

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-965**

**CORRESPONDENCE**

Printed by Olga Cintron  
**Electronic Mail Message**

**Priority:** COMPANY CONFIDENTIAL

**Date:** 06-Apr-1999 03:05pm  
**From:** Patricia Tuegel  
TUEGELP  
**Dept:** HFD-805 PKLN 18B08  
**Tel No:** 301-827-7340 FAX 301-443-9281

**TO:** Olga Cintron

( CINTRONO )

**Subject:** NDA 20-965

Your consult request for the above application has been assigned to Review Microbiologist Bryan Riley on 4/5/99. Please make sure the COMIS assignment for microbiology is updated with the correct reviewer.

Microbiology Staff, HFD-805

**APPEARS THIS WAY  
ON ORIGINAL**

TO: Division/Office) <i>Rector Cooney HFD-160</i>		FROM: <i>Olga Cintron HFD-540</i>		
DATE: <i>3/10/99</i>	IND NO.	NDA NO. <i>20-965</i>	TYPE OF DOCUMENT <i>new NDA</i>	DATE OF DOCUMENT <i>June 29, 1998.</i>
NAME OF DRUG <i>Levulin Kerstick</i>		PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE <i>-</i>
NAME OF FIRM <i>DUSA Pharmaceuticals</i>				

REASON FOR REQUEST

I. GENERAL

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> NEW PROTOCOL                  | <input type="checkbox"/> PRE-NDA MEETING         | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER    |
| <input type="checkbox"/> PROGRESS REPORT               | <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> FINAL PRINTED LABELING           |
| <input type="checkbox"/> NEW CORRESPONDENCE            | <input type="checkbox"/> RESUBMISSION            | <input type="checkbox"/> LABELING REVISION                |
| <input type="checkbox"/> DRUG ADVERTISING              | <input type="checkbox"/> SAFETY/EFFICACY         | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE      |
| <input type="checkbox"/> ADVERSE REACTION REPORT       | <input type="checkbox"/> PAPER NDA               | <input type="checkbox"/> FORMULATIVE REVIEW               |
| <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION | <input type="checkbox"/> CONTROL SUPPLEMENT      | <input checked="" type="checkbox"/> OTHER (Specify below) |
| <input type="checkbox"/> MEETING PLANNED BY _____      |  | <i>NEW NDA</i>  |

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER	<input type="checkbox"/> CHEMISTRY <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER

III. BIOPHARMACEUTICS

<input type="checkbox"/> TOLERATION <input type="checkbox"/> AVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES	<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL- BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST
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IV. DRUG EXPERIENCE

<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSEMENT ON GENERIC DRUG GROUP	<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS
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V. SCIENTIFIC INVESTIGATIONS

CLINICAL  PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS (Attach additional sheets if necessary)

*Please find Volume 1.1 (disk copy) and Volumes 1.3-4.5 of this new NDA for your review & comments. (P 3-232 257)*  
*The division is planning to issue an action by the end of May 1999.*  
*Your help is greatly appreciated.*

*ISI*

SIGNATURE OF REQUESTER <i>ISI</i>	DATE <i>3/10/99</i>	METHOD OF DELIVERY (Check one) <input checked="" type="checkbox"/> MAIL <input type="checkbox"/> HAND <i>Doc Com</i>
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Printed by Olga Cintron  
**Electronic Mail Message**

**Subject:** COMPANY CONFIDENTIAL

**Date:** 16-Sep-1998 04:20pm  
**From:** Olga Cintron  
CINTRONO  
**Dept:** HFD-540 CRP2 N248  
**Tel No:** 301-827-2023 FAX 301-827-2075

**TO:** Steve Hathaway

( HATHAWAYS )

**CC:** Wilson DeCamp

( DECAMP )

**Subject:** NDA 20-965 Levulan

Steve:

Please advise if a CMC micro consult is needed for this NDA. If that's the case, then we should send the consult as soon as possible.

Thanks, Olga

**APPEARS THIS WAY  
ON ORIGINAL**

Printed by Olga Cintron  
**Electronic Mail Message**

ity: COMPANY CONFIDENTIAL

Date: 23-Apr-1999 02:51pm  
From: Martin Okun  
OKUNM  
Dept: HED-540 CRP2 N241  
Tel No: 301-827-2021 FAX 301-827-2075

O: Olga Cintron

( CINTRONO )

subject: Re: NDA 20-965 Levulan

o concerns

arty  
Marty:

Dr. Carreras, from the DSI, informed me that no inspections will be issued for this NDA. Do you have any concerns?

Olga

**APPEARS THIS WAY  
ON ORIGINAL**

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