CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-452

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)
An OCPB consult is requested for this NDA supplement.

The purpose of this NDA supplement is to update methods validation package, including updated labeling, which was also submitted in the filing of October 11, 2002. The October 11, 2002 filing included a list of NDA samples, regulatory specifications, analytical methods, and methods validation reports utilized to control the quality of carboplatin drug substance and PARAPLATIN® Injection. PARAPLATIN® is indicated for the treatment for the initial treatment of advanced ovarian carcinoma in established combination with other approved chemotherapeutic agents.

The updated labeling does not contain any change in the Clinical Pharmacology/Pharmacokinetics, Precautions, and Dosage and Administration sections regarding the use of PARAPLATIN® Injection.

**RECOMMENDATION**

No action is indicated.

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**Team Leader:** Atiqur Rahman, Ph.D.  
**Division of Pharmaceutical Evaluation I**  

**Reviewer:** Sophia Abraham, Ph.D.  
**Division of Pharmaceutical Evaluation I**

**cc:**  
NDA: 20-452  
HFD-150/Division file  
HFD-150/Cottrell, Cohen, Dagher, Farrell  
HFD-860/Mehta, Sahajwella, Rahman, Abraham  
CDR/Biopharm
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/s/

Sophia Abraham
2/11/03 02:27:13 PM
BIOPHARMACEUTICS

Atiqur Rahman
2/12/03 11:07:14 AM
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