

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-965

MICROBIOLOGY REVIEW(S)

JUN 7 1999

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.

JUN 7 1999

/S/

6-3-99

Bryan Riley, Ph.D.

/S/

6/7/99

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,

APPEARS THIS WAY
ON ORIGINAL

APR 30 1999

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, 19982. 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".

/S/ 4-20-99
Bryan Riley, Ph.D.
/S/ 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,

APPEARS THIS WAY
ON ORIGINAL