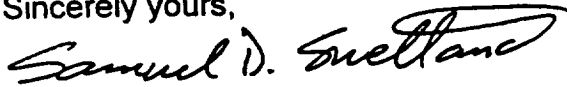


We consider all the information contained in this application proprietary and confidential. Please be advised that the confidentiality of all enclosed information is provided for under 18 USC, Section 1905 and/or USC, Section 331j.

Sincerely yours,



Samuel D. Swetland  
Vice President, Regulatory Affairs and Compliance

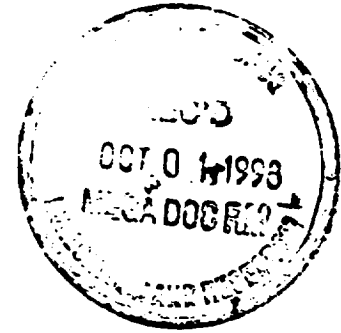
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DUSA\NDA Documents\Cover Letter-8.doc

APPEARS THIS WAY  
ON ORIGINAL



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  
2<sup>nd</sup> 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  
Vice President, Regulatory Affairs and Compliance

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DUSAWDA Documents\Cover Letter-6.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

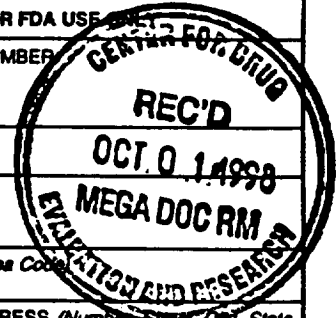
APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN  
ANTIBIOTIC DRUG FOR HUMAN USE

(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 DUSA Pharmaceuticals, Inc.	DATE OF SUBMISSION 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) Aminolevulinic Acid HCl	PROPRIETARY NAME (trade name) IF ANY Levulan Kerastick <sup>TM</sup>
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any) 5-amino-4-oxopentanoic acid	CODE NAME (if any) 5-ALA HCl, 5-ALA, ALA
DOSAGE FORM: Solution	STRENGTHS: 20%
	ROUTE OF ADMINISTRATION: Topical
(PROPOSED) INDICATION(S) FOR USE: Treatment of [redacted] actinic keratoses of the face and scalp	

APPLICATION INFORMATION

APPLICATION TYPE (check one)	<input checked="" type="checkbox"/> NEW DRUG APPLICATION (21 CFR 314.50)	<input type="checkbox"/> ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
	<input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (21 CFR part 601)	
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE	<input checked="" type="checkbox"/> 505 (b) (1)	<input type="checkbox"/> 505 (b) (2) <input type="checkbox"/> 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)	<input type="checkbox"/> ORIGINAL APPLICATION <input type="checkbox"/> AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT <input type="checkbox"/> SUPAC SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input checked="" type="checkbox"/> OTHER	
REASON FOR SUBMISSION	General Correspondence	
PROPOSED MARKETING STATUS (check one)	<input checked="" type="checkbox"/> PRESCRIPTION PRODUCT (Rx) <input type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)	
NUMBER OF VOLUMES SUBMITTED <u>1</u>	THIS APPLICATION IS <input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC	

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). 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

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



# 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  
DUSA/ANDA Documents/Cover Letter-7.doc



**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  
Vice President, Regulatory Affairs and Compliance

SDS/sds  
DUSA/ANDA Documents/Cover Letter-5.doc

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