NDA 021005/S-024

SUPPLEMENT APPROVAL

Fougera Pharmaceuticals Inc
Attention: Gregory Seitz
Executive Director, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Mr. Seitz:

Please refer to your supplemental new drug application (sNDA) dated and received May 13, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Solaraze (diclofenac sodium) topical gel, 3%.

This Prior Approval sNDA provides for the addition of section 6.2 within the prescribing information (PI) and formatting changes in the Medication Guide (MG).

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.

- Prescribing Information:
  - HIGHLIGHTS OF PRESCRIBING INFOMRATION:
    - Updated Revised: XX/XXXX **to** Revised: 11/2022
  - 5.2 Exacerbation of Asthma Related to Aspirin Sensitivity
    - At the end of the second sentence delete the space before the period.
  - 5.3 Serious Skin Reactions
    - At the end of the second sentence delete the space before the period.
  - 6.1 Clinical Trials Experience
    - In the second paragraph change (183subjects) **to** (183 subjects)
- Medication Guide:
  - Updated Revised: XX/XXXX **to** Revised 11/2022

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 and Medication Guide), 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]

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 H. F. Van Horn III, PharmD, MBA, Regulatory Project Manager, at (301) 837-7389.

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[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.

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
11/14/2022 10:06:18 AM