DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18748/S-025

APPROVAL LETTER

Medimetriks Pharmaceuticals Inc.
Attention: Donna Heren, VP Regulatory Affairs & Quality Assurance
383 Route 46 West
Fairfield, NJ 07004

Dear Ms. Heren:

Please refer to your Supplemental New Drug Application (sNDA) dated December 15, 2014, received December 16, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Loprox (ciclopirox) Cream.

We acknowledge receipt of your amendment dated July 14, 2015, which constituted a complete response to our June 16, 2015, action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4) for drug product manufacturing, packaging, and testing.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

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 labeling submitted on December 16, 2014. 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*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate container labels submitted on July 14, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to

the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 18748**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teshara G. Bouie, Regulatory Business Process Manager, at (301) 796-1649.

Sincerely,

David Lewis, Ph.D., CMC Lead, on behalf of:

David B. Lewis -S
Digitally signed by David B. Lewis -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=David B. Lewis -S, 0.9.2342.19200300.100.1.1=1300124430
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