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>
<thead>
<tr>
<th>Levonorgestrel</th>
<th>Mean (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$C_{\text{max}}$ (ng/mL)</td>
<td>19.14 (9.766)</td>
</tr>
<tr>
<td>AUC$_t$ (ng·hr/mL)*</td>
<td>294.80 (208.80)</td>
</tr>
<tr>
<td>AUC$_{\text{inf}}$ (ng·hr/mL)*</td>
<td>307.54 (218.45)</td>
</tr>
<tr>
<td>$T_{\text{max}}$ (hr)**</td>
<td>1.67 (1.04-4.04)</td>
</tr>
<tr>
<td>$t_{1/2}$ (hr)</td>
<td>27.49 (5.59)</td>
</tr>
</tbody>
</table>

$C_{\text{max}}$ = maximum concentration

AUC$_t$ = area under the drug concentration curve from time 0 to time of last determinable concentration

AUC$_{\text{inf}}$ = area under the drug concentration curve from time 0 to infinity

$T_{\text{max}}$ = time to maximum concentration

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

* N=29

** median (range)
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hyunjin Kim
7/9/2009 04:13:42 PM
BIOPHARMACEUTICS

Myong-Jin Kim
7/9/2009 10:30:00 PM
BIOPHARMACEUTICS