DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-965/S-002

DUSA Pharmaceticals, Incorporated
Attention: William R. McIntyre, Ph.D.
Regulatory Consultant
400 Columbus Avenue
Valhalla, New York 10595

Dear Dr. McIntyre:

Please refer to your supplemental new drug application dated February 6, 2002, received February 11, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levulan® (aminolevulinic acid HC1) for Topical Solution, 20%.

This "Changes Being Effected" supplemental new drug application provides for the Package Insert to be updated to include the statement "Excessive irritation may be experienced if this product is applied under occlusion" under the Warning section.

We completed our review of the supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 17, 2002.

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
FDA
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}

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/

John Kelsey
3/26/03 01:14:34 PM
for Dr. Wilkin