BLA 761391/S-001
BLA 761390/S-002

SUPPLEMENT APPROVAL

Galderma Laboratories, LP
c/o Galderma Laboratories, LLP
Attention: Chase Edwards
Director, Regulatory Affairs
2001 Ross Avenue, Suite 1600
Dallas, TX 75201

Dear Chase Edwards:

Please refer to your supplemental biologics license applications (sBLAs) received January 17, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Nemluvio (nemolizumab-ilto) injection.

These Prior Approval supplemental biologics applications provide for combined labeling based on the approval of BLAs 761390 and 761391 and an administrative closure of BLA 761391.

APPROVAL & LABELING

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 enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

HIGHLIGHTS OF PRESCRIBING INFORMATION

- Update "Revised:" date to 06/2025.

FULL PRESCRIBING INFORMATION

- **12.3 Pharmacokinetics**
  - Specific Populations
    - Changed the subheadings to title case.
- **12.6 Immunogenicity**
  - Add a hard return at the end of the first paragraph.
- **14.2 Atopic Dermatitis**
  - Maintenance and Durability of Response (Week 16 to Week 48)
    - Remove the extra space after the leading word "The" in the first paragraph.

PATIENT PACKAGE INSERT

- Update "Revised:" date to 06/2025.

INSTRUCTIONS FOR USE

- Delete the extra line prior to **Step 7: Dissolve the medicine.**
- **Step 9: Check the medicine in the inspection window**
  - Delete the extra line prior to B. **Injecting NEMLUVIO.**
- **Step 13: Place the NEMLUVIO pen**
  - Correct the line spacing before Step 13.
- **Step 16: Lift the NEMLUVIO pen**
  - Correct the line spacing before Step 16.
- Update "Issued:" date to 06/2025.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (Prescribing Information, Patient Package Insert, and Instructions for Use) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

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*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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

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

the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplement application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

ADMINISTRATIVE CLOSURE

We have now administratively closed BLA 761391. Therefore, carton and container final printed labeling (if requested above), all 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, promotional materials and other submissions should be addressed to the parent BLA 761390 for this product, not to BLA 761391. In the future, do not make submissions to this BLA.

If you have any questions, email H. F. Van Horn III, PharmD, MBA, Senior Regulatory Project Manager, at Howard.VanHornIII@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Jill Lindstrom, MD, FAAD
Director
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use

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/

JILL A LINDSTROM
06/26/2025 02:28:32 PM