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/NDAT/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.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
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Jean Saleemme
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)