NDA 206255/S-005
NDA 206255/S-009

SUPPLEMENT APPROVAL

Galderma Laboratories, L.P.
Attention: Nakia Holmes
Senior Regulatory Affairs Associate
2001 Ross Ave, Suite 1600
Dallas, TX 75201

Dear Ms. Holmes:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 10, 2019, and March 28, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Soolantra (ivermectin) cream, 1%.

These Prior Approval supplemental new drug applications provide for labeling updates to comply with the Pregnancy and Lactation Labeling Rule (PLLR) requirements and a Patient Package Insert.

APPROVAL & LABELING

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (Prescribing Information, Patient Package Insert, Instructions for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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]

[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 SPL will be accessible from publicly available labeling repositories.

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 Qianyiren Song, Regulatory Project Manager, at 301-796-2581.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

TATIANA OUSSOVA
10/14/2022 01:32:57 PM