CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-965

MICROBIOLOGY REVIEW(S)
REVIEW FOR HFD-540
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF AMENDMENT

June 3, 1999

A. 1. NDA  20-965 Amendment

SPONSOR DUSA Pharmaceuticals
400 Columbus Avenue
Valhalla, NY 10595

2. PRODUCT NAMES: Levulan®, (aminolevulinic acid HCl) Kerastik™ for Topical Solution 20%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 20% Topical Solution

4. METHOD(S) OF STERILIZATION: na

5. PHARMACOLOGICAL CATEGORY: Photosensitizer

6. DRUG PRIORITY CLASSIFICATION: 

B. 1. DATE OF INITIAL SUBMISSION: June 29, 1998

2. DATE OF AMENDMENT: June 2, 1999

3. RELATED DOCUMENTS: 

4. ASSIGNED FOR REVIEW: na

C. REMARKS: This review addresses the microbial limit specifications of the drug product. The amendment was faxed to the Agency, with the hard copy to follow.

APPEARS THIS WAY ON ORIGINAL
D. **CONCLUSIONS**: This application is recommended for approval on the basis of product quality microbiology.

\[ /S/ \]

Bryan Riley, Ph.D.

\[ /S/ \]

6-3-99

\[ /S/ \]

4-1-99

cc:

HFD 540/Consult File
HFD 540/O. Cintron
HFD 540/Rev Chemist
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 6/3/99
R/D initialed by: P. Cooney,
REVIEW FOR HFD-540  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW # 1 OF NDA  

April 20, 1999

A.  1. **NDA** 20-965

   **SPONSOR**  
   DUSA Pharmaceuticals  
   400 Columbus Avenue  
   Valhalla, NY 10595

2. **PRODUCT NAMES**: Levulan®, (aminolevulinic acid HCl) Kerastik™ for Topical Solution 20%

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION**: 20% Topical Solution in a Kerastick™ Applicator

4. **METHOD(S) OF STERILIZATION**: N/A

5. **PHARMACOLOGICAL CATEGORY**: Photosensitizer

6. **DRUG PRIORITY CLASSIFICATION**: 

B.  1. **DATE OF INITIAL SUBMISSION**: June 29, 1998

2. **DATE OF AMENDMENT**: 

3. **RELATED DOCUMENTS**: 

4. **ASSIGNED FOR REVIEW**: April 1, 1999

C. **REMARKS**: The drug product (Levulan Kerastick) is a two component applicator in which Levulan and the Topical Solution Vehicle are admixed immediately prior to administration. This review addresses the validation of the Microbial Limit Test for this non-sterile topical product.

**APPEARS THIS WAY ON ORIGINAL**
D. CONCLUSIONS: This application is approvable, pending resolution of microbiological deficiencies. Please see "Microbiologists List of Deficiencies".

\[\text{Signed: } 4-20-99\]

Bryan Riley, Ph.D.

\[\text{Signed: } 4/30/99\]

cc:
HFD 540/Consult File
HFD 540/O. Cintron
HFD 540/Rev Chemist
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 4/20/99
R/D initialed by: P. Cooney,