DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20965/S-006 **APPROVAL LETTER**

DUSA Pharmaceuticals, Inc.
Attention: Scott Lundahl
25 Upton Drive
Wilmington, MA 01887

Dear Mr. Lundahl:

Please refer to your supplemental new drug application dated November 19, 2007, received November 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levulan® Kerastick® (aminolevulinic acid HCl) Topical Solution, 20% for treatment of minimally to moderately thick actinic keratoses of the face or scalp.

We acknowledge receipt of your submission dated May 2, 2008.

This supplemental new drug application provides for modification of the "Dosage and Administration" section of the approved product labeling to allow for the user to mix the contents of the ampoules prior to use in a period of 30 seconds rather than the current 3 minute mixing time. In addition, this supplement proposes revised labeling that supports the use of a new tool, the "Kerastick Krusher", which assists the user in crushing the ampoules prior to admix.

We completed our review of this application, as amended. This application 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 patient package insert submitted November 19, 2007.

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 supplement NDA 20-965/S-006**." Approval of this submission by the FDA is not required before the labeling is used.

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 Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Elaine Smoot, Regulatory Project Manager, at (301) 796-3986.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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/

Stanka Kukich

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