SCAN

21-045

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 21045

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Chemistry Review(s)	X			
EA/FONSI			X	
Pharmacology Review(s)	X			
Statistical Review(s)			X	
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)	X			
Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 21045

Trade Name:Plan B 0.75 mg Tablets

Generic Name:(levonorgestrel)

Sponsor:Women's Capital Corporation

Approval Date:July 28, 1999

Indication: Provides for the use of Plan B (levonorgestrel) 0.75 mg Tablets for Emergency Contraception.

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 21045

APPROVAL LETTER

NDA 21-045

Women's Capital Corporation
Attention: Sharon Camp, Ph.D.
President
550 Kirkland Way, Suite 204
Kirkland, WA 98033

JUL 28 1999

Dear Dr. Camp:

Please refer to your new drug application (NDA) dated January 29, 1999, received January 29, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plan B™ (levonorgestrel) 0.75 mg Tablets.

We acknowledge receipt of your submissions dated February 3 and 11, March 29, April 12, 22, 26, 27, 28 (3), and 29, May 6, 18, 21, 25, and 26 (2), June 2, 10, 17, 21, and 28, July 6, 8, 12, 13, 23, and 27.

This new drug application provides for the use of Plan B (levonorgestrel) 0.75 mg Tablets for Emergency Contraception.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 27, 1999, patient package insert submitted July 27, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-045." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless

this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this application at this time.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Jennifer Mercier, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

/S/ 7/28/97

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 21-045
HFD-580/Div. Files
HFD-580/J.Mercier/Rumble
HFD-580/Rarick/Mann/Davis/Rhee/Lin/Parekh/Kammerman/Hoberman
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-103/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-170/C.Moody (if controlled substance)
HFD-95/DDMS (with labeling)
HFD-820/DNDCII Division Director
DISTRICT OFFICE

Drafted by: JM/July 28, 1999
Initialed by: Rarick/Mann7.28.99/Davis7.9.99/Rhee7.27.99/Lin7.27.99/Parekh7.22.99
/Nevius7.22.99/Hoberman7.22.99
final:
filename: 21045AP.WPD

APPROVAL (AP)