

OFFICE OF CLINICAL PHARMACOLOGY ADDENDUM

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

This addendum is to correct the error in the Clinical Pharmacology review (Dr. Hyunjin Kim, DFS, June 22, 2009) of resubmission of the NDA 21-998 (submission dates: 01/24/2006 & 01/09/2009). See the following table 2 in section 12.3 pharmacokinetics of the label. Strikes are used for deletion and double underline is used for addition.

Table 2. Pharmacokinetic Parameter Values Following Single Dose Administration of Plan B One-Step (levonorgestrel) tablet 1.5 mg to 30 Healthy Female Volunteers under Fasting Conditions

	Mean (\pm SD)				
	C_{max} (ng/mL)	AUC_t (ng·hr/mL)*	AUC_{inf} (ng·hr/mL)*	T_{max} (hr)**	$t_{1/2}$ (hr)
Levonorgestrel	19.14 (<u>9.766</u>)	294.80 (208.80)	307.54 (218.45)	1.67 (1.00-4.00)	27.49-5 (<u>5.596</u>)

C_{max} = maximum concentration

AUC_t = area under the drug concentration curve from time 0 to time of last determinable concentration

AUC_{inf} = area under the drug concentration curve from time 0 to infinity

T_{max} = time to maximum concentration

$t_{1/2}$ = elimination half life

* N=29

** median (range)

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/s/

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7/9/2009 04:13:42 PM
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7/9/2009 10:30:00 PM
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