

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**21-045/S011**

**CHEMISTRY REVIEW(S)**

CHEMIST REVIEW #1

1. **ORGANIZATION:** HFD-580
2. **NDA Number:** 21-045
3. **SUPPLEMENT NO/DATES:** SE6-011  
**Letter Date:** 14-Apr-2003  
**Stamp Date:** 22-Apr-2003  
**Due Date:** 21-Feb-2004  
**Amended Due Date:** 21-May-2003

6. **SPONSOR NAME AND ADDRESS**  
Women's Capital Corporation  
1990 M Street, NW, Suite 250  
Washington, DC 20036
7. **DRUG PRODUCT NAME:** PLAN B
8. **NONPROPRIETARY NAME:** levonorgestrel
9. **DRUG SUBSTANCE NAME/STRUCTURE:** Levonorgestrel. See USP 26 for the chemical structure.
- 10/11. **DOSAGE FORM/ STRENGTH** Tablet / 0.75 mg
12. **INDICATION:** progestin/emergency contraception
13. **HOW DISPENSED:** Rx
14. **RECORDS AND REPORTS CURRENT:** Yes
15. **RELATED IND/NDA/DMF:** None
16. **SUPPLEMENT PROVIDES FOR:** a switch to Over-the-Counter (OTC)
17. **COMMENTS:** The product proposed for OTC is identical to the approved product with regard to all CMC information. The Environmental Assessment portion of the submission is the subject of this review.  
  
The calculation to show that the Expected Introduction Concentration (EIC) of levonorgestrel in the aquatic environment is below 1 ppb has been provided by the sponsor. The calculation is based on an estimate for the fifth year production as provided in the Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications. The fifth year sales are estimated to represent the largest amount of active expected to be produced in the five years after approval of the supplement. Fifth year production is estimated to be \_\_\_\_\_ of active. Based on ' \_\_\_\_\_', the EIC is calculated to be approximately \_\_\_\_\_.
18. **SPECIAL PRODUCTS:** None

19. **CONCLUSIONS AND RECOMMENDATIONS:** The calculation based on the production estimate shows that the amount of levonorgestrel expected to be introduced into the aquatic environment is less than 1 ppb. Therefore, the categorical exclusion is justified and acceptable.

20. **REVIEWER NAME/Date** J. Salemme, Ph.D., HFD-580, 6-Apr-2004

Project Manager: K. Kirchberg

Chemistry Team Leader: Moo-Jhong Rhee, Ph.D.

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Jean Saleme  
4/6/04 10:17:51 AM  
CHEMIST

Moo-Jhong Rhee  
4/6/04 10:40:51 AM  
CHEMIST  
I concur

NDA 21-045/S011  
Plan B (levonorgestrel) Tablets

Barr Laboratories, Inc.  
Women's Capital Corporation

PM: Karen Anderson, N.P.  
HFD-580

PM: Tia Frazier, R.N.  
HFD-560

CMC Information – See Vol. 1 (original NDA)