DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-965/S-004

DUSA Pharmaceuticals, Inc.
Attention: Scott Lundahl
Director, Regulatory Affairs (Acting)
25 Upton Drive
Wilmington, MA 01887

Dear Mr. Lundahl:

Please refer to your supplemental new drug application dated March 11, 2003, received March 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LEVULAN® KERASTICK® (aminolevulinic acid hydrochloride) for Topical Solution, 20%.

This supplemental new drug application provides for a new manufacturing site for the production of LEVULAN® KERASTICK® for Topical Solution finished drug product.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the submitted labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (for the text of the package insert) and to the submitted labeling (immediate container and carton labels submitted March 11, 2003) and must be formatted in accordance with the requirements of 21 CFR 201.66. Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-965/S-004." Approval of this submission by 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 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

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, HF-2
Food and Drug Administration
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 Jacquelyn Smith, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp II, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
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/

Steve Hathaway
7/11/03 12:34:18 PM
Signed on behalf of W H DeCamp, as Acting CMC Team Leader