

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-965**

**ADMINISTRATIVE DOCUMENTS**

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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: AADA No:

Profile: CSN OAI Status: NONE

FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT

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

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Responsibilities: **DRUG SUBSTANCE  
MANUFACTURER**

**APPEARS THIS WAY  
ON ORIGINAL**

# 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<sup>®</sup> (aminolevulinic acid HCl) Kerastick<sup>™</sup>  
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 / 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 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.**

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer  
Paperwork Reduction Project (0910-0297)  
Hubert H. Humphrey Building, Room 531-H  
200 Independence Avenue, S.W.  
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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**

# DUSA

DUSA PHARMACEUTICALS, INC.

400 COLUMBIA AVENUE

VALHALLA, NY 10595

TEL 914 747 4300

FAX 914 747 7563

WWW.DUSEPHARMA.COM

## PATENT DECLARATION

The applicant, DUSA Pharmaceuticals, Inc., hereby declares to the best of its knowledge, with respect to the claimed indication for the subject drug, and excluding patents owned or licensed by the applicant: that there are no patents which claim the drug or the drug product or which claim a method of using the drug product and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

[21 CFR § 314.53 (c)(3)]



Stuart Marcus, MD, Ph.D.  
Senior Vice President, Scientific Affairs  
and Chief Scientific Officer  
DUSA Pharmaceuticals, Inc.

APPEARS THIS WAY  
ON ORIGINAL

# DUSA

DUSA PHARMACEUTICALS, INC.  
400 COLUMBUS AVENUE  
VALHALLA, NY 10595  
  
TEL 914.747.4300  
FAX 914.747.7563  
WWW.DUSA-PHARMA.COM

## PATENT INFORMATION

DUSA Pharmaceuticals, Inc. is covered by the following United States patents for LEVULAN® (aminolevulinic acid HCl) KERASTICK™ for Topical Solution, 20%.

U. S. Patent or Appl. No.	Expiration Date	Patent Type	Patent Owner
5,079,262	7/28/2009	Method of use	Queens University at Kingston exclusively assigned to DUSA Pharmaceuticals, Inc.
5,211,938	5/18/2010	Method of use	Queens University at Kingston exclusively assigned to DUSA Pharmaceuticals, Inc.
5,422,093	7/28/2009	Method of use	Queens University at Kingston exclusively assigned to DUSA Pharmaceuticals, Inc.

The undersigned declares that Patent Nos. 5,079,262, 5,211,938 and 5,422,093 cover the method of use of the claimed indication of LEVULAN® (aminolevulinic acid HCl) KERASTICK™ for Topical Solution, 20%. This product is the subject of this application for which approval is being sought.

[21 CFR §314.50(i)]



Stuart Marcus, MD, Ph.D.  
Senior Vice President, Scientific Affairs  
and Chief Scientific Officer  
DUSA Pharmaceuticals, Inc.

**APPEARS THIS WAY  
ON ORIGINAL**

DUSA

DUSA PHARMACEUTICALS, INC.  
400 COLUMBUS AVENUE  
VALHALLA, NY 10585

TEL 914 747 4300

FAX 914 747 7563

WWW.DUSAPHARMA.COM

### CLAIM FOR EXCLUSIVITY

The applicant is claiming a period of exclusivity under 35 USC §§355(b)(j) and 21 CFR §314.108(b)(2). DUSA Pharmaceuticals, Inc. certifies that to the best of its knowledge or belief, a drug has not been previously approved under section 505(b) of the Act or 21 CFR §314.108, containing the same active ingredient or active moiety respectively, in the drug for which the applicant is seeking approval.

[21 CFR §314.50(j)(3)]



Stuart Marcus, MD, Ph.D.  
Senior Vice President, Scientific Affairs  
and Chief Scientific Officer  
DUSA Pharmaceuticals, Inc.

APPEARS THIS WAY  
ON ORIGINAL

6-4  
**ORIGINAL**



**GUIDELINES  
INCORPORATED**

6-4-99



June 21, 1999

NEW CORRESP

NC (CM)

Division of Dermatologic and Dental Drug Products (HFD-540)  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
Food and Drug Administration  
9201 Corporate Boulevard  
Rockville, MD 20850

**RE: Authorization Letter: NDA #20-965  
New Drug Application for Levulan® Kerastick™  
For Topical Solution Vehicle, 20%**

Dear Sir or Madam:

On behalf of our client, DUSA Pharmaceuticals, Inc., we hereby authorize the Food and Drug Administration to refer to the above referenced New Drug Application, in its entirety, on behalf of:

DUSA Pharmaceuticals, Inc.  
400 Columbus Avenue  
Valhalla, New York 10595

in support of any new Investigational New Drug applications (INDs).

Please note that these files are considered CONFIDENTIAL and are not to be made available other than by cross-reference.

Sincerely,

Emma A. Lopez

**APPEARS THIS WAY  
ON ORIGINAL**

Cc: R. Carroll  
S. Marcus, MD, PhD

**EXCLUSIVITY SUMMARY FOR NDA # 20-965**

SUPPL # N/A

Trade Name: LEVULAN® KERASTICK™ for Topical Solution, 20%

Generic Name: 5-aminolevulinic acid HCl

Applicant Name: DUSA Pharmaceuticals

HFD # 540

Approval Date If Known: \_\_\_\_\_

**PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?**

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?

YES / X / NO /    /

b) Is it an effectiveness supplement?

YES /    / NO / X /

If yes, what type? (SE1, SE2, etc.) \_\_\_\_\_

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES / X / NO /    /

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

\_\_\_\_\_

\_\_\_\_\_

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

\_\_\_\_\_

\_\_\_\_\_

d) Did the applicant request exclusivity?

YES /  / NO /  /

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

Not specified by the applicant.

e) Has pediatric exclusivity been granted for this Active Moiety? No.

**IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.**

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO - please indicate as such)

YES /  / NO /  /

If yes, NDA # \_\_\_\_\_ . Drug Name \_\_\_\_\_

**IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.**

3. Is this drug product or indication a DESI upgrade?

YES /  / NO /  /

**IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).**

**PART II: FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES.**

(Answer either #1 or #2 as appropriate)

**1. Single active ingredient product.**

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /  / NO /  /

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# \_\_\_\_\_

NDA# \_\_\_\_\_

NDA# \_\_\_\_\_

**2. Combination product.**

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /  / NO /  / N/A

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# \_\_\_\_\_

NDA# \_\_\_\_\_

NDA# \_\_\_\_\_

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

**PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS.**

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations?  
(The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES / \_\_\_ / NO / \_\_\_ /

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES / \_\_\_ / NO / \_\_\_ /

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

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(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES / \_\_\_ / NO / \_\_\_ /

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES / \_\_\_ / NO / \_\_\_ /

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES / \_\_\_ / NO / \_\_\_ /

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /  / NO /  /

Investigation #2 YES /  / NO /  /

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

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b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /  / NO /  /

Investigation #2 YES /  / NO /  /

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

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c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

\_\_\_\_\_

\_\_\_\_\_

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1

IND # \_\_\_\_\_ YES / \_\_\_ / NO / \_\_\_ / Explain: \_\_\_\_\_

Investigation #2

IND # \_\_\_\_\_ YES / \_\_\_ / NO / \_\_\_ / Explain: \_\_\_\_\_

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1

YES / \_\_\_ / Explain \_\_\_\_\_ NO / \_\_\_ / Explain \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Investigation #2

YES / \_\_\_ / Explain \_\_\_\_\_ NO / \_\_\_ / Explain \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /    / NO /    /

If yes, explain: \_\_\_\_\_  
\_\_\_\_\_

   /S/    / Regulatory Health Project Coordinator 5/25/99.  
Signature: Date: Title:

Signature of Office/Division Director    /S/    6/12/99

Signature: Date:    /S/    12/1/99

cc: Original NDA 20-965; HFD-540 Division File

HFD-93 Mary Ann Holovac

APPEARS THIS WAY  
ON ORIGINAL

# PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

IBLA # 20-965

Supplement # \_\_\_\_\_ Circle one: SE1 SE2 SE3 SE4 SE5 SE6

HFD-540 Trade and generic names/dosage form: Suvelan Kerastick (aminolevulinic acid) for Topical Solution, 20% Action:  AP  AE  NA

Applicant DUSA Therapeutic Class IS

Indication(s) previously approved none

Pediatric information in labeling of approved indication(s) is adequate  inadequate

Proposed indication in this application for the treatment of sebic Keratosis of the face and scalp

FOR SUPPLEMENTS, ANSWER THE FOLLOWING QUESTIONS IN RELATION TO THE PROPOSED INDICATION.

IS THE DRUG NEEDED IN ANY PEDIATRIC AGE GROUPS?  Yes (Continue with questions)  No (Sign and return the form)

WHAT PEDIATRIC AGE GROUPS IS THE DRUG NEEDED? (Check all that apply)

Neonates (Birth-1month)  Infants (1month-2yrs)  Children (2-12yrs)  Adolescents(12-16yrs)

- 1. PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS. Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric age groups. Further information is not required.
- 2. PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS. Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.
- 3. PEDIATRIC STUDIES ARE NEEDED. There is potential for use in children, and further information is required to permit adequate labeling for this use.
  - a. A new dosing formulation is needed, and applicant has agreed to provide the appropriate formulation.
  - b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.
  - c. The applicant has committed to doing such studies as will be required.
    - (1) Studies are ongoing,
    - (2) Protocols were submitted and approved.
    - (3) Protocols were submitted and are under review.
    - (4) If no protocol has been submitted, attach memo describing status of discussions.
  - d. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.
- 4. PEDIATRIC STUDIES ARE NOT NEEDED. The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.
- 5. If none of the above apply, attach an explanation, as necessary.

ARE THERE ANY PEDIATRIC PHASE IV COMMITMENTS IN THE ACTION LETTER?  Yes  No  
ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

This page was completed based on information from the medical officer (e.g., medical review, medical officer, team leader)

IS/ Project Manager  
Signature of Preparer and Title

11/17/99  
Date

See attached ->

Orig NDA/BLA # 20-965  
HFD-540 Div File  
NDA/BLA Action Package  
HFD-006/ KRoberts

IS/ 12/1/99

The principal risk factors for the development of actinic keratoses are skin type and cumulative sun exposure over many years. The age group most commonly affected are 60 years old and older. Prevalence of actinic keratoses is extremely low in the pediatric population. Therefore, pediatric studies are not warranted.

/S/ 2/1/99

APPEARS THIS WAY  
ON ORIGINAL



DEPARTMENT OF HEALTH & HUMAN SERVICES

44-540 [S/]  
Public Health Service

Food and Drug Administration

Rockville MD 20857

NDA 20-965

JUL 24 1998

DUSA Pharmaceuticals, Inc.  
Attention: Stuart L. Marcus, MD, Ph.D.  
400 Columbus Avenue  
Valhalla, NY 10595

Dear Dr. Stuart::

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Levulan Kerastick (aminolevulinic acid ) for Topical Solution , 20%

Therapeutic Classification: Standard (S)

Date of Application: June 29, 1998

Date of Receipt: July 1, 1998

Our Reference Number: 20-965

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 30, 1998 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be July 1, 1999.

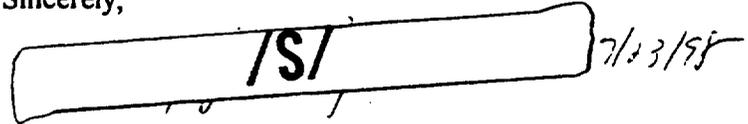
Under 21 CFR 314.102(c) of the new drug regulations, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

**APPEARS THIS WAY  
ON ORIGINAL**

If you have any questions, contact Olga Cintron, Project Manager, at (301) 827-2020.

Sincerely,



Mary Jean Kozma-Fornaro  
Supervisor, Project Management Staff  
Division of Dermatologic and Dental Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

cc:

Archival NDA 20-965

HFD-540/Div. Files

HFD-540/O.Cintron

S.Walker

A.Jacobs

W.DeCamp

DISTRICT OFFICE

Drafted by: smc/July 23, 1998

Initialed by:

final:

filename: 20965ACK

ACKNOWLEDGEMENT (AC)

**APPEARS THIS WAY  
ON ORIGINAL**

**ATTACHMENT TO FORM FDA 356h**

**ESTABLISHMENT INFORMATION:**

**Drug Substance**

The drug substance will be manufactured, packaged, controlled and shipped by [redacted] the drug substance manufacturer. Stability studies of the drug substance will be conducted by [redacted]

Name and Address of Manufacturing Site:

[redacted]

Establishment Registration No.:

Not Applicable

Contact Person and Phone No.:

[redacted]

Site Inspection by FDA:

The facility is ready for inspection.

**Drug Product**

The drug product will be manufactured, packaged, labeled, controlled and shipped by North Safety Products, the drug product manufacturer. North Safety Products will be responsible for the manufacture of the bulk solution vehicle, filling and sealing of the glass ampules and assembly of the Levulan Kerastick. North Safety Products is responsible for the in-process testing of the bulk Levulan Topical Solution Vehicle.

Name and Address of the Manufacturing Site:

North Safety Products  
2000 Plainfield Pike  
Cranston, RI 02921

Establishment Registration No.:

#1217998

Contact Person and Phone No.:

Jonny Smith  
Manager, Business Quality  
(401)-946-4400

Site Inspection by FDA: This facility is ready for inspection.

The raw materials, process intermediates and finished products are analyzed by a contract analytical laboratory. The finished product stability studies are also conducted by the contract laboratory listed below:

Guidelines Analytical Laboratories, Inc. (GAL)  
10320 USA Today WAY  
Miramar, FL 33025  
DMF No. [redacted]

Establishment Registration No.: #1052961  
Contact Person and Phone No.: Mike Ray  
President  
(954)-433-7480

Site Inspection by FDA: This facility is ready for inspection.

CROSS REFERENCES:

DUSA's IND for Aminolevulinic Acid HCl:  
GAL's DMF:

[redacted] DMF:  
[redacted] DMF:  
[redacted] DMF:

IND:  
DMF  
DMF  
DMF  
DMF

APPEARS THIS WAY  
ON ORIGINAL