Memorandum of Statistical Review

NDA/Serial Number:	21-998 / 000	
Drug Name:	Levonorgestrel 1.5 mg Tablet	
Indication(s):	Emergency Contraception	
Applicant:	Duramed Research, Inc.	
Date(s):	*Letter Date*: January 9, 2009	*PDUFA Date*: July 10, 2009
Review Priority:	1 Standard	
Biometrics Division:	Division of Biometrics 3	
Statistical Reviewer:	Sonia Castillo, Ph.D.	
Biometrics Team Leader:	Mahboob Sobhan, Ph.D.	
Medical Division:	Division of Reproductive and Urologic Products	
Clinical Team:	Daniel Davis, M.D., Clinical Reviewer	
	Lisa Soule, M.D., Team Leader	
Project Manager:	Pamela Lucarelli	

This Class 2 resubmission to an approvable letter sent to the Applicant on November 22, 2006 contains the proposed labeling. The Statistical review of the NDA submission dated January 24, 2006 was entered into DFS on September 26, 2006.

Recommendations on Labeling:
The red text from the clinical studies section of the label presented below is based on Table 1.1, which is from the statistical review of the January 24, 2006 submission for this NDA. Using this information, this portion of the clinical studies section of the label in this Class 2 labeling resubmission is acceptable from a statistical perspective.

Table 1.1
Study 97902: Observed and Expected Pregnancies with Prevented Fractions and 95% Confidence Intervals for Women Receiving Emergency Contraception from 0 to 72 Hours after Unprotected Intercourse – Full ITT Population

	N	Observed Pregnancies			Expected Pregnancies	PF* (%)	95% C.I.
		n	Rate (%)	95% C.I.	n		
Levonorgestrel 1.5 mg × 1	1198	16	1.34	(0.76, 2.16)	99.7	83.95	(73.94, 90.83)
Levonorgestrel 0.75 mg × 2	1183	20	1.69	(1.04, 2.60)	94.9	78.92	(67.44, 87.12)

Source: Table 1.1 of Addendum to Statistical Review and Evaluation of submission dated January 1, 2006 and first table on page 2/10 of Amendment 1to Statistical Report on WHO Study 97902 dated June 13, 2003
* PF = Prevented Fraction = *1.0 – (Observed pregnancies/Expected pregnancies)*

14. CLINICAL STUDIES

A double-blind, randomized, multicenter, multinational study evaluated and compared the efficacy and safety of three different regimens for emergency contraception. Subjects were enrolled at 15 sites in 10 countries; the racial/ethnic characteristics of the study population overall were 54% Chinese, 34% Caucasian, and 12% Black or Asian (other than Chinese). 2,381 healthy women with a mean age of 27 years, who needed emergency contraception within 72 hours of unprotected intercourse were involved and randomly allocated into one of the two levonorgestrel groups. A single dose of 1.5 mg of levonorgestrel (Plan B One-Step) was administered to women allocated into group 1. Two doses of 0.75 mg levonorgestrel 12-hour apart (Plan B) were administered to women in group 2. In the Plan B One-Step group, 16 pregnancies occurred in 1,198 women and in the Plan B group, 20 pregnancies occurred in 1,183 women. Among women receiving Plan B One-Step, 84% of 100 expected pregnancies were prevented and 79% of 95 expected pregnancies were prevented among those women taking Plan B. The expected pregnancy rate of 8% (with no contraceptive use) was reduced to approximately 1% with Plan B One-Step.

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/s/

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6/16/2009 01:48:20 PM
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Mahboob Sobhan
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