

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-965

ADMINISTRATIVE DOCUMENTS

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
Action Goal:
Org Code: 540
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 DMF No:
GUIDELINES ANALYTICAL LABORA AADA No:
10320 USA TODAY WAY
MIRIMAR, FL 33025

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

Establishment: 1217998 DMF No:
NORTH SAFETY PRODUCTS AADA No:
2000 PLAINFIELD PIKE
CRANSTON, RI 02920

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

Establishment: DMF No:
AADA No:

Profile: CSN OAI Status: NONE

FDA CDER EES
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. 0910-0277
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:

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 / NOA 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
COMMERCIALY
(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 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.

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DHHS, Reports Clearance Officer
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Hubert H. Humphrey Building, Room 531-H
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Washington, DC 20201

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Please DO NOT RETURN this form to this address.

SIGNATURE 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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