DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208945/S-001

SUPPLEMENT APPROVAL

Ferrer Internacional S.A.

c/o Cutanea Life Sciences, Inc.
Attention: Jennifer Phillips, PharmD.
Vice President, Regulatory Affairs and Quality Assurance
1500 Liberty Ridge Drive, Suite 3000
Wayne, PA 19087

Dear Dr. Phillips:

Please refer to your Supplemental New Drug Application (sNDA) dated April 6, 2018, received April 6, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XEPI (ozenoxacin) Cream, 1%.

This Prior Approval supplemental new drug application proposes the following changes:

- Change in contact information for **SUSPECTED ADVERSE REACTIONS** in **HIGHLIGHT OF PRESCRIBING INFORMATIION**
- Changes in package insert and container labeling to reflect the change in US distributor from Medimetriks Pharmaceuticals, Inc. to Cutanea Life Sciences, Inc.
- Changes to **HOW SUPPLIED/STORAGE AND HANDLING** Section (16).

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 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.

The SPL will be accessible from 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).

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 Eva Zuffova, PhD, Regulatory Project Manager, at (301) 796-0697.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
- Prescribing Information
- Carton & Container Labeling

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/

DMITRI IARIKOV
02/04/2019 10:46:23 AM