CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-965

ADMINISTRATIVE DOCUMENTS

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 20965/000
Stamp: 01-JUL-1998 Regulatory Due: 04-DEC-1999
Applicant: DUSA
400 COLUMBUS AVE
VALHALLA, NY 10595

Priority: 1S Org Code: 540
Action Goal: District Goal: 02-MAR-1999
Brand Name: LEVULAN KERASTICK(AMINOLEVULINIC ACID HC
Established Name:
Generic Name: AMINOLEVULINIC ACID HCL
Dosage Form: SOL (SOLUTION)
Strength: 20%

FDA Contacts:

O. CINTRON	(HFD-540)	301-827-2023	, Project Manager
J. HATHAWAY	(HFD-540)	301-827-2069	, Review Chemist
W. DECAMP II	(HFD-540)	301-827-2041	, Team Leader

Overall Recommendation:

ACCEPTABLE on 12-NOV-1999 by M. EGAS (HFD-322) 301-594-0095
WITHHOLD on 07-APR-1999 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: 1052961
GUIDELINES ANALYTICAL LABORA
10320 USA TODAY WAY
MIRIMAR, FL 33025

DMF No: [redacted]
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 28-JUL-1998
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: FINISHED DOSAGE STABILITY TESTER

Establishment: 1217998
NORTH SAFETY PRODUCTS
2000 PLAINFIELD PIKE
CRANSTON, RI 02920

DMF No:
AADA No:

Profile: LIQ OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 07-APR-1999
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities: FINISHED DOSAGE MANUFACTURER

Establishment: [redacted]

DMF No: [redacted]
AADA No:

Profile: CSN OAI Status: NONE

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **04-NOV-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0297
Expiration Date: 04-30-01

USER FEE COVER SHEET

See Instructions on Reverse Side Before Completing This Form

APPLICANT'S NAME AND ADDRESS

DUSA Pharmaceuticals, Inc.
400 Columbus Avenue
Valhalla, NY 10595

3. PRODUCT NAME
LEVULAN® (aminolevulinic acid HCl) Kerastick™ for Topical Solution, 20%

4. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL?
IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

IF RESPONSE IS 'YES', CHECK THE APPROPRIATE RESPONSE BELOW:

[X] THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION.

[ ] THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO _____ (APPLICATION NO. CONTAINING THE DATA).

2. TELEPHONE NUMBER *(Include Area Code)*
(914) 747-4300

5. USER FEE I.D. NUMBER
3494

6. LICENSE NUMBER / NDA NUMBER
20-965

7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

[ ] A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92 *(Self Explanatory)*

[ ] A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE *(See item 7, reverse side before checking box.)*

[ ] THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act *(See item 7, reverse side before checking box.)*

[ ] THE APPLICATION IS A PEDIATRIC SUPPLEMENT THAT QUALIFIES FOR THE EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food, Drug, and Cosmetic Act *(See item 7, reverse side before checking box.)*

[ ] THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY *(Self Explanatory)*

FOR BIOLOGICAL PRODUCTS ONLY

[ ] WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

[ ] A CRUDE ALLERGENIC EXTRACT PRODUCT

[ ] AN APPLICATION FOR A BIOLOGICAL PRODUCT FOR FURTHER MANUFACTURING USE ONLY

[ ] AN "IN VITRO" DIAGNOSTIC BIOLOGICAL PRODUCT LICENSED UNDER SECTION 351 OF THE PHS ACT

[ ] BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? [ ] YES [X] NO *(See reverse side if answered YES)*

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment.

GNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
/S/	Vice President, Scientific Affairs	06/16/98

DUSA

DUSA PHARMACEUTICALS, INC
400 COLUMBUS AVENUE
VALHALLA NY 10595

TEL 914 747 4300
FAX 914 747 7563
WWW.DUSAPHARMA.COM

DEBARMENT CERTIFICATION

DUSA Pharmaceuticals, Inc., hereby certifies that pursuant to Section 306 (k) (1) of the act (21 U.S.C. 335a (k) (1), we did not and will not use in any capacity the services of any person debarred under Subsections (a) or (b) [Section 306 (a) or (b)], of the Federal Food, Drug, and Cosmetic (FDC) Act in connection with this application.

Stuart L. Marcus, MD, PhD
Senior Vice President, Scientific Affairs
And Chief Scientific Officer
DUSA Pharmaceuticals, Inc.

APPEARS THIS WAY
ON ORIGINAL

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