DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020965/S-007 **SUPPLEMENT APPROVAL**

DUSA Pharmaceuticals, Inc.
Attention: Scott Lundahl
Vice President Regulatory Affairs/Intellectual Property
25 Upton Drive
Wilmington, MA 01887

Dear Mr. Lundahl:

Please refer to your supplemental new drug application dated May 13, 2009, received May 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%.

We acknowledge receipt of your submissions dated June 17, June 18, June 22, June 25, July 6, July 7, October 28, and February 26, 2010.

This "Prior Approval" supplemental new drug application provides for revisions to the Clinical Studies section of the labeling. In addition, Levulan® Kerastick® for Topical Solution full prescribing information was revised to meet the new labeling content and format requirements for human prescription drug and biological products according to 21 CDR 201.56(d) and 201.57.

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

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 020965/S-007.

## LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

**REPORTING REQUIREMENTS**

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 Jeannine M. Helm, Regulatory Project Manager, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-20965 | SUPPL-7 | DUSA PHARMACEUTICALS INC | LEVULAN KERASTICK(AMINOLEVULINIC ACID HC |

---

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

---

/s/

SUSAN J WALKER
03/12/2010