OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA: 21-998	Submission Dates: 01/24/2006, 01/09/2009
Brand Name	Plan B One-Step
Generic Name	Levonorgestrel
Reviewer	Hyunjin Kim, Pharm.D., M.S.
Team Leader	Myong-Jin Kim, Pharm.D.
OCP Division	Division of Clinical Pharmacology 3
OND Division	Division of Reproductive and Urologic Products (DRUP)
Sponsor	Duramed Research Inc.
Relevant IND, NDA	IND 45,796, NDA 21-045
Submission Type	Class 2 resubmission
Formulation; Strength	Tablet; levonorgestrel 1.5 mg
Indication	Emergency contraception

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1. Executive Summary

Plan B (NDA 21-045), levonorgestrel tablets consisting of two 0.75 mg doses taken 12 hours apart, was approved for emergency contraception for prescription-only use in women of reproductive age on July 28, 1999. Subsequently, Plan B was approved (NDA 21-045/S-011) for emergency contraception for prescription-only use in women age 17 and younger and for over-the-counter (OTC) use in women age 18 and older on August 24, 2006.

On January 24, 2006, the sponsor submitted NDA 21-998 (levonorgestrel 1.5 mg tablet, Plan B One-Step) to seek approval of Plan B One-Step for emergency contraception. NDA 21-998 received an approvable (AE) action on November 22, 2006. However, the overall human pharmacokinetic section of the submission was acceptable from a Clinical Pharmacology perspective (see Clinical Pharmacology Review of NDA 21-998, DFS date, October 23, 2006, Dr. Myong-Jin Kim). Although the sponsor sought the approval of Plan B One-Step for a prescription-only product for women of reproductive age, the Division found that Plan B One-Step can be used as an OTC product for women age 18 and older. Therefore, the Division requested the sponsor to submit revised labeling for marketing 1.5 mg levonorgestrel tablet as a prescription-only product in women age 17 and younger, and as an OTC product for women age 18 and older. In addition, the safety updates of Plan B One-Step were requested.

The current resubmission is the sponsor's response to the Division's AE letter on November 22, 2006. There were no additional studies related to Clinical Pharmacology submitted. During the review cycle of the current resubmission, there was a court order for FDA to allow distribution of Plan B product without a prescription for women age 17 years and older on March 23, 2009. On April 22, 2009, the agency announced that FDA would comply with the court order on the use of Plan B. Since the distribution plan of OTC or prescription-only use for Plan B One-Step was to rely on Plan B's program, the following label revision of Plan B One-Step reflects the change to meet the FDA's compliance to the court order of Plan B use.

1.1 Recommendation

The Division of Clinical Pharmacology 3, Office of Clinical Pharmacology finds the clinical pharmacology information submitted in NDA 21-998 acceptable provided that agreement is reached between the sponsor and the Division regarding the language in the package insert.

1.2 Phase IV Commitments

None.

5 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

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