

NUSHIN F TODD
06/17/2021 02:41:15 PM