DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-415

PhotoCure, ASA
Attn: William Clementi, Pharm.D., F.C.P.
8 Tower Bridge, Suite 1045
161 Washington Street
Conshohocken, PA 19428

Dear Dr. Clementi:

Please refer to your new drug application (NDA) dated September 26, 2001, received September 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TRADENAME (methyl aminolevulinate) Cream, 16.8%, in combination with the CureLight BroadBand Model CureLight 01, which was submitted under premarket approval application (PMA) P010061.

We acknowledge receipt of your submissions dated January 22 and 23, May 25, June 8 and 10, and July 21, 2004.

The May 25, 2004, submission constituted a complete response to our January 16, 2004, action letter.

This new drug application provides for the use of TRADENAME (methyl aminolevulinate) Cream, 16.8%, in combination with the CureLight BroadBand Model CureLight 01 for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation (debridement using a sharp dermal curette) in the physician's office when other therapies are unacceptable or considered medically less appropriate.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-415**." Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated July 21, 2004. These commitments are listed below.

1. Conduct a systemic bioavailability study following application of methyl aminolevulinate cream with different concentrations ranging between (b)(4) 1(b)(4) in patients with multiple (8 – 10) actinic keratosis lesions. Please revise your submitted protocol to include the amount of TRADENAME Cream used (number of tubes and amount used from each tube) as well as the total body surface area in cm^2 treated for each patient.

Protocol Submission:	August 2004
Study Start:	January 2005
Final Report Submission:	December 2006

2. Conduct a 12-month safety study in at least 200 evaluable patients with 10 or more actinic keratosis lesions with diameters of ≥4 mm, documenting the effects of retreatment of lesions with partial response and treatment of new lesions. In this study, representative numbers of patients with higher Fitzpatrick skin types, e.g. Asians and Hispanics, should be included. Location of lesions should be sufficiently identified for long-term follow-up. The gram amount of TRADENAME Cream applied with each treatment session should be documented. Laboratory parameters should be collected, and patients should be monitored for photoallergic reactions.

Protocol Submission:	August 2004
Study Start:	January 2005
Final Report Submission:	December 2006

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to

the Division of Dermatologic and Dental Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Melinda Harris, M.S., Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonathan Wilkin
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