

**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**

REQUEST FOR CONSULTATION

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
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"/> CHEMISTRY
<input type="checkbox"/> END OF PHASE II MEETING	<input type="checkbox"/> PHARMACOLOGY
<input type="checkbox"/> CONTROLLED STUDIES	<input type="checkbox"/> BIOPHARMACEUTICS
<input type="checkbox"/> PROTOCOL REVIEW	<input type="checkbox"/> OTHER
<input type="checkbox"/> OTHER	

III. BIOPHARMACEUTICS

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

IV. DRUG EXPERIENCE

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

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 Rom</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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