We consider all the information contained in this application proprietary and confidential. Please be advised that the confidentiality of all enclosed information is provided for under 18 USC, Section 1905 and/or USC, Section 331j.

Sincerely yours,

Samuel D. Swetland

Samuel D. Swetland
Vice President, Regulatory Affairs and Compliance

SDS/sds
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APPEARS THIS WAY
ON ORIGINAL

SUPPL NEW CORRES

DUPLICATE

GUIDELINES INCORPORATED

September 30, 1998

Olga Cintron, Project Manager
Division of Dermatologic and Dental Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
2nd Floor North
9201 Corporate Boulevard
Rockville, MD 20850

REFERENCE: New Drug Application for Levulan® (aminolevulinic acid HCl) Kerastick™ for Topical Solution, 20% - **NDA No. 20-965**

Dear Olga:

Attached please find copies of two correspondences submitted regarding the above application. This information was provided directly to the requesting parties as a result of a telephone correspondence. In each case, no new information has been provided that was not available in the original NDA submission. These correspondences are being provided to you for informational purposes and to maintain a record of the NDA correspondence. Please feel free to call me if you have any questions regarding either of these correspondences.

Sincerely yours,

Samuel D. Swetland

Samuel D. Swetland
Vice President, Regulatory Affairs and Compliance

SDS/sds
DUSA\NDA Documents\Cover Letter-6.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on last page.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
DUSA Pharmaceuticals, Inc.	September 30, 1998
TELEPHONE NO. *(Include Area Code)* (914) 747-4300	FACSIMILE (FAX) Number *(Include Area Code)* (914) 747-7563

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:

400 Columbus Avenue
Valhalla, NY 10595

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

Guidelines, Inc.
10320 USA Today Way
Miramar, FL 33025
(954) 433-7480 FAX: (954) 432-9015

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 20-965

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Aminolevulinic Acid HCl	Levulan® Kerastick™

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
5-amino-4-oxopentanoic acid	5-ALA HCl, 5-ALA, ALA

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Solution	20%	Topical

(PROPOSED) INDICATION(S) FOR USE:
Treatment of [redacted] actinic keratoses of the face and scalp

LICATION INFORMATION

APPLICATION TYPE (check one) ☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☒ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Holder of Approved Application

TYPE OF SUBMISSION (check one) ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

REASON FOR SUBMISSION General Correspondence

PROPOSED MARKETING STATUS (check one) ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessar y). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attachment to Form FDA 356h

ross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current lication)

GUIDELINES INCORPORATED

September 30, 1998

Richard Felten, PhD
Division of General and Restorative Devices
Office of Device Evaluation
Center for Device and Radiological Health
Food and Drug Administration
HFZ-410, Room 310K
9200 Corporate Boulevard
Rockville, MD 20850

REFERENCE: DESK COPY –
New Drug Application for Levulan® (aminolevulinic acid HCl) Kerastick™ for Topical Solution, 20% - **NDA No. 20-965**

Dear Dr. Felten:

On behalf of our client, DUSA Pharmaceuticals, Inc., and pursuant to our phone conversation yesterday regarding the above referenced NDA, attached please find additional copies of the following NDA volumes:

1. Volume 1.1.1
2. Volume 1.10.1
3. Volume 1.10.2

If you require any further information please feel free to call me.

Sincerely yours,

Samuel D. Swetland
Vice President, Regulatory Affairs and Compliance

CC: NDA 20-965
SDS/sds
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GUIDELINES INCORPORATED

FAXED 9-18-98

September 18, 1998

Jose Carreras, MD
Division of Scientific Investigations (HFD-344)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North 1, Room 125
7520 Standish Place
Rockville, MD 20855

REFERENCE: New Drug Application for Levulan® (aminolevulinic acid HCl) Kerastick™ for Topical Solution, 20% - **NDA No. 20-965**

Dear Dr. Carreras:

On behalf of our client, DUSA Pharmaceuticals, Inc., and pursuant to our phone conversation yesterday regarding the above referenced NDA, attached please find the requested information as outlined below.

1. A list of the names and addresses of the clinical investigators who participated in the Phase III clinical trials (Protocols ALA-018 and ALA-019).

2. The number of patients enrolled in each center (Protocols ALA-018 and ALA-019) by treatment arm.

3. A list of all serious adverse reactions for Protocols ALA-018 and ALA-019.

Please note that the page numbers on the bottom right corner of each page reference the location of this data in the original NDA submission. If you require any further information please feel free to call me.

Sincerely yours,

Samuel D. Swetland

Samuel D. Swetland
Vice President, Regulatory Affairs and Compliance

SDS/sds
DUSA\NDA Documents\Cover Letter-5.doc

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