



NDA 213872/S-001

## SUPPLEMENT APPROVAL

Bayer HealthCare, LLC  
Attention: Hans Knapp, PhD  
Director, Regulatory Affairs  
100 Bayer Boulevard  
PO Box 0915  
Whippany, NJ 07981-0915

Dear Dr. Knapp:

Please refer to your supplemental new drug application (sNDA) dated and received July 1, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Astepro Allergy and Children's Astepro Allergy (azelastine hydrochloride) nasal spray, 205.5 mg per spray.

This "Prior Approval" supplemental new drug application provides for the addition of a new 4 mL fill size container providing 22 metered sprays for Children's Astepro Allergy.

### **APPROVAL & LABELING**

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **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.

<b>Submitted Draft Labeling</b>	<b>Date submitted</b>
Children's 22-spray outer container	7/1/2021
Children's 22-spray immediate container	7/1/2021

The FPL 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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 213872/S-001.**” 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.<sup>2</sup> Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and 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.

## **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 Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

*{See appended electronic signature page}*

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

### ENCLOSURE(S):

- Carton and Container Labeling

---

<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

-----  
**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  
11/01/2021 09:59:49 AM