



NDA 021005/S-023

## 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 March 11, 2021, 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:

- Physician Labeling Rule (PLR) Conversion of the prescribing information (PI)
- Pregnancy and Lactation Labeling Rule (PLLR) conversion of the PI
- updates to the Medication Guide
- updates to the carton and container labels

### **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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Prescribing Information (PI):
  - FULL PRESCRIBING INFORMATION CONTENTS:
    - 5.4 Cardiovascular Thrombotic Event changed to 5.4 Cardiovascular Thrombotic Events.
  - HIGHLIGHTS OF PRESCRIBING INFORMATION:
    - Updated Revised: XX/XXXX to Revised: 04/2022
- Medication Guide:
  - Updated Revised: XX/XXXX to Revised 04/2022

## **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.<sup>1</sup> 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*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

## **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted via email on February 8, 2022, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 021005/S-023.**” Approval of this submission by FDA is not required before the labeling is used.

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</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>.

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

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling

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**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.**  
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/s/  
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TATIANA OUSSOVA  
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