NDA 208081/S-026

SUPPLEMENT APPROVAL

Biofrontera Bioscience Gmbh
c/o Cardinal Health Regulatory Sciences
Attention: Rebecca Lamb-Wharton
Principal Scientist, RAPD
7400 West 110th Street
Commerce Plaza II, Suite 150
Overland Park, KS 66210

Dear Rebecca Lamb-Wharton:

Please refer to your Supplemental New Drug Application (sNDA) dated November 15, 2023, received November 15, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ameluz (aminolevulinic acid hydrochloride) gel.

We also refer to our approval letter dated March 11, 2024, which did not contain the User Manual.

This replacement approval letter incorporates the User Manual. The effective approval date will remain March 11, 2024, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for changes to one of the devices of the combination product, namely the RhodoLED XL lamp. The following changes are proposed:

- Reduction of the LED amperage from 1A to 844 mA and subsequent adjustment of illumination time from 10 min to approx. 13.5 min
- The additional modifications comprise minor alterations of the hard- and software of RhodoLED XL:
  - Implementation of hardware status detection of the panel system
  - Adaptation of ADC measurement frequency
  - Storage of CSV log and log files
  - Optimization in error detection and error handling
  - Optimization of update process
  - Several minor software changes

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

If you have any questions, email Rajani Ranga, Regulatory Business Process Manager, at Rajani.Ranga@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Supervisor, Division of Product Quality Assessment XI
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
User Manual

David
Lewis

Digitally signed by David Lewis
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