NDA 019824/S-025

SUPPLEMENT APPROVAL

Medimetriks Pharmaceuticals, Inc.
Attention: Donna Heren
Head of Regulatory Affairs, QA and CMC
383 Route 46 West
Fairfield, NJ 07004-2402

Dear Donna Heren:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 7, 2025, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Loprox (ciclopirox olamine topical suspension), 1.0%.

This "Changes Being Effected" supplemental new drug application provides for the following revisions as requested within a CBE-0 Supplement Request Letter dated March 31, 2025:

1. The established name from ciclopirox cream to ciclopirox olamine cream to be consistent with the official USP monograph title for the drug product.

2. The expression of strength statement as 1.0%.

3. The equivalency statement between the salt form and active moiety (e.g., each gram of ciclopirox olamine is equivalent to 770 mg of ciclopirox).

4. The list of inactive ingredients to appear in alphabetical order per USP <1091> Labeling of Inactive Ingredients.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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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 NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

CARTON AND CONTAINER LABELS

We acknowledge your May 7, 2025, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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

REPORTING REQUIREMENTS

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

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[1].

If you have any questions, please contact Shazma Aftab, PharmD, Regulatory Business Process Manager, at shazma.aftab@fda.hhs.gov or (301) 796 - 3138.

Sincerely,

{See appended electronic signature page}

Nina Ni, PhD
Supervisor
Division of Product Quality Assessment VII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

- Content of Labeling: Prescribing Information

[1] https://www.uspnf.com/

Nina Ni

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