CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-701

STATISTICAL REVIEW(S)

Statistical Consultation

MAY 23 1997

NDA#: 20-701/Class 3S

Applicant: Columbia Research Laboratories, Inc.

Name of Drug: Crinone® (progesterone gel)

Indication: Secondary amenorrhea

Document Reviewed: Vols. 1.1, 1.2, 1.29
Submission dated July 23, 1996

The 95% confidence interval of the efficacy outcome for the intent-to-treat population and the efficacy population for the three studies and the overall patient population are displayed in the following tables:

Table 1. Patients With Successful Bleeding Any Time After First Dose of CRINONE® - ITT Population

Study	Number of Patients	Patients with Successful Bleeding n(%)	95% Confidence Limits
COL1620-004US			
45 mg q.o.d.	13	10(77%)	46.2%, 95.0%
90 mg q.o.d.	14	11(79%)	49.2%, 95.3%
COL1620-005US			
45 mg q.o.d.	15	12(80%)	51.9%, 95.7%
90 mg q.o.d.	17	14(82%)	56.6%, 96.2%
COL1620-009US			
45 mg q.o.d.	34	28(82%)	65.5%, 93.2%
90 mg q.o.d.	34	28(82%)	65.5%, 93.2%
Overall			
45 mg q.o.d.	62	50(81%)	68.6%, 89.6%
90 mg q.o.d.	65	53(82%)	70.0%, 90.1%

Table 2. Patients With Successful Bleeding Any Time After First Dose of CRINONE® - Efficacy Population

Study	Number of Patients	Patients with Successful Bleeding n(%)	Lower 95% Confidence Limits	
COL1620-004US				
45 mg q.o.d.	13	10(77%)	46.2%,	95.0%
90 mg q.o.d.	13	10(77%)	46.2%,	95.0%
COL1620-005US				
45 mg q.o.d.	12	9(75%)	42.8%,	94.5%
90 mg q.o.d.	11	8(73%)	39.0%,	94.0%
COL1620-009US				
45 mg q.o.d.	32	26(81%)	63.5%,	92.8%
90 mg q.o.d.	28	22(79%)	59.1%,	91.7%
Overall				
45 mg q.o.d.	57	45(79%)	66.1%,	88.6%
90 mg q.o.d.	52	40(77%)	63.2%,	87.5%

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Lee-Ping Pian, Ph.D.
Mathematical Statistician

Concur: Kammerman 5/23/97

Nevius 5/23/97

cc:
Archival NDA 20-701
HFD-580
HFD-580/PPrice
HFD-580/LRarick
HFD-580/HJolson
HFD-580/PCorfman
HFD-580/CKish, LPauls
HFD-715/division file, LKammerman, LPian