Appendix A.1, Table 25 (Continued)
Adverse Events
(Patients with Any Adverse Event)

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
121	02/06/95	02/08/95	02/20/95	NAUSEA	02/06/95	02/06/95	2	1	3	1
				VOMITING	02/06/95	02/06/95	2	1	3	1
				INTESTINAL CRAMP	02/07/95	02/07/95	2	1	3	1
				CRAMPING	02/07/95	02/08/95	1	1	3	1
				CRAMPING	02/08/95	02/08/95	2	2	7	1
				CRAMPING	02/13/95	02/13/95	1	1	7	1
				NAUSEA	02/13/95	02/13/95	1	1	6	1
122	02/06/95	02/08/95	02/20/95	CRAMPS	02/06/95	02/06/95	2	2	3	1
				GAS PAINS	02/06/95	02/06/95	2	1	3	1
				CRAMPS	02/08/95	02/09/95	2	2	7	1
				HEADACHE	02/09/95	02/09/95	1	1	7	1
				HEADACHE	02/10/95	02/10/95	2	2	7	1
				CRAMP	02/10/95	02/10/95	2	1	7	1
				BACKACHE	02/11/95	02/11/95	2	2	7	1
				SORE THROAT	02/11/95	Ongoing	1	1	1	2
				NON-PRODUCTIVE COUGH	02/11/95	Ongoing	1	1	1	2
123	02/06/95	02/08/95	02/20/95	VAGINAL INFECTION		02/14/95	1	2	1	1
				CRAMPING	02/06/95	02/06/95	1	1	3	1
				COUGH & COLD	02/06/95	02/19/95	2	2	1	1
				CONSTIPATION	02/06/95	02/06/95	2	2	1	1
				EXCESSIVE BLEEDING	02/08/95	02/08/95	3	1	7	1
				CRAMPING	02/08/95	02/08/95	1	1	7	4

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
123 (Cont.)				CRAMPING	02/08/95	02/08/95	2	1	5	1
				CRAMPING	02/09/95	02/09/95	1	1	7	1
				HEADACHE	02/10/95	02/10/95	2	2	7	1
				SLEEPLESSNESS	02/10/95	02/11/95	1	2	6	1
				PLEURISY PAIN	02/13/95	02/19/95	2	2	6	1
				HA	02/14/95	02/14/95	2	2	6	1
				ALLERGIC REACTION	02/18/95	Ongoing	2	2	1	3
124	02/06/95		02/20/95	NAUSEA	02/06/95	02/06/95	2	1	2	1
				CRAMPS	02/06/95	02/06/95	2	1	3	2
				CRAMPS	02/07/95	02/07/95	2	1	3	3
				CRAMPS	02/08/95	02/08/95	2	2	3	3
				CRAMPS	02/09/95	02/09/95	2	1	3	2
				FLU	02/09/95	02/13/95	2	2	1	1
				CRAMPS	02/10/95	02/10/95	1	1	3	3
				CRAMPS	02/11/95	02/11/95	1	1	3	1
				CRAMPS	02/15/95	02/20/95	1	1	3	1
125	02/06/95	02/08/95	02/20/95	CRAMPING	02/06/95	02/07/95	1	1	3	1
				HEADACHE	02/06/95	02/06/95	2	2	3	1
				FATIGUE	02/07/95	02/07/95	1	2	3	1
				CRAMPING	02/08/95	02/09/95	3	2	7	1
				CRAMPING	02/10/95	02/11/95	1	2	7	1
				CRAMPING	02/15/95	02/15/95	1	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
125 (Cont.)				NO ENERGY, FATIGUE	02/15/95	02/15/95	1	2	7	1
126	02/06/95		02/20/95	NAUSEA	02/06/95	02/06/95	1	1	3	4
				NAUSEA	02/07/95	02/07/95	2	1	3	1
				CRAMPING	02/07/95	02/07/95	2	2	3	4
				FEVER	02/07/95	02/10/95	1	1	1	1
				DEHYDRATION (VERY THIRSTY; DRY MOUTH)	02/07/95	02/07/95	3	1	3	1
				VOMITING	02/08/95	02/08/95	2	1	3	1
				CRAMPS	02/08/95	02/08/95	3	2	3	3
				CRAMPS	02/09/95	02/09/95	3	2	3	3
				CRAMPS	02/10/95	02/10/95	3	2	3	2
				CRAMPS	02/11/95	02/11/95	1	2	3	3
				CRAMPS	02/12/95	02/12/95	1	2	3	3
				CRAMPS	02/13/95	02/13/95	1	2	3	1
127	02/06/95	02/08/95	02/20/95	POST NASAL DRIP, SWALLOWING MUCUS	02/06/95	02/06/95	1	1	1	1
				NAUSEA	02/07/95	02/07/95	2	1	3	1
				VOMITING	02/07/95	02/07/95	2	1	3	1
				VOMITING	02/08/95	02/08/95	1	1	7	1
				CRAMPS	02/08/95	02/08/95	3	2	7	1
				HA	02/08/95	02/08/95	2	2	6	1
				CRAMPING	02/08/95	02/08/95	2	2	5	4
				CRAMPS	02/09/95	02/09/95	1	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
127 (Cont.)				COLD; POST NASAL DRIP	02/18/95	02/20/95	2	1	1	1
128	02/06/95	02/08/95	02/27/95	CRAMPS	02/06/95	02/06/95	1	1	3	1
				NAUSEA	02/07/95	02/07/95	3	1	3	3
				VOMITING	02/07/95	02/07/95	3	1	3	3
				CRAMPS	02/07/95	02/07/95	2	1	3	1
				NAUSEA	02/08/95	02/08/95	3	2	3	1
				VOMITING	02/08/95	02/08/95	3	2	3	1
				CRAMPS	02/08/95	02/08/95	2	1	7	1
				CRAMPS	02/09/95	02/09/95	1	1	7	1
				CRAMPS	02/11/95	02/11/95	1	1	7	1
129	02/06/95	02/08/95	02/23/95	NAUSEA	02/06/95	02/08/95	1	1	3	1
				FEVER	02/06/95	02/07/95	1	1	3	1
				CRAMPS	02/07/95	02/07/95	1	1	3	1
				HA	02/07/95	02/07/95	1	2	3	1
				CRAMPS	02/08/95	02/11/95	2	2	7	1
				DIARRHEA	02/08/95	02/08/95	1	1	5	1
				HA	02/09/95	02/09/95	2	2	6	1
				CRAMPS	02/12/95	02/14/95	1	2	7	1
				HA - INTERMITTENT	02/12/95	02/14/95	1	2	6	1
				HA	02/13/95	02/13/95	3	2	6	2
				CRAMPS	02/17/95	02/17/95	1	1	7	1
				HA	02/18/95	02/18/95	2	2	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
129 (Cont.)				CRAMPS	02/21/95	02/21/95	2	1	6	1
130	02/06/95	02/08/95	02/20/95	CRAMPING	02/06/95	02/06/95	2	1	3	2
				CRAMPING	02/07/95	02/07/95	1	1	3	1
				HA	02/07/95	02/07/95	1	1	3	1
				CRAMPING	02/08/95	02/08/95	2	2	7	1
				CRAMPING	02/08/95	02/08/95	3	2	7	1
				HA	02/08/95	02/08/95	2	2	7	1
				HA	02/16/95	02/16/95	1	2	6	1
131	02/07/95	02/09/95	02/21/95	PINCHING/CRAMPING	02/07/95	02/07/95	1	1	3	1
				CRAMPING	02/08/95	02/09/95	2	2	3	1
				CRAMPING	02/09/95	02/09/95	3	2	7	1
				CRAMPING	02/10/95	02/12/95	2	2	7	1
				CRAMPING	02/13/95	02/14/95	1	2	7	1
132	02/07/95	02/09/95	02/21/95	BACTERIAL VAGINOSIS		02/19/95	2	2	1	1
				NAUSEA	02/07/95	02/07/95	1	1	2	1
				VOMITING	02/08/95	02/08/95	2	1	2	1
				NAUSEA	02/08/95	02/08/95	2	1	2	1
				CRAMPS	02/09/95	02/09/95	2	1	5	1
				EDEMA TO JOINTS - WRIST, FINGERS, ANKLES, ELBOWS	02/13/95	02/15/95	3	2	6	1
				SWOLLEN JOINTS	02/16/95	02/17/95	1	1	1	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
133	03/02/95	03/04/95	03/16/95	CRAMPS	03/04/95	03/05/95	3	2	7	2
				EXCESSIVE BLEEDING	03/04/95	03/07/95	3	1	7	1
				DIARRHEA	03/04/95	03/05/95	3	1	7	2
				CRAMPS	03/06/95	03/06/95	2	1	7	1
				DIARRHEA	03/06/95	03/07/95	2	1	7	2
				DIARRHEA	03/08/95	03/08/95	1	1	7	4
				DIARRHEA	03/09/95	03/10/95	2	1	7	1
				CRAMPS	03/14/95	03/16/95	2	1	6	3
134	03/02/95	03/04/95	03/17/95	CRAMPING	03/04/95	03/04/95	3	2	7	1
				DIARRHEA	03/04/95	03/04/95	1	1	7	1
				EXCESSIVE BLEEDING	03/04/95	03/04/95	3	1	7	1
135	03/02/95	03/04/95	03/16/95	CRAMPS	03/02/95	03/03/95	2	2	3	2
				FEVER	03/02/95	03/02/95	1	2	3	1
				CRAMPS	03/04/95	03/04/95	1	2	3	4
				CRAMPS	03/04/95	03/04/95	3	2	7	2
				EXCESSIVE BLEEDING	03/04/95	03/04/95	3	1	7	1
				CHILLS	03/04/95	03/04/95	2	1	7	1
				CRAMPS	03/05/95	03/06/95	1	2	7	1
136	03/02/95	03/04/95	03/16/95	HA	03/02/95	03/02/95	2	2	1	1
				HA	03/03/95	03/03/95	2	2	1	1
				SOUR STOMACH	03/03/95	03/03/95	1	1	1	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
136 (Cont.)				CRAMPS	03/04/95	03/04/95	3	2	5	1
				CRAMPS	03/05/95	03/05/95	3	2	7	1
				CRAMPS	03/06/95	03/06/95	2	2	7	1
137	03/02/95	03/04/95	05/04/95	CRAMPING	03/02/95	03/03/95	1	1	3	1
				CRAMPING	03/04/95	03/04/95	3	1	3	3
				CRAMPING	03/04/95	03/06/95	3	2	7	2
				CRAMPING - INTERMITTENT	03/07/95	03/08/95	2	2	7	2
				INTERMITTENT CRAMPING	03/09/95	03/10/95	1	2	7	3
				INTERMITTENT CRAMPING	03/11/95	03/11/95	1	1	7	1
138	03/06/95	03/08/95	03/22/95	BACTERIAL VAGINOSIS		03/07/95	2	2	1	1
				CRAMPING	03/08/95	03/08/95	1	1	7	1
				FREQUENCY OF URINATION	03/19/95	03/19/95	1	2	1	1
				STUFFY NOSE	03/20/95	03/20/95	1	1	1	1
				SCRATCHY THROAT	03/20/95	03/20/95	1	1	1	1
139	03/06/95	03/08/95	03/20/95	BACK PAIN	03/08/95	03/13/95	2	2	7	1
				CRAMPS	03/08/95	03/08/95	3	2	7	2
				CHILLS	03/08/95	03/08/95	2	1	7	1
				CRAMPS	03/09/95	03/11/95	2	2	7	1
				CRAMPS	03/12/95	03/13/95	1	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
140	03/06/95	03/08/95	03/20/95	CRAMPS	03/07/95	03/07/95	2	2	3	1
				CRAMPS	03/08/95	03/08/95	1	2	7	1
				CRAMPS	03/09/95	03/09/95	1	1	7	1
				CRAMPS	03/10/95	03/10/95	1	2	7	1
				CRAMPS	03/11/95	03/11/95	1	1	7	1
141	03/06/95	03/08/95	03/30/95	NAUSEA	03/06/95	03/06/95	1	1	3	1
				VOMITING	03/06/95	03/06/95	2	1	3	1
				CRAMPS	03/06/95	03/06/95	1	1	3	3
				VOMITING	03/07/95	03/07/95	1	1	3	1
				CRAMPS	03/07/95	03/07/95	1	2	3	1
				HA	03/07/95	03/08/95	2	2	1	1
				BACTERIAL VAGINOSIS	03/07/95	03/07/95	1	2	1	1
				CRAMPS	03/08/95	03/08/95	2	2	7	3
				EXCESSIVE BLEEDING (6 PADS IN 8H)	03/08/95	03/08/95	2	1	3	1
				CRAMPS	03/09/95	03/09/95	2	2	7	3
				CRAMPS	03/10/95	03/10/95	2	2	7	1
142	03/06/95	03/08/95	03/21/95	NAUSEA	03/06/95	03/06/95	2	1	3	1
				NAUSEA	03/07/95	03/08/95	2	1	3	1
				NAUSEA	03/08/95	03/08/95	2	1	7	1
				CRAMPS	03/08/95	03/09/95	1	1	7	1
				CRAMPING	03/08/95	03/08/95	1	1	3	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
143	03/08/95	03/10/95	03/22/95	CRAMPS	03/08/95	03/08/95	1	2	3	1
				CRAMPS	03/09/95	03/09/95	1	2	3	1
				BACTERIAL VAGINOSIS	03/09/95	03/09/95	1	2	1	1
				VOMITING	03/10/95	03/10/95	1	1	3	1
				CRAMPING	03/10/95	03/10/95	3	2	7	3
				CRAMPS	03/11/95	03/11/95	3	2	7	2
				CRAMPS	03/12/95	03/12/95	1	2	7	3
				CRAMPS	03/13/95	03/13/95	1	2	7	1
144	03/08/95	03/10/95	03/28/95	CRAMPS	03/08/95	03/09/95	2	2	3	4
				HEARTBURN/UPSET STOMACH	03/08/95	03/08/95	2	2	2	4
				HEARTBURN	03/09/95	03/09/95	3	2	2	1
				HA	03/09/95	03/09/95	3	2	2	1
				EARS RINGING & THROBBING	03/09/95	03/09/95	3	2	2	1
				CRAMPS	03/10/95	03/14/95	3	2	7	2
				EXCESSIVE BLEEDING	03/10/95	03/10/95	3	1	7	1
				MIGRAINE HA	03/13/95	03/13/95	3	2	7	1
				CRAMPS	03/15/95	03/15/95	2	1	7	1
				HA	03/15/95	03/15/95	3	1	7	1
				VOMITING	03/15/95	03/15/95	3	1	7	1
				HA	03/20/95	03/20/95	3	1	6	1
				VOMITING	03/20/95	03/20/95	3	1	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
145	03/13/95	03/15/95	03/27/95	NAUSEA	03/14/95	03/14/95	1	1	3	1
				CHILLS	03/14/95	03/14/95	1	1	3	1
				HA	03/14/95	03/14/95	1	2	3	1
				HA	03/15/95	03/15/95	2	2	3	1
				NAUSEA	03/15/95	03/15/95	2	1	3	1
146	03/13/95	03/15/95	03/27/95	CRAMPS	03/15/95	03/15/95	2	2	7	2
				CRAMPS	03/16/95	03/16/95	2	1	7	1
147	03/13/95	03/15/95	03/27/95	CRAMPS	03/14/95	03/14/95	1	1	3	1
				CRAMPS	03/15/95	03/15/95	2	1	7	1
				CRAMPS	03/17/95	03/17/95	2	1	7	1
				HA	03/19/95	03/20/95	1	2	6	1
148	03/13/95	03/15/95	03/27/95	CRAMPS	03/13/95	03/14/95	1	1	3	1
				CRAMPS	03/14/95	03/14/95	2	1	3	1
				CRAMPS	03/15/95	03/15/95	3	2	7	1
				CRAMPS	03/16/95	03/16/95	1	1	7	1
				CRAMPS	03/24/95	03/24/95	3	2	6	1
				CRAMPING	03/27/95	03/28/95	1	1	6	1
				PAIN IN LEG	03/28/95	03/28/95	3	1	1	1
				CAR ACCIDENT	03/29/95	03/29/95	2	3	1	2
				LACERATED HEAD FROM CAR ACCIDENT	03/29/95	03/29/95	3	3	1	2

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
149	03/13/95	03/15/95	03/27/95	BACTERIAL VAGINOSIS		03/14/95	2	2	1	1
				NAUSEA	03/13/95	03/14/95	2	1	3	1
				CRAMPS	03/14/95	03/14/95	3	2	3	1
				VOMITED	03/15/95	03/15/95	2	1	3	1
				CRAMPING	03/15/95	03/15/95	2	1	5	1
				CRAMPS	03/16/95	03/16/95	1	1	7	1
				HEAVY BLEEDING	03/17/95	03/17/95	3	1	7	1
				CRAMPS	03/18/95	03/18/95	2	2	7	1
150	03/13/95	03/15/95	03/27/95	CRAMPS	03/14/95	03/14/95	1	1	3	1
				CRAMPS	03/15/95	03/15/95	2	2	7	1
				CRAMPS	03/15/95	03/15/95	3	1	7	1
				CRAMPS	03/16/95	03/16/95	2	2	7	1
				CRAMPS	03/17/95	03/17/95	2	2	7	1
				CRAMPS	03/18/95	03/18/95	2	2	7	1
				HA	03/19/95	03/19/95	2	2	7	1
				HA	03/20/95	03/20/95	1	2	7	1
				HA	03/21/95	03/21/95	1	2	7	1
				HA	03/22/95	03/22/95	2	2	7	1
				HA	03/23/95	03/23/95	2	2	7	1
151	03/14/95	03/16/95	03/28/95	CRAMPS	03/14/95	03/14/95	1	1	3	1
				NAUSEA	03/14/95	03/14/95	2	1	3	1
				CRAMPS	03/16/95	03/16/95	1	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
151 (Cont.)				CRAMPS	03/19/95	03/19/95	2	2	7	4
				NAUSEA	03/19/95	03/19/95	2	1	7	4
				CRAMPS	03/20/95	03/21/95	3	2	7	1
				NAUSEA	03/20/95	03/20/95	3	1	7	1
				CRAMPS	03/25/95	03/25/95	2	1	7	1
152	03/15/95	03/17/95	03/29/95	CRAMPS	03/15/95	03/15/95	2	2	3	1
				DIZZINESS	03/16/95	03/16/95	3	1	3	1
				NAUSEA	03/16/95	03/16/95	3	1	3	1
				COLD SWEATS	03/16/95	03/16/95	3	1	3	1
				CRAMPS	03/17/95	03/18/95	3	1	7	1
				RUNNY NOSE	03/17/95	03/19/95	1	2	1	1
				PLUGGED EARS	03/17/95	03/19/95	1	2	1	1
				CRAMPS	03/19/95	03/22/95	2	1	7	1
153	03/15/95	03/17/95	03/30/95	CRAMPS	03/15/95	03/17/95	2	2	3	1
				NAUSEA	03/15/95	03/15/95	2	1	3	1
				HA	03/15/95	03/15/95	3	2	3	1
				LIGHT-HEADED	03/15/95	03/15/95	2	1	3	1
				CRAMPING	03/17/95	03/30/95	2	2	7	1
154	04/06/95	04/08/95	04/21/95	NAUSEA	04/06/95	04/07/95	3	1	3	2
				CRAMPS	04/06/95	04/06/95	1	1	3	1
				NAUSEA	04/07/95	04/07/95	1	1	3	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
154 (Cont.)				CRAMPS	04/07/95	04/07/95	2	1	3	1
				CRAMPS	04/08/95	04/08/95	3	2	7	1
				NAUSEA	04/08/95	04/08/95	2	1	3	1
				NAUSEA	04/08/95	04/08/95	3	1	7	1
				FEVER	04/08/95	04/09/95	1	1	1	1
				CRAMPS	04/10/95	04/12/95	3	2	7	1
				CRAMPS	04/16/95	04/17/95	1	1	7	1
155	04/06/95	04/08/95	04/20/95	ALLERGIES	04/06/95	Ongoing	2	2	1	1
				ABD CRAMPS	04/07/95	04/07/95	1	2	3	1
				FINGER PAIN	04/07/95	04/07/95	1	2	1	1
				CRAMPS	04/08/95	04/09/95	3	2	7	1
				CRAMPS	04/10/95	04/10/95	2	2	7	1
				CRAMPS	04/11/95	04/11/95	1	2	7	1
				HEADACHE	04/12/95	04/12/95	2	2	1	1
				ABD CRAMPS	04/14/95	04/14/95	2	2	7	1
				LEG CRAMPS	04/14/95	04/14/95	2	2	6	1
156	04/06/95	04/08/95	04/20/95	CRAMPING	04/07/95	04/07/95	1	1	3	1
				CRAMPING	04/08/95	04/11/95	1	1	7	1
157	04/10/95	04/12/95	05/03/95	BACTERIAL VAGINOSIS		04/11/95	1	2	1	1
				CRAMPS	04/12/95	04/12/95	1	1	3	4
				CRAMPS	04/13/95	04/13/95	3	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
158	04/10/95	04/12/95	04/26/95	VOMITING	04/11/95	04/12/95	2	1	3	1
				EXCESSIVE BLEEDING	04/12/95	04/12/95	3	2	7	1
				FEELING TIRED	04/12/95	Ongoing	1	2	7	3
				DIZZINESS	04/12/95	Ongoing	1	2	7	3
159	04/10/95	04/12/95	05/01/95	NAUSEA	04/11/95	04/11/95	1	1	3	1
				CRAMPS	04/11/95	04/11/95	2	1	3	1
				YELLOW DISCHARGE	04/11/95	04/11/95	1	1	2	1
				CRAMPS	04/12/95	04/12/95	3	2	7	1
				CRAMPS	04/13/95	04/22/95	2	2	7	1
160	04/10/95	04/12/95	04/25/95	SHOOTING PAINS (R) OVARY AREA	04/11/95	04/11/95	2	1	3	1
				NAUSEA	04/11/95	04/11/95	1	1	3	1
				VOMITING	04/12/95	04/12/95	1	1	2	1
				CRAMPS	04/12/95	04/12/95	1	1	2	1
				CRAMPS	04/15/95	04/15/95	3	2	7	1
				CRAMPS	04/16/95	05/01/95	1	2	7	1
161	04/10/95	04/12/95	04/26/95	CRAMPS	04/12/95	04/12/95	2	1	7	2
				CRAMPS	04/13/95	04/14/95	1	1	7	1
162	04/10/95	04/12/95	04/26/95	CRAMPS	04/11/95	04/11/95	2	2	3	1
				CRAMPS	04/12/95	04/12/95	3	1	3	1
				VOMITING X 3	04/12/95	04/12/95	2	1	3	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
162 (Cont.)				CRAMPS	04/12/95	04/12/95	2	2	7	2
				CRAMPS	04/13/95	04/13/95	1	2	7	1
163	04/10/95	04/12/95	04/26/95	BACTERIAL VAGINOSIS		04/11/95	1	2	1	1
				CRAMPS	04/11/95	04/11/95	2	2	3	1
				CRAMPS	04/12/95	04/12/95	3	2	7	2
				CRAMPS	04/13/95	04/13/95	1	2	7	1
				CRAMPS	04/19/95	04/19/95	1	2	7	1
				CRAMPS	04/21/95	04/22/95	2	2	7	2
				CRAMPS	04/23/95	04/23/95	1	2	7	1
				CRAMPS	04/24/95	04/25/95	2	2	7	1
164	04/13/95	04/15/95		HA	04/13/95	04/13/95	1	1	3	1
				BACKACHE	04/14/95	04/14/95	2	2	3	1
				CRAMPING	04/15/95	04/15/95	3	2	7	1
165	04/13/95	04/15/95		CRAMPING	04/15/95	04/15/95	2	1	3	4
				CRAMPING	04/15/95	Unknown	3	2	7	[5]
166	04/13/95	04/15/95	04/27/95	CRAMPS	04/13/95	04/13/95	3	2	3	1
				CRAMPS	04/14/95	04/14/95	1	2	3	1
				EXCESSIVE BLEEDING	04/15/95	04/15/95	3	1	5	1
				CRAMPING	04/15/95	04/15/95	3	2	5	2
				CRAMPING	04/16/95	04/17/95	1	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
167	04/17/95	04/19/95	05/04/95	CRAMPS	04/18/95	04/18/95	2	1	3	1
				CRAMPS	04/19/95	04/19/95	3	2	7	2
				CRAMPS	04/20/95	04/20/95	1	2	7	4
				CRAMPS	04/21/95	04/21/95	3	1	7	2
				CRAMPS	04/22/95	04/22/95	2	1	7	1
				CRAMPS	04/23/95	04/23/95	[5]	1	7	1
168	04/17/95	04/19/95	05/01/95	CRAMPS	04/19/95	04/19/95	3	2	7	2
				CRAMPS	04/20/95	04/21/95	1	2	7	1
				CRAMPS	04/30/95	04/30/95	1	2	7	1
169	04/17/95	04/19/95	05/04/95	HA	04/17/95	04/17/95	1	1	2	1
				HA	04/18/95	04/18/95	1	2	2	1
				CRAMPS	04/19/95	04/19/95	1	1	7	1
				CRAMPS	04/19/95	04/19/95	3	2	7	1
				CRAMPS	04/20/95	04/20/95	2	2	7	1
				CRAMPS	04/21/95	04/22/95	1	2	7	1
				CRAMPS	04/27/95	04/27/95	2	2	7	1
170	04/17/95	04/19/95	05/05/95	CRAMPS	04/17/95	04/19/95	2	2	3	3
				HEARTBURN	04/18/95	04/18/95	1	1	2	1
				NAUSEA	04/19/95	04/19/95	2	1	3	1
				LIGHT-HEADED	04/19/95	04/19/95	1	1	1	1
				HEADACHE	04/19/95	04/19/95	2	1	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
170 (Cont.)				CRAMPING	04/19/95	04/19/95	3	2	7	1
				HEARTBURN	04/25/95	04/25/95	1	1	6	1
171	04/18/95	04/20/95	05/03/95	CRAMPING	04/19/95	04/19/95	1	1	3	1
				INCREASED HEART RATE	04/19/95	04/19/95	2	1	3	1
172	04/19/95	04/21/95	05/02/95	UPSET STOMACH	04/19/95	04/21/95	2	2	3	1
				HA	04/19/95	04/20/95	2	2	3	1
				NAUSEA	04/21/95	04/22/95	2	1	7	2
				CRAMPS	04/21/95	04/21/95	1	1	7	1
				NAUSEA	04/22/95	04/24/95	1	1	7	1
				CRAMPS	04/22/95	04/22/95	3	2	7	2
				CRAMPS	04/23/95	04/23/95	2	2	7	2
				CRAMPS	04/24/95	04/25/95	1	2	7	1
173	04/19/95	04/21/95		NAUSEA	04/19/95	04/19/95	3	1	2	1
				NAUSEA	04/20/95	04/21/95	3	2	2	1
				CRAMPING	04/20/95	04/20/95	1	1	3	1
				CRAMPING	04/21/95	04/21/95	3	2	7	1
				NAUSEA	04/21/95	04/21/95	3	1	7	1
				VOMITING	04/21/95	04/21/95	3	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
174	04/19/95	04/21/95	05/11/95	HA	04/19/95	04/19/95	3	2	2	1
				HA	04/20/95	04/20/95	2	2	2	1
				UPSET STOMACH	04/20/95	04/20/95	2	2	3	1
				CRAMPS	04/20/95	04/21/95	2	1	3	2
				SHARP PAIN (L) SIDE	04/21/95	04/21/95	2	1	1	1
				CRAMPS	04/22/95	04/29/95	1	1	7	1
				HA	04/23/95	04/23/95	2	2	7	1
175	05/15/95	05/17/95	06/13/95	EARACHE	05/15/95	05/15/95	3	2	1	1
				BACTERIAL VAGINOSIS	05/15/95	05/16/95	1	2	1	1
				1/4 C. CLEAR SLIMY VAG DISCHARGE	05/15/95	05/15/95	1	1	2	1
				NAUSEA	05/16/95	05/17/95	3	1	3	3
				VOMITED	05/16/95	05/17/95	2	1	3	1
				CRAMPING INTERMITTENT	05/17/95	05/30/95	1	1	7	1
176	05/15/95	05/17/95	05/30/95	CRAMPS INTERMITTENT	05/15/95	05/16/95	1	2	3	4
				CRAMPS INTERMITTENT	05/16/95	05/16/95	2	2	3	2
				CRAMPS	05/17/95	05/17/95	1	2	3	3
				CRAMPS	05/18/95	05/19/95	1	2	7	1
				CRAMPS	05/20/95	05/20/95	2	2	7	4
				CRAMPS INTERMITTENT	05/21/95	05/24/95	3	2	7	2
				CRAMPS	05/25/95	05/25/95	2	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
177	05/15/95	05/17/95	05/30/95	CRAMPS	05/15/95	05/16/95	1	2	3	4
				CRAMPS	05/16/95	05/16/95	2	2	3	4
				NAUSEA	05/16/95	05/17/95	3	1	3	1
				VOMITING	05/16/95	05/17/95	2	1	3	1
				CRAMPS	05/17/95	05/17/95	3	2	7	2
				CRAMPS	05/18/95	05/19/95	1	2	7	4
				CRAMPS	05/20/95	05/21/95	3	2	7	2
				CRAMPS	05/22/95	05/24/95	1	2	7	1
				ANXIETY ATTACKS	05/22/95	05/22/95	2	1	6	1
178	05/15/95	05/17/95	05/30/95	BACTERIAL VAGINOSIS		05/16/95	2	2	1	1
				NAUSEA	05/15/95	05/15/95	1	1	3	1
				CRAMPING	05/15/95	05/15/95	1	2	3	1
				HEADACHE	05/15/95	05/15/95	1	2	3	1
				CRAMPING	05/16/95	05/16/95	1	1	3	1
				CRAMPING	05/17/95	05/17/95	1	2	3	1
				CRAMPING	05/17/95	05/17/95	3	1	7	1
179	05/15/95	05/17/95	05/30/95	BACTERIAL VAGINOSIS		05/15/95	2	2	1	1
				NAUSEA	05/16/95	05/17/95	2	1	3	1
				VOMITING	05/16/95	05/17/95	2	1	3	1
				CRAMPS	05/17/95	05/17/95	2	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
180	05/15/95	05/17/95	05/30/95	CRAMPS	05/17/95	05/17/95	2	1	3	1
				CRAMPING	05/17/95	05/17/95	2	1	7	3
				EXCESSIVE BLEEDING	05/17/95	05/17/95	3	1	7	1
				CRAMPING	05/18/95	05/23/95	2	1	7	2
				CRAMPING	05/24/95	05/25/95	1	1	7	4
				CRAMPING	05/26/95	05/26/95	2	1	7	2
				CRAMPING	05/27/95	05/29/95	1	1	7	1
181	05/15/95	05/17/95	05/30/95	CRAMPS	05/16/95	05/16/95	2	1	3	1
				CRAMPS	05/17/95	05/17/95	2	2	7	1
				CRAMPS	05/18/95	05/18/95	1	2	7	1
				CRAMPS	05/19/95	05/19/95	1	1	7	1
				CRAMPS	05/20/95	05/20/95	1	2	7	1
182	05/15/95	05/17/95	05/30/95	CRAMPS	05/15/95	05/16/95	1	1	3	4
				CRAMPS	05/17/95	05/17/95	2	2	7	1
				DIARRHEA	05/17/95	05/17/95	1	1	7	1
183	05/15/95	05/17/95	06/01/95	CRAMPS	05/16/95	05/16/95	2	1	3	1
				CRAMPS	05/17/95	05/17/95	3	2	7	1
				HEADACHE	05/20/95	05/20/95	2	2	6	1
				HEADACHE	05/21/95	05/21/95	3	2	6	1
				HEADACHE	05/22/95	05/22/95	3	2	6	1
				HEADACHE	05/24/95	05/24/95	2	2	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
184	05/22/95	05/24/95	06/16/95	BACTERIAL VAGINOSIS		05/23/95	2	2	1	1
				NAUSEA	05/22/95	05/22/95	2	1	3	4
				VOMITING	05/23/95	05/23/95	1	1	3	3
				VOMITING	05/24/95	05/24/95	1	1	3	1
				CRAMPING	05/24/95	05/24/95	1	1	7	1
186	05/22/95	05/24/95	06/06/95	CRAMPS	05/23/95	05/24/95	2	1	3	3
				CRAMPS	05/24/95	05/24/95	2	1	7	1
				NAUSEA	05/24/95	05/24/95	1	1	2	1
187	05/22/95	05/24/95	06/05/95	CRAMPS	05/24/95	05/24/95	1	1	7	1
				CRAMPS	05/24/95	05/24/95	3	1	7	2
				HA	05/26/95	05/26/95	1	2	6	1
188	05/23/95	05/25/95	06/06/95	CRAMPS	05/25/95	05/25/95	1	1	3	1
				NAUSEA	05/25/95	05/25/95	1	1	3	1
				VOMITING	05/25/95	05/25/95	3	1	3	1
				CRAMPING	05/25/95	05/25/95	3	2	7	2
				CRAMPING	05/26/95	05/26/95	2	2	7	1
189	05/30/95	06/01/95	06/13/95	CRAMPS	05/30/95	05/30/95	1	1	3	1
				NAUSEOUS	05/30/95	05/30/95	1	1	3	1
				MUSCLE TENSION	05/31/95	06/01/95	2	2	1	3
				HEADACHE	05/31/95	06/01/95	3	2	1	3

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
189 (Cont.)				VOMIT	06/01/95	06/01/95	3	1	7	1
				BLACK OUT	06/01/95	06/01/95	3	1	7	1
				HEADACHE	06/01/95	06/13/95	3	2	1	1
				MUSCLE TENSION	06/01/95	06/13/95	2	2	1	1
				CRAMPING	06/01/95	06/01/95	1	1	7	1
				LIGHT HEADED	06/02/95	06/03/95	1	1	7	1
190	05/30/95	06/01/95	06/13/95	SINUS CONGESTION	05/30/95	05/30/95	3	2	1	1
				INSOMNIA	05/30/95	06/01/95	3	1	3	1
				CRAMPS	05/30/95	05/30/95	1	1	3	1
				CRAMPS	05/31/95	05/31/95	1	2	3	1
				CRAMPING	06/01/95	06/01/95	3	1	3	3
				CRAMPING	06/01/95	06/01/95	3	2	7	2
				DIARRHEA	06/01/95	06/01/95	3	2	7	1
				CRAMPING	06/02/95	06/04/95	2	2	7	1
				SINUS CONGESTION	06/02/95	06/05/95	2	2	1	1
				HEADACHE INTERMITTENT	06/03/95	06/04/95	2	1	6	1
				CRAMPING	06/05/95	06/05/95	3	2	7	1
				CRAMPING	06/06/95	06/07/95	1	1	7	4
				CRAMPING	06/08/95	06/10/95	3	2	7	1
				NAUSEA	06/08/95	06/08/95	3	1	6	1
				CHILLS	06/08/95	06/08/95	3	1	6	1
				FEVER	06/08/95	06/08/95	3	1	6	1
				CRAMPING	06/12/95	06/12/95	1	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
191	05/30/95	06/01/95	06/20/95	NAUSEA	05/30/95	05/30/95	2	1	3	4
				DIZZINESS	05/30/95	05/31/95	3	1	3	1
				COUGHED UP BLOOD	05/31/95	05/31/95	3	1	3	1
				NAUSEA	05/31/95	05/31/95	3	1	3	1
				NAUSEA	06/01/95	06/01/95	1	1	3	1
				CRAMPING	06/01/95	06/01/95	1	2	7	3
				CRAMPING	06/02/95	06/02/95	1	2	7	1
192	05/30/95	06/01/95	06/13/95	NAUSEA	05/31/95	05/31/95	2	1	3	1
				INTERMITTENT CRAMPS	05/31/95	05/31/95	1	1	3	1
				CRAMPING	06/01/95	06/01/95	3	2	7	2
				CRAMPING	06/02/95	06/02/95	1	2	7	1
				HEADACHE	06/06/95	06/06/95	2	2	6	1
193	05/30/95	06/01/95	06/13/95	CRAMPING	06/01/95	06/01/95	3	1	7	2
				CRAMPS	06/02/95	06/02/95	2	1	7	1
194	06/06/95	06/08/95	06/21/95	CRAMPS	06/06/95	06/06/95	2	2	3	4
				CRAMPS	06/07/95	06/07/95	3	2	3	2
				NAUSEA	06/07/95	06/07/95	3	1	3	1
				CRAMPS	06/08/95	06/09/95	3	2	7	1
				NAUSEA	06/08/95	06/09/95	3	1	7	1
				CRAMPS	06/10/95	06/10/95	2	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
195	06/06/95	06/08/95	06/21/95	NAUSEA	06/06/95	06/07/95	1	2	3	1
				CRAMPS	06/06/95	06/06/95	1	1	3	1
				TIRED	06/06/95	06/06/95	1	1	3	1
				COLD	06/06/95	06/07/95	1	2	3	1
				CRAMPS	06/07/95	06/07/95	1	2	3	1
				CRAMPS	06/08/95	06/08/95	2	2	7	2
				CRAMPS	06/09/95	06/11/95	1	2	7	1
				CRAMPS	06/12/95	06/12/95	2	2	7	1
				CRAMPS	06/13/95	06/14/95	1	2	7	1
196	06/06/95	06/08/95	06/21/95	HEADACHE	06/06/95	06/06/95	2	2	2	1
				CRAMPING	06/06/95	06/07/95	1	2	3	1
				NAUSEA INTERMITTENT	06/07/95	06/07/95	2	1	3	1
				NAUSEA INTERMITTENT	06/08/95	06/08/95	1	1	3	1
				CRAMPING	06/08/95	06/08/95	2	1	7	1
				CRAMPING	06/10/95	06/10/95	1	1	7	1
				CRAMPING	06/11/95	06/12/95	2	2	7	1
				HEADACHE	06/14/95	06/14/95	1	2	6	1
				HEADACHE	06/19/95	06/20/95	2	2	6	1
197	06/06/95	06/08/95		CRAMPING	06/06/95	06/06/95	1	1	3	1
				CRAMPING	06/08/95	Unknown	3	[5]	7	[5]

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
(Patients with Any Adverse Event)

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
198	06/06/95	06/08/95	06/21/95	CRAMPS	06/07/95	06/08/95	1	1	3	1
				NAUSEA	06/08/95	06/08/95	1	1	3	1
				CRAMPS	06/08/95	06/08/95	3	2	7	2
				CRAMPS	06/09/95	06/09/95	1	2	7	1
				CRAMPS	06/10/95	06/10/95	2	2	7	1
199	06/06/95	06/08/95	06/21/95	HEADACHE	06/07/95	06/07/95	2	2	2	1
				CRAMPING	06/07/95	06/07/95	1	2	2	3
				CRAMPING	06/08/95	06/08/95	1	1	2	4
				CRAMPING	06/08/95	06/08/95	3	2	7	1
				NAUSEA	06/08/95	06/09/95	2	1	7	1
				HEADACHE	06/08/95	06/08/95	2	2	7	1
				CRAMPING	06/09/95	06/10/95	1	1	7	1
				VOMITING	06/09/95	06/09/95	2	1	7	1
				CRAMPING	06/17/95	06/17/95	1	1	7	1
200	06/09/95	06/11/95	07/06/95	TIRED	06/09/95	06/09/95	2	1	3	1
				PMS	06/09/95	06/10/95	2	1	3	1
				IRRITABLE	06/09/95	06/09/95	2	1	3	1
				CRAMPING	06/10/95	06/10/95	1	1	3	1
				NAUSEA	06/11/95	06/11/95	1	1	3	1
				CRAMPING	06/15/95	06/15/95	1	1	6	1
				VAGINAL ITCHING	06/20/95	06/20/95	1	1	1	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
201	06/12/95	06/14/95	06/29/95	EXCESSIVE BLEEDING	06/14/95	06/14/95	3	1	7	1
202	06/12/95	06/14/95	06/26/95	HEADACHE	06/13/95	06/13/95	1	2	3	1
				CRAMPING	06/13/95	06/13/95	1	1	3	4
				CRAMPING	06/13/95	06/13/95	2	1	3	1
				CRAMPING	06/14/95	06/14/95	2	1	7	1
				CRAMPING	06/16/95	06/16/95	2	1	7	1
				DIARRHEA	06/16/95	06/16/95	1	1	7	1
				SINUS HA	06/18/95	06/18/95	2	2	6	1
				SINUS HA	06/25/95	06/25/95	2	2	6	1
203	06/12/95	06/14/95	06/26/95	NAUSEA	06/13/95	06/14/95	2	1	3	1
				CRAMPING	06/13/95	06/13/95	1	2	3	4
				CRAMPING	06/13/95	06/13/95	3	2	3	3
				CRAMPING	06/14/95	06/17/95	1	1	7	1
				CRAMPING	06/14/95	06/14/95	3	1	3	2
				CRAMPING	06/20/95	06/22/95	1	1	6	1
				CRAMPS	06/28/95	06/30/95	3	2	1	1
				INTERMITTENT BRIEF LRQ PAIN	06/28/95	07/02/95	2	1	1	1
				INTERMITTENT BRIEF LRQ PAIN	07/16/95	07/16/95	2	1	1	1
204	06/12/95	06/14/95	06/26/95	DIARRHEA	06/13/95	06/13/95	1	1	3	1
				CRAMPING	06/14/95	06/14/95	2	1	7	2
				HA	06/14/95	06/14/95	3	1	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
204 (Cont.)				CRAMPING	06/15/95	06/17/95	1	1	7	1
				NAUSEA	06/15/95	06/15/95	1	1	7	1
205	06/13/95	06/15/95	06/28/95	CRAMPING	06/13/95	06/15/95	1	1	3	1
				CRAMPING	06/15/95	06/15/95	3	1	7	1
				EXCESSIVE BLEEDING	06/16/95	06/18/95	3	1	7	1
206	06/13/95	06/15/95	06/28/95	ANXIETY DUE TO TAKING PILLS.	06/13/95	06/13/95	2	1	1	1
				CRAMPS	06/13/95	06/14/95	1	2	3	4
				CHEST TIGHTNESS	06/13/95	06/15/95	2	2	2	1
				CRAMPS	06/15/95	06/16/95	3	2	7	2
				CRAMPS	06/17/95	06/17/95	2	2	7	1
207	06/19/95	06/21/95	07/03/95	CRAMPS	06/19/95	06/19/95	1	1	3	1
				NAUSEA	06/20/95	06/20/95	1	1	3	1
				EXCESSIVE BLEEDING	06/21/95	06/22/95	3	1	7	1
				CRAMPS	06/21/95	06/21/95	3	1	7	1
208	06/20/95	06/22/95	08/15/95	HA	06/20/95	06/20/95	3	2	3	1
				NAUSEA	06/21/95	06/22/95	2	1	3	1
				CRAMPS	06/21/95	06/21/95	2	2	3	2
				CRAMPS	06/22/95	06/22/95	1	1	3	1
				VOMITING	06/22/95	06/22/95	2	1	3	1
				CRAMPING	06/22/95	06/22/95	2	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
208 (Cont.)				CRAMPING	06/23/95	06/24/95	3	2	7	2
				CRAMPING	06/25/95	06/26/95	2	2	7	1
				CRAMPING	06/27/95	06/27/95	1	2	7	1
				CRAMPING	06/29/95	06/29/95	1	2	7	1
				HEADACHE	07/01/95	07/01/95	2	2	1	1
209	06/26/95	06/28/95	07/05/95	DIZZINESS	06/26/95	06/26/95	2	1	3	1
				HEADACHE	06/26/95	06/26/95	1	1	3	1
				DIZZINESS	06/27/95	06/27/95	2	1	3	1
				HEADACHE	06/27/95	06/27/95	2	2	3	1
				NAUSEA	06/27/95	06/27/95	2	1	3	1
				FATIGUE	06/27/95	06/27/95	2	1	3	1
				CRAMPS	06/27/95	06/27/95	1	1	3	1
				HA INTERMITTENT	06/27/95	07/06/95	3	1	1	1
				CRAMPS	06/28/95	06/28/95	2	1	3	1
				CRAMPS	07/05/95	07/05/95	1	1	1	1
				HA INTERMITTENT	07/07/95	07/07/95	3	2	1	1
				HA INTERMITTENT	07/08/95	07/09/95	3	1	1	1
210	06/26/95	06/28/95	07/10/95	CRAMPING INTERMITTENT	06/26/95	06/27/95	1	1	3	4
				INTERMITTENT CRAMPS	06/28/95	06/30/95	3	2	7	2
				INTERMITTENT CRAMPS	07/01/95	07/05/95	2	2	7	2
				INTERMITTENT CRAMPS	07/06/95	07/10/95	1	2	7	1
				EXCESSIVE BLEEDING	07/19/95	07/19/95	3	1	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
210 (Cont.)				CRAMPING	07/19/95	07/19/95	2	2	6	1
211	06/26/95	06/28/95	07/10/95	NAUSEA	06/26/95	06/27/95	3	1	3	1
				VOMITING	06/26/95	06/27/95	3	1	3	1
				CRAMPS	06/26/95	06/26/95	2	1	3	2
				LIGHT HEADEDNESS	06/27/95	06/27/95	2	1	3	1
				DIZZINESS	06/27/95	06/27/95	2	1	3	1
				SORE JOINTS AT LEG MUSCLES	06/27/95	06/27/95	2	1	3	1
				CRAMPS	06/27/95	06/28/95	3	1	3	4
				DIARRHEA	06/28/95	06/29/95	2	1	7	1
				CRAMPING	06/28/95	06/28/95	2	1	7	1
				CRAMPS	06/29/95	06/29/95	2	1	7	1
212	07/03/95	07/05/95	07/17/95	CRAMPING	07/03/95	07/05/95	2	1	2	1
				NAUSEATED	07/04/95	07/04/95	2	1	3	1
				CRAMPS	07/05/95	07/05/95	1	1	7	1
213	07/03/95	07/05/95	07/24/95	CRAMPS	07/03/95	07/03/95	1	1	3	1
				CRAMPS	07/04/95	07/04/95	3	2	3	2
				CRAMPS	07/05/95	07/05/95	3	1	7	1
				NAUSEA	07/05/95	07/05/95	3	1	7	1
				CRAMPING	07/06/95	07/06/95	3	2	7	1
				NAUSEA	07/06/95	07/06/95	3	1	7	1
				VOMITING	07/06/95	07/06/95	3	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
(Patients with Any Adverse Event)

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
213 (Cont.)				CRAMPING	07/07/95	07/07/95	1	2	7	1
				CRAMPING	07/08/95	07/08/95	1	1	7	1
214	07/03/95	07/05/95	08/07/95	NAUSEA	07/03/95	07/05/95	2	1	3	3
				CRAMPS	07/04/95	07/04/95	1	1	3	1
				CRAMPS	07/05/95	07/05/95	3	2	7	1
				CRAMPS	07/05/95	07/05/95	2	1	3	1
215	07/10/95	07/12/95	07/24/95	UPSET STOMACH	07/10/95	07/10/95	1	1	3	1
				DIARRHEA	07/10/95	07/10/95	1	1	2	1
				DRY HEAVES	07/11/95	07/11/95	2	1	3	1
				UPSET STOMACH	07/11/95	07/11/95	2	1	3	1
				DIARRHEA	07/12/95	07/12/95	2	1	7	1
				CRAMPING	07/12/95	07/12/95	3	2	7	1
216	07/10/95	07/12/95	07/24/95	INTERMITTENT CRAMPS	07/10/95	07/10/95	2	1	3	1
				INTERMITTENT CRAMPS	07/12/95	07/12/95	3	2	7	1
				INTERMITTENT CRAMPS	07/13/95	07/13/95	2	2	7	1
				DIARRHEA	07/13/95	07/13/95	1	1	7	1
				HA	07/14/95	07/14/95	1	2	7	1
217	07/10/95	07/12/95	07/24/95	NAUSEA	07/10/95	07/10/95	1	1	3	1
				VOMITED	07/10/95	07/10/95	1	1	3	1
				CRAMPING	07/11/95	07/12/95	1	1	3	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
(Patients with Any Adverse Event)

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
217 (Cont.)				CRAMPS	07/12/95	07/12/95	2	2	7	1
218	07/10/95	07/12/95	07/24/95	CRAMPS	07/10/95	07/10/95	1	1	3	3
				CRAMPS	07/11/95	07/11/95	1	2	3	3
				CRAMPS	07/12/95	07/12/95	1	1	3	1
				HA	07/12/95	07/12/95	1	2	3	1
				CRAMPING	07/12/95	07/12/95	2	2	7	1
				CRAMPS	07/13/95	07/13/95	1	1	7	1
				HA	07/16/95	07/17/95	1	2	6	1
				SUNBURN	07/16/95	07/16/95	1	1	1	1
219	07/10/95	07/12/95	07/24/95	HA	07/10/95	07/10/95	1	1	3	1
				NAUSEA	07/10/95	07/10/95	1	1	3	1
				TIREDNESS	07/10/95	07/10/95	1	1	2	1
				CRAMPS	07/10/95	07/11/95	2	1	3	1
				VOMITING	07/11/95	07/11/95	2	1	3	1
				WEAKNESS	07/11/95	07/11/95	2	1	2	1
				CRAMPING	07/12/95	07/12/95	3	2	7	1
220	07/11/95	07/13/95	07/25/95	VOMITING	07/12/95	07/12/95	1	1	3	1
				CRAMPS	07/13/95	07/15/95	1	1	7	1
				NAUSEA	07/13/95	07/13/95	1	1	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
221	07/17/95	07/19/95	08/01/95	NAUSEA	07/18/95	07/19/95	2	1	2	1
				STOMACH PAINS	07/18/95	07/18/95	2	1	2	1
				LOWER BACKACHE	07/18/95	07/18/95	3	1	2	1
				CRAMPING	07/18/95	07/19/95	1	1	2	1
				NAUSEA	07/19/95	07/19/95	3	1	7	1
				CRAMPING	07/19/95	07/19/95	3	2	7	1
				EXCESSIVE BLEEDING	07/20/95	07/21/95	3	1	7	1
222	07/17/95	07/19/95	07/31/95	NAUSEA	07/17/95	07/17/95	2	1	3	1
				HA	07/17/95	07/18/95	1	1	3	1
				JITTERS, SHAKES	07/17/95	07/18/95	2	1	2	1
				NAUSEA	07/18/95	07/18/95	3	1	3	1
				CRAMPS	07/18/95	07/18/95	2	2	3	1
				ANXIETY	07/18/95	07/18/95	1	1	3	1
				CRAMPS	07/19/95	07/19/95	3	2	7	1
				HA	07/19/95	07/19/95	1	2	6	1
				LOW BACK PAIN	07/19/95	07/19/95	1	2	7	1
				CRAMPS	07/21/95	07/21/95	1	2	7	1
				CRAMPS	07/23/95	07/23/95	1	1	7	1
				CRAMPS	07/24/95	07/24/95	1	1	7	1
				CRAMPS	07/26/95	07/26/95	1	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
223	07/17/95	07/19/95		LIGHT HEADACHE	07/17/95	07/17/95	1	1	2	1
				INTERMITTENT CRAMPS	07/18/95	07/19/95	1	1	3	1
				DRY HEAVES	07/19/95	07/19/95	1	1	3	1
				HALLUCINATION	07/19/95	07/19/95	1	1	2	1
				CRAMPS	07/19/95	Unknown	2	[5]	7	[5]
224	07/17/95	07/19/95	07/31/95	NAUSEA	07/17/95	07/17/95	1	1	2	1
				CRAMPS	07/19/95	07/19/95	3	1	7	2
				CRAMPS	07/20/95	07/20/95	2	1	7	2
				CRAMPS	07/21/95	07/23/95	1	1	7	1
225	07/24/95	07/26/95	08/07/95	NAUSEA	07/25/95	07/25/95	1	1	2	1
				VOMITING	07/25/95	07/25/95	1	1	2	1
226	07/24/95	07/26/95	08/07/95	ALLERGIC REACTION TO PIZZA; RASH	08/06/95	08/06/95	2	2	1	1
				SWOLLEN EYES	08/06/95	08/06/95	2	2	1	1
				RASH	08/06/95	08/06/95	2	2	1	1
227	07/24/95	07/26/95	08/07/95	CRAMPS (OCCASIONAL)	07/25/95	07/25/95	1	1	3	1
				CRAMPS (OCCASIONAL)	07/26/95	07/26/95	1	1	7	1
				NAUSEA	07/29/95	07/30/95	1	1	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
229	07/24/95	07/26/95	08/08/95	CRAMPS	07/26/95	07/26/95	3	2	7	1
				CRAMPS	07/26/95	07/26/95	2	2	7	1
				HA	07/26/95	07/26/95	2	2	6	1
				COLD SORES	08/01/95	08/01/95	2	2	1	1
230	07/24/95	07/26/95	08/07/95	VOMITING	07/24/95	07/24/95	1	1	2	1
				CRAMPS	07/24/95	07/26/95	1	1	3	1
				CRAMPS	07/26/95	07/26/95	2	1	7	2
				CRAMPS	07/26/95	07/30/95	1	1	7	1
231	07/31/95	08/02/95	08/22/95	DIZZINESS	07/31/95	07/31/95	1	1	2	1
				NAUSEA	08/01/95	08/01/95	1	1	2	1
				CRAMPS	08/01/95	08/02/95	2	1	3	3
				CRAMPING	08/02/95	08/02/95	3	1	7	1
				CRAMPING	08/03/95	08/04/95	2	2	7	4
				CRAMPING	08/05/95	08/05/95	3	2	7	2
				CRAMPING	08/06/95	08/06/95	1	2	7	1
232	08/01/95	08/03/95	08/21/95	CRAMPS	08/06/95	08/06/95	1	2	7	1
233	08/07/95	08/09/95	08/21/95	CRAMPS	08/09/95	08/09/95	2	1	7	2
				CRAMPS	08/10/95	08/13/95	1	2	7	1
				LOW, LEFT BACK PAIN	08/12/95	08/13/95	1	2	6	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
234	08/15/95	08/17/95	08/30/95	CRAMPING	08/15/95	08/15/95	1	1	3	4
				NAUSEA	08/15/95	08/15/95	2	1	3	1
				HEADACHE	08/15/95	08/15/95	1	1	3	1
				VOMITING	08/15/95	08/15/95	2	1	3	1
				CRAMPING	08/16/95	08/17/95	3	2	3	3
				DIZZINESS	08/16/95	08/16/95	2	1	3	1
				EXCESSIVE BLEEDING	08/16/95	08/16/95	3	1	3	1
				CRAMPING	08/17/95	08/19/95	3	2	7	1
				EXCESSIVE BLEEDING	08/18/95	08/18/95	3	1	7	1
				CONSTIPATION	08/18/95	08/19/95	3	1	1	1
				CRAMPS	08/21/95	08/21/95	3	2	7	1
				CRAMPS	08/22/95	08/23/95	1	1	7	1
				UTERUS TENDERNESS	08/22/95	08/25/95	2	2	6	1
				CRAMPS	08/24/95	08/24/95	3	2	7	1
				EXCESSIVE BLEEDING	08/24/95	08/24/95	3	1	7	1
				CRAMPS	08/26/95	08/26/95	1	1	7	1
				CRAMPS	08/27/95	08/27/95	2	1	7	1
235	08/15/95	08/17/95	08/29/95	NAUSEA	08/15/95	08/15/95	1	1	3	1
				VOMITING	08/15/95	08/15/95	1	1	3	1
				ACHEY	08/15/95	08/15/95	2	2	3	1
				NAUSEA	08/16/95	08/16/95	2	1	3	1
				VOMITING	08/16/95	08/16/95	2	1	3	1
				CRAMPS	08/16/95	08/16/95	1	2	3	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
235 (Cont.)				CRAMPING	08/17/95	08/17/95	3	1	7	1
				CRAMPS	08/19/95	08/19/95	2	2	7	1
				CRAMPS	08/20/95	08/20/95	3	1	7	1
				PAIN	08/20/95	08/20/95	3	1	7	1
				PAIN	08/21/95	08/21/95	3	2	7	1
				EXCESSIVE BLEEDING	08/21/95	08/23/95	3	1	7	1
				CRAMPS	08/22/95	08/23/95	2	2	7	1
236	08/15/95	08/17/95	08/29/95	NAUSEA	08/15/95	08/16/95	1	1	2	1
				CRAMPS	08/17/95	08/17/95	1	1	7	1
				CRAMPING	08/17/95	08/17/95	2	1	7	2
				CRAMPS	08/19/95	08/20/95	1	1	7	1
				HA	08/25/95	08/25/95	2	2	6	1
				HA	08/27/95	08/27/95	2	2	6	1
				CRAMPS	08/27/95	08/27/95	1	1	6	1
237	08/16/95	08/18/95	08/30/95	LOWER BACKACHE	08/16/95	08/18/95	1	1	3	3
				CRAMPS	08/17/95	08/17/95	1	1	3	1
				CRAMPS	08/18/95	08/18/95	1	1	3	4
				CRAMPS	08/18/95	08/18/95	3	2	7	2
				LOWER BACKACHE	08/18/95	08/22/95	1	1	7	1
				CRAMPING	08/18/95	08/18/95	2	1	7	4
				CRAMPS	08/19/95	08/20/95	1	1	7	4
				CRAMPS	08/21/95	08/22/95	3	2	7	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

Appendix A.1, Table 25 (Continued)
Adverse Events
[Patients with Any Adverse Event]

Center Number: 2

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
238	08/16/95	08/18/95	09/01/95	CRAMPING	08/18/95	08/18/95	2	1	7	1
				CRAMPING	08/18/95	08/18/95	2	1	3	1

[1] Severity: 1=Mild, 2=Moderate, 3=Severe
[2] Action Taken: 1=None, 2=Drug Therapy, 3=Hospitalization, 4=Other
[3] Study Drug Related: 1=Not Related, 2=Possible w/ Mifepristone, 3=Probable w/ Mifepristone, 4=Possible w/ Misoprostol, 5=Probable w/ Misoprostol, 6=Possible w/ Combination, 7=Probable w/ Combination
[4] Outcome: 1=Recovered, 2=Improved, 3=Unchanged, 4=Worse, 5=Death
[5] Value is unknown.

APPEARS THIS WAY
ON ORIGINAL

Planned Parenthood®
of Greater Iowa
P.O. Box 4557 Des Moines, Iowa 50306-4557 515/280-7000 FAX 515/280-9525

March 6, 1996

[redacted]
Institutional Review Board under the
[redacted]

Dear [redacted]

This is to advise the IRB that our study center enrolled no further patients after 8-16-95.

During the course of the study, "The Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea [redacted]", we enrolled a total of 238 patients; reported a total of 7 adverse experiences; and performed a total of 23 surgical rescues.

Sincerely,

Sue Haskell DO

Sue Haskell, D.O.
Medical Director
Principal Investigator

APPEARS THIS WAY
ON ORIGINAL

EIR 11/16=18/99
Dr. Susan C. Haskell CFN 19-34550
Des Moines, Iowa 50314
Exhibit C Page 1 of 1

INSTITUTIONAL REVIEW BOARD

Under the Auspices of

[redacted]

IRB ROSTER

The following is a list of voting members:

[redacted]	-	Chairman
[redacted]	-	Nurse
[redacted]	-	School Principal
[redacted]	-	Lawyer
[redacted]	-	Clergy
[redacted]	-	Health Charity Executive
[redacted]	-	Community Activist
[redacted]	-	Physician

EIR [redacted] 11/16=18/99
Dr. Susan C. Haskell CFN 19-34550
Des Moines. Iowa 50314
Exhibit 7 Page 1 of 1

DATE: October 1, 1999

/S/

TO: Bioresearch Monitors
Los Angeles, Seattle and St. Louis District Offices

FROM: [redacted]
Good Clinical Practice Branch I
Division of Scientific Investigations

SUBJ: FY 99 High Priority CDER User Fee NDA Pre-Approval, Study-Oriented, Clinical Investigator Data Validation Inspection. Bioresearch Monitoring, CP7348.811.

Re: Drug- Mifepristone & Misoprostol
Sponsor-Population Council
NDA #20-687-S

Please select the name(s) of the investigator(s) given below in your District, and conduct inspections on the listed studies, completing the clinical investigator compliance program.

In addition to those points in the compliance program that you traditionally address, DSI is particularly interested in focusing on the part of the compliance program that pertains to the monitoring of these studies by the sponsor or a contract research organization. Please find attached to this memo, a list of instructions and questions to be answered during your inspection that will help us gather information about the monitoring process. Return the list with your EIR.

No on-site Headquarters participation is anticipated for these inspections. If you need consultation on medical or scientific matters, contact [redacted] of this office at [redacted] If you have any questions concerning the inspection assignments, please contact [redacted]. A copy of any Form FDA 483 that you issue should be FAXed as soon as it is available to [redacted] at FAX number [redacted]

Background material is being forwarded by mail. Please return a copy of the protocol and consent form actually used in the study with your EIR. If the protocol used in the study is the same as the one we sent, just return the one we sent; it is not necessary to send us two identical protocols. These are to be considered HIGH-PRIORITY inspections. The due date for these assignments is November 30, 1999.

LOS ANGELES DISTRICT
Daniel R. Mishell, Jr., M.D.
LAC/Univ Southern California
Medical Center
1240 North Mission Road
Room ——
Los Angeles, CA 90033
Protocol 166A

SEATTLE DISTRICT OFFICE
Suzanne T. Poppema, M.D.
Aurora Medical Service, Inc.
1207 N. 200 Street, Ste 214
Seattle, WA 98133
Protocol 166A

ST. LOUIS DISTRICT OFFICE
Susan Haskell, M.D.
Planned Parenthood of Greater Iowa
851 19th Street
Des Moines, IA 50314
Protocol 166A

cc:
HFA-224
HFD-46/47/C.R.

APPEARS THIS WAY
ON ORIGINAL

MONITORING INFORMATION

1. Please obtain from the study site, a copy of the log of on-site monitoring visits and phone contacts.

2. Determine if the monitor(s) compared CRFs to original records at the study site to verify the accuracy of the CRFs. If CRFs were compared with original records, determine approximately how many were verified (all, most, some, few).

CRFs were compared Y N How many?_____

3. Ask the investigator if the study protocol and record keeping requirements were adequately explained to him/her by the monitor. If not, briefly describe what the investigator feels was not adequately explained.

_____

_____

_____

_____

4. Please obtain copies of any written reports or correspondence left at the site by the monitor, regarding this study.

APPEARS THIS WAY
ON ORIGINAL

STUDY PERSONNEL SIGNATURE REGISTRY

PROTOCOL NO.: _____

INVESTIGATOR: _____

ADDRESS: _____

_____

_____

INVESTIGATOR/CO-INVESTIGATORS

Name (Print)	Signature	Init.	Date	Position/Title
SUE HASKELL D.O.	Sue Haskell DO	SH	4-6-95	DO / PI

EIR 11/16=18/99
Dr. Susan C. Haskell CFN 19-34550
Des Moines, Iowa 50314
Exhibit 1 Page 1 of 3

STUDY NURSES/COORDINATOR

Name (Print)	Signature	Init.	Date	Position/Title

STUDY PERSONNEL SIGNATURE REGISTRY

PROTOCOL NO.: _____

INVESTIGATOR: _____

ADDRESS: _____

_____

_____

INVESTIGATOR/CO-INVESTIGATORS

Name (Print)	Signature	Init.	Date	Position/Title

EIR 11/16=18/99
Dr. Susan C. Haskell CFN 19-34550
Des Moines. Iowa 50314
Exhibit 1 Page 2 of 3

STUDY NURSES/COORDINATOR

Name (Print)	Signature	Init.	Date	Position/Title

STUDY PERSONNEL SIGNATURE REGISTRY

PROTOCOL NO.: _____

INVESTIGATOR: _____

ADDRESS: _____

_____

_____

INVESTIGATOR/CO-INVESTIGATORS

Name (Print)	Signature	Init.	Date	Position/Title

EIR 11/16=18/99
- Dr. Susan C. Haskell CFN 19-34550
Des Moines. Iowa 50314
- Exhibit 1 Page 3 of 3

STUDY NURSES/COORDINATOR

Name (Print)	Signature	Init.	Date	Position/Title

File No: 09917 Name: Susan Haskell

GCP1

DATE	TO:	ACTION REQUESTED
12-6 99		
12/6		
1-13-		
1/14		
1/14		SIGNED → DISTRIBUTE
		APPEARS THIS WAY ON ORIGINAL

50 70 237 subject

SITE VISIT RECORD

Protocol No. 166 A

Investigator DR. SUSAN Haskell Location PP of Greater Iowa

Visit Date(s)	Signature — Personnel	Purpose of Visit	Signature Investigator or Staff
8/23/94		PI SC	Sue Haskell DO
11/01/94		Initial Visit	Sue Haskell DO
11/29/94		1st Visit to Monitor	—
1/23/95		2nd Visit to Monitor	—
3-7-95 3/9/95		monitoring visit	—
4/4/95 - 4/6/95		monitoring visit	—
5/9-11/95		monitoring visit	—
6-21-6/23/95		monitoring visit	—
8-17 - 8-18/95		monitoring visit	—
9/21, 22, 23/95		Monitoring Visit	—
10/16, 17, 18/95		Monitoring Visit	—
11/15/95		Monitoring Visit	—

EIR
Dr. Susan C. Haskell CFN 19-34550
Des Moines, Iowa 50314
Exhibit 5 Page 1 of 1

11/16-18/99

STUDY PERSONNEL SIGNATURE REGISTRY

PROTOCOL NO.: 1166A

INVESTIGATOR: Poppema

ADDRESS: 1207 N. 200th, #214
Seattle, WA 98133

[redacted]

INVESTIGATOR/CO-INVESTIGATORS

Name (Print)	Signature	Init.	Date	Position/Title
Suzanne Poppema		STP	3-16-95	Medical Director

STUDY NURSES/COORDINATOR

Name (Print)	Signature	Init.	Date	Position/Title

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 2 Page 1 of 2

STUDY PERSONNEL SIGNATURE REGISTRY

PROTOCOL NO.: 1666A

INVESTIGATOR: Poppema

ADDRESS: 1207 N. 200th, #214
Seattle, WA 98133

Health Care Workers Cont.

~~INVESTIGATOR/CO-INVESTIGATORS~~

Name (Print)	Signature	Init.	Date	Position/Title

STUDY NURSES/COORDINATOR

Name (Print)	Signature	Init.	Date	Position/Title

SITE VISIT RECORD

Protocol No. 164A

Investigator 003 - Poppema Location Seattle, Washington

Visit Date(s)	Signature Personnel	Purpose of Visit	Signature Investigator or Staff
8/16/94		PSV	
11/8/94		initiation	
11/30/94		monitoring	
1/5/95		monitoring	
2/6-9/95		monitoring	
3/14-3/16 95		monitoring	
21 March 95		Site Visit	
4/26-27/95		monitoring	
5/23-25/95		monitoring	
7/12-13/95		monitoring	
9/25/95		Monitoring visit	
9/26/95		monitoring visit	
9/27/95		monitoring visit	
9/28/95		Monitoring Visit	
~~FPO~~ 11/15/95		Monitoring visit	
3/18-20/96		Audit	

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 9 Page 1 of 1

STUDY PROGRESS REPORT TO

The Institutional Review Board

[ ]

Name of Principal Investigator: Suzanne Poppema, M.D.

Name/Title of Study: Population Council - Mifepristone

Date Approval Granted from IRB: October 12, 1994

TOTAL Number of Patients Entered: 164

Any Deviations from the Approved Protocol? ____ Yes ✓ No

If YES, describe: ____

Any Serious or Unexpected Adverse Experiences Associated with the Use of the Drug Reported to Date? ____ Yes ____ No

If YES, describe giving 1) Adverse Reaction and its Frequency or Incidence, 2) Action Taken, 3) Outcome:

Adverse Experience	Frequency or Incidence	Action	Outcome
failure	4	suction	improved
retained tissue/ excessive bleeding	18	suction	improved
vomiting - hyperemesis	1	suction	improved

If Study Completed, Date Study Completed: August 9, 1995

Comments: ____

Signature of Investigator: Suzanne Poppema MD Date: 3-14-96

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 1 of 9

Aurora Medical Services Inc, PS

1207 North
200th Street
Suite 214

Seattle
Washington
3133

(206) 546-8891
FAX 546-9641

February 27, 1996

_____ Chairman
Institutional Review Board under the
_____

_____

Dear _____

This is to advise the IRB that our study center enrolled no further patients after August 9, 1995.

During the course of the study we enrolled a total of 164 patients; reported a total of 3 adverse experiences; and performed a total of 20 surgical rescues.

Sincerely,

Suzanne T. Poppema, M.D.

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 2 of 9

INSTITUTIONAL REVIEW BOARD

May 25, 1995

Suzanne Poppema M.D.
Aurora Medical Services, Inc. P.S.
1207 North 200th Street, Suite 214
Seattle, WA 98133

Dear Dr. Poppema:

On May 24, 1995 this IRB met regarding the Population Council clinical trial entitled: "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of Up to 63 Days", protocol #166A/B. This IRB meeting all Federal Regulations for membership requirements and consisting of 8 individuals (of which 6 were in attendance), of different backgrounds and professions met and approved (by majority) the revised protocol dated May 5, 1995 which includes Amendment #1, Amendment #2, Amendment #3, and the revised informed consent.

The IRB members included the following professions:

Physicians, Clergy, School Principal, Nurse, a Community Activist and a Lawyer

Enclosed please find a copy of the protocol with Amendments #1, #2, and #3, along with the informed consent form. Both bear the stamped approval of this IRB. If needed, please have any informed consent forms translated and submitted to this IRB for a formal approval, as soon as possible.

Please note that all regulatory requirements previously stipulated remain in effect.

Your continuing cooperation with this IRB is greatly appreciated.

/s/

Enclosure

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 3 of 9

STUDY PROGRESS REPORT TO

The Institutional Review Board

[ ]

Name of Principal Investigator: Suzanne Poppema, M.D.

Name/Title of Study: Population Council - Mifepristone (RU 486)

Date Approval Granted from IRB: October 12, 1994

TOTAL Number of Patients Entered: 103

Any Deviations from the Approved Protocol? ____ Yes ✓ No

If YES, describe: _____

Any Serious or Unexpected Adverse Experiences Associated with the Use of the Drug Reported to Date? ____ Yes ____ No

If YES, describe giving 1) Adverse Reaction and its Frequency or Incidence, 2) Action Taken, 3) Outcome:

Adverse Experience	Frequency or Incidence	Action	Outcome
vomiting-hyperemesis	1	suction	improved
failure	4	suction	improved
excessive bleeding/Tissue	9	suction	improved

If Study Completed, Date Study Completed: _____

Comments: _____

Signature of Investigator: Suzanne Poppema Date: 3-28-95

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 4 of 9

INSTITUTIONAL REVIEW BOARD

October 27, 1994

Suzanne Poppema, M.D.
Aurora Medical Services, Inc. PS
1207 North 200th Street, Suite 214
Seattle, WA 98133

Dear Dr. Poppema:

On Thursday, October 27, 1994, under the provisions of Expedited Approval, I reviewed and approved the changes to the Population Council protocol entitled: "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misprostol in Inducing Abortion in Pregnant Women with Amenorrhea of Up to 63 Days", protocol #166A. The changes from the previously approved protocol were of an administrative nature that do not pose any additional risk to the patient or increase the risk to benefit ratio.

Also, I am enclosing a copy of the Informed Consent Form approved for use at your site that bears the stamped approval of the Institutional Review Board under the auspices of _____ _____ Please be sure to utilize this informed consent in obtaining patient enrollment at your site.

Please note that all regulatory requirements previously stipulated remain in effect.

Your continuing cooperation with this IRB is greatly appreciated.

/s/

_____

Enclosure

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 5 of 9

Date: 10/27/94

To: [redacted]

CC: IRB members and [redacted]

From: [redacted]

Subject: Mifepristone Protocol

The following is a list specifying which investigators in the Population Council Mifepristone clinical trial are using either Protocol #166A or Protocol #166B.

[redacted]	Protocol #166B
Dr. Susan Haskell	Protocol #166A
Dr. Tyrone Malloy	Protocol #166A
Dr. Suzanne Poppema	Protocol #166A
[redacted]	Protocol #166A
[redacted]	Protocol #166A
Dr. Katherine Sheehan	Protocol #166B
Dr. Lazlo Sogor	Protocol #166B
Dr. Judy Tyson	Protocol #166A
Dr. Peter Vargas	Protocol #166B

[redacted]

APPROVED BY
IRB

OCT 27 1994

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 6 of 9

INSTITUTIONAL REVIEW BOARD

[ ]

October 12, 1994

Suzanne Poppema, M.D.
Aurora Medical Services, Inc. PS
1207 North 200th Street, Suite 214
Seattle, WA 98133

Dear Dr. Poppema:

Thank you for your request to this IRB of September 15, 1994 for review and approval to conduct a study under the Population Council protocol entitled, "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of Up to 63 Days", protocol #166A and #166B. The IRB is aware that both protocols are identical and that desgination of investigators to either protocol will be considered an administrative procedure not affecting the conduct of the study.

This will inform you that on October 12, 1994, this IRB, meeting all Federal Regulations for membership requirements and consisting of 7 individuals of different backgrounds and professions met and approved (by majority) your site to conduct the above mentioned study.

The IRB members included the following professions:

> Physicians, Clergy, School Principal, Nurse, a Community Activist and a Health Charity Executive

The Protocol (revised and dated October 12, 1994), the attached Informed Consent Form be utilized at your site, your C.V., pre-investigational site visit and other regulatory documents were reviewed and approved by majority voting.

Please be informed that all documentation required for IRB review to conduct your proposed study has been approved. A copy of the approved consent form is attached.

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 7 of 9

It is also a regulatory requirement that you promptly inform this IRB of any proposed changes in the approved research during the period for which IRB approval has been given. Furthermore, no such proposed changes may be initiated without IRB review except where necessary to eliminate apparent immediate hazards to the study patients or subjects.

Investigators conducting studies under the surveillance of this IRB are required to report all adverse reactions of either an unusual nature, unusual frequency or unusual severity to the Chairman without delay and in no event later than ten (10) working days after the event.

A further regulatory requirement is that the IRB receives periodic reports on the progress of your study. For the purposes of this IRB such reports must be submitted to the chairman of the IRB at the above address at regular intervals of not more than six (6) months. The initial six month follow-up report is due April 12, 1995. This regulation must be adhered to and is the investigator's responsibility. If the reports are not received within a reasonable length of time from the date required, IRB approval may be withdrawn. Also, the IRB is to be informed of the date of completion (or premature termination giving the reasons for termination) of your study and supplied with a final report at that time. Should your study be completed in less than six months, then a final study report is all that is required.

Your cooperation with the IRB with regard to these regulations will be much appreciated.

Sincerely,

151

Enclosure

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 8 of 9

INSTITUTIONAL REVIEW BOARD

[ ]

IRB ROSTER

The following is a list of voting members:

_____	-	Chairman
_____	-	Nurse
_____	-	School Principal
_____	-	Lawyer
_____	-	Clergy
_____	-	Health Charity Executive
_____	-	Community Activist
_____	-	Physician

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 15 Page 9 of 9

APPROVED BY

IRB

OCT 27 1994

October 13, 1994

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

1. Purpose and aims of the study

It is possible to induce abortion in women with unwanted pregnancies by taking mifepristone in combination with a prostaglandin (misoprostol). Mifepristone is a drug which blocks the action of progesterone, a hormone needed to maintain pregnancy. One of mifepristone's actions is to interrupt pregnancy in its early stages. Prostaglandins are natural substances made by the lining of the womb during menstruation and cause contraction of the womb. During the early stages of pregnancy, mifepristone plus misoprostol cause abortion in approximately 95 per cent of women. Major advantages of this method of pregnancy termination are that no surgical instruments are pushed into the womb. Approximately 250,000 women in 20 countries have used mifepristone and a prostaglandin as a medical method of pregnancy interruption. Mifepristone and misoprostol have been used by over 50,000 women at the dose to be used in this study. The dosage to be studied has been approved for routine use in France for women who have been pregnant for seven weeks or less. Mifepristone in combination with a prostaglandin has also been approved for use in China, Britain and Sweden. In the latter two countries, it is used in women who are pregnant for nine weeks or less.

The aims of the present study are to determine the safety, efficacy and acceptability of mifepristone plus misoprostol for pregnancy termination in women who are 63 days or less from the first day of the last menstrual period. Three groups of women who are less than 50 days; 50 through 56 days and 57 through 63 days from the first day of the last menstrual period will be included in the study. This study is being performed as a requirement for registration of mifepristone plus misoprostol with the U.S. Food and Drug Administration (FDA) so that these products can be used for pregnancy termination in the U.S.

2. Clinic visits

I understand that at my initial visit (visit 1) I will receive counseling about the method, and a urine and blood sample will be collected to make sure I am pregnant. I will be given a physical, and a pelvic exam and my medical history will be taken. Using a vaginal ultrasound, which is a small probe that is placed in the vagina, the duration of my pregnancy will be determined. Also I will be given a blood test for the Rh factor in my blood. If I have an Rh negative blood type, I will be given an injection at the second visit to prevent the development of antibodies that could endanger any future pregnancy. In order to terminate my pregnancy, I will take three tablets of mifepristone (first medication) orally in the presence of study personnel.

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 16 Page 1 of 6

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

Two days later, I will return to the clinic (visit 2) even if I believe I have aborted and will take two misoprostol tablets (second medication) by mouth if I have not aborted. If I take the second medication, the duration of my stay at the clinic at the second visit will be approximately four hours, during which time I will be closely monitored by the study team. During this time, there is an 60-80% chance that abortion will occur. If I come to the clinic in a car, I will be sure to arrange for someone else to drive me home from this visit, and understand that I will not drive myself home. I understand that if the abortion does not occur at the clinic, it is likely to occur at home and I may continue to have uterine bleeding similar to a heavy menstrual period for several days. I should use sanitary napkins until the uterine bleeding or spotting ends and not use tampons. As with surgical abortion, I cannot resume douching until the bleeding stops (about 10-12 days). I should not resume sexual intercourse for eight to ten days after taking the prostaglandin, by which time most abortions would have been completed.

I understand that I may see the product of conception on my sanitary napkin or in the toilet. This may happen at the clinic, at home or work. Through the seventh week after conception, this product is called an embryo; it is smaller than a quarter and is usually embedded in a blood clot. Even if I see the products of conception, I will not be able to tell whether the method has been effective as part of the placenta may still remain in the uterus. This is why it is important to return to the clinic for a follow-up, visit 3, so that the clinic staff can determine if the abortion is complete.

A further appointment will be made for me to return to the clinic two weeks after taking the first tablet (visit 3), to ensure that the treatment has been effective. If the treatment has not been effective, then a surgical procedure called vacuum aspiration or dilatation and curettage will be carried out at that time to complete the abortion. This is the same surgical procedure that would have been used had I elected to undergo surgical abortion in the first instance. I will be sure to have arranged for someone else to drive me home from this visit, and understand that I will not drive myself home. If I notice a vaginal discharge with odor after treatment, this may indicate an infection. I will contact my physician for an appointment.

I understand that bleeding may continue beyond my third visit. If this occurs the clinic will contact me by telephone to determine if it has stopped or if I need additional treatment.

October 13, 1994

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

I understand that there are no indications at present that use of an antiprogestin to end a pregnancy has prevented or harmed a woman's ability to have a baby in the future. Women who have taken mifepristone have been able to conceive and subsequently bear a healthy child. Since it is possible to become pregnant again after the abortion, I will be asked to select and use a contraceptive method.

3. Benefits

I understand that an advantage of the mifepristone/misoprostol medical method for pregnancy termination is that it avoids a surgical procedure. There is no anesthesia-related risks or risk of uterine perforation or cervical canal injury which may rarely be observed after surgical termination of pregnancy. Another benefit is the satisfaction of participating in the study that may make mifepristone/misoprostol available to women in the U.S.

4. Risks and discomforts

I understand that drawing blood for the tests at the first visit may be associated with discomfort, bruising, and possibly infection at the site of withdrawal. I understand that experience gained so far with the combination of drugs and the termination of early pregnancy indicates that this therapy has few side effects. The frequency of short-term complications are comparable to that observed after surgical abortion performed by vacuum aspiration. The most common complaint during treatment (particularly following administration of the second medication) is lower abdominal pain or cramps which are similar to those associated with a very heavy menstrual period. I will receive appropriate medication for pain when required. I understand that I should not take aspirin, Motrin®, ibuprofen (Advil®) or any other drug known to block the action of prostaglandins. However, I may take Tylenol® and I may receive stronger medications for pain from my doctor. I understand that cramps and abdominal pains are usual and an expected part of the abortive process. Nausea, vomiting, and diarrhea have been observed following administration of the second medication. Therefore, at the second visit it is necessary to remain at the clinic under appropriate medical supervision for approximately four hours before returning home. Uterine bleeding, similar to a heavy period and lasting at least one week, may be expected. In rare instances very heavy uterine bleeding may occur requiring surgical abortion and/or blood transfusion.

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 16 Page 3 of 6

APPROVED BY
IRB
OCT 27 1994

October 13, 1994

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

I understand that it is not advisable to allow a pregnancy to continue after taking mifepristone and/or misoprostol, since the full effects of mifepristone on the fetus are not known and misoprostol administration in early pregnancy has been associated with abnormal development of the fetus. I understand that abortion after mifepristone/misoprostol is successful in termination of pregnancy in approximately 95% of treated women. When abortion is incomplete, vacuum aspiration or dilatation and curettage are recommended to terminate bleeding and prevent anemia. *When abortion does not occur, surgical termination of pregnancy is recommended because of the possible risk to the fetus. I have previously agreed to this procedure.*

There have been no serious heart conditions in the 52,000 women using the combination of drugs in the study for pregnancy termination. However, serious cardiovascular complications, including one fatal heart attack occurred during medical abortion using a different drug combination. These heart conditions have occurred usually in women who are heavy smokers or have increased blood fats, diabetes, high blood pressure, or family history of heart disease. This risk also increased in women who are over 35 years of age. These complications have been seen only following an injected prostaglandin and are rare (one in 20,000 cases). To date there is no evidence that the oral prostaglandin (misoprostol) that I will be taking in this study and which has been used widely for prolonged periods of time in the prevention of stomach ulcers, is associated with such cardiovascular side effects.

5. Alternative Statement

I know that my pregnancy could be terminated by a surgically performed abortion procedure (dilatation and curettage or vacuum aspiration). The possible advantages and disadvantages of a surgical rather than a medical termination have been explained to me. The advantages of surgical termination of pregnancy is that this is a one day procedure. The risks associated with surgical abortion are minimal. These include the risk of an anesthetic procedure. In the U.S., less than 1% of patients who undergo a surgical abortion experience a major complication associated with the procedure such as a serious pelvic infection, cervical tear, bleeding requiring a blood transfusion or unintended major surgery (for a uterine perforation).

APPROVED BY

IRB

OCT 27 1994

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 16 Page 4 of 6

October 13, 1994

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

6. Physical Injury Statement

If I require medical treatment as a result of physical injury arising from my participation in this study, immediate, essential, short-term medical care and treatment as determined by the doctors in this study will be made available without charge to me. There will be no monetary compensation for any other care, but medical consultation and appropriate referral services are available. Further information on the availability of medical care and treatment for any physical injury resulting from my participation in this study may be obtained from the Investigator, Dr. Poppema (telephone: (206) 546-8891).

7. Whom to Call in an Emergency

I understand that if severe uterine bleeding, or abdominal pain, or any other medical emergency arises in association with this method, I will report immediately to Aurora Medical Services, 1207 N. 200th Street, Suite 214, Seattle, WA. In addition, I will contact Dr. Poppema, _____ (telephone:(206) 546-8891). If he or she cannot be reached in a medical emergency related to the study, I may contact the physician on call at (206) 726-2101.

8. Offer to Answer Questions and Freedom to Withdraw from the Study

I have been told that I may withdraw from the study at any time without jeopardy to my present or future medical care from the hospital or clinic. If I withdraw I will be offered a surgical abortion. I have been told to contact Dr. Poppema, _____ (telephone: (206) 726-2101) if I have any questions about the research. These physicians may appoint their associates to answer my questions.

I also understand that the Principal Investigator may require me to withdraw from the study, if in his/her medical judgement it is in the best interest of my health or if it becomes impossible for me to follow the experimental procedure of this study.

I understand that, if my treatment under the study does not result in an abortion, and if I refuse surgical abortion and continue with my pregnancy, I risk and the infant may risk, complications, including fetal or infant malformation.

APPROVED BY

IRB

OCT 27 1994

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 16 Page 5 of 6

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

9. Confidentiality

I understand that information obtained in this study will be transmitted only in a form that cannot be identified with me, and that all records will be kept in a locked cabinet. I understand that the Population Council or their designated monitors, as well as the U.S. Food and Drug Administration may request access to my medical records.

10. Subject's Statement

I, the undersigned, have had the risks and benefits of this study explained to me in a language that I understand. I agree to participate in this study as a volunteer subject.

Date _____ Signature of Volunteer _____

11. Investigator's Statement

I, the undersigned, have explained to the volunteer in the language which she speaks the procedures to be followed in this study and the risks and benefits involved.

Date _____ Signature of Investigator _____

Date _____ Signature of Witness to the Above Signatures and Explanation _____

APPROVED BY
IRB

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 16 Page 6 of 6

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

1. Purpose and aims of the study

It is possible to induce abortion in women with unwanted pregnancies by taking mifepristone in combination with a prostaglandin (misoprostol). Mifepristone is a drug which blocks the action of progesterone, a hormone needed to maintain pregnancy. One of mifepristone's actions is to interrupt pregnancy in its early stages. Prostaglandins are natural substances made by the lining of the womb during menstruation and cause contraction of the womb. **Recently obtained information supports the statement that mifepristone plus misoprostol cause abortion in approximately 95 percent of women whose first day of their last menstrual period occurred no more than 49 days before administration of mifepristone. In women whose first day of their last menstrual period occurred from 50 to 63 days before they received mifepristone, this new information suggests that as many as one in four may require some form of surgical procedure. There are a number of reasons for such a surgical procedure including continued pregnancy, incomplete abortion, or excess bleeding. The possibility of experiencing excess bleeding increases with increasing duration of amenorrhea**** [1] Major advantages of this method of pregnancy termination are that no surgical instruments are pushed into the womb. Over 150,000 women in 20 countries have used mifepristone and a prostaglandin as a medical method of pregnancy interruption. Mifepristone and misoprostol have been used by over 50,000 women at the dose to be used in this study. The dosage to be studied has been approved for routine use in France for women who have been pregnant for seven weeks or less. Mifepristone in combination with a prostaglandin has also been approved for use in China, Britain and Sweden. In the latter two countries, it is used in women who are pregnant for nine weeks or less.

[redacted]

APPROVED BY
IRB
MAY 24 1995

[1]Amendment 3 dated May 2, 1995

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 17 Page 1 of 8

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

The aims of the present study are to determine the safety, efficacy and acceptability of mifepristone plus misoprostol for pregnancy termination in women who are 63 days or less from the first day of the last menstrual period. Three groups of women who are less than 50 days; 50 through 56 days and 57 through 63 days from the first day of the last menstrual period will be included in the study. This study is being performed as a requirement for registration of mifepristone plus misoprostol with the U.S. Food and Drug Administration (FDA) so that these products can be used for pregnancy termination in the U.S.

2. Clinic visits

I understand that at my initial visit (visit 1) I will receive counseling about the method, and a urine and blood sample will be collected to make sure I am pregnant. I will be given a physical, and a pelvic exam and my medical history will be taken. Using a vaginal ultrasound, which is a small probe that is placed in the vagina, the duration of my pregnancy will be determined. Also I will be given a blood test for the Rh factor in my blood. If I have an Rh negative blood type, I will be given an injection at the second visit to prevent the development of antibodies that could endanger any future pregnancy. **I understand that I may be asked for additional blood samples (about 2 teaspoons) to be collected to measure the levels of different substances normally in my blood, as well as determine the normal characteristics of my blood. If I decide not to have additional blood samples taken, I may still continue to participate in the study*** [2]. In order to terminate my pregnancy, I will take three tablets of mifepristone (first medication) orally in the presence of study personnel. Two days later, I will return to the clinic (visit 2) even if I believe I have aborted and will take two misoprostol tablets (second medication) by mouth if I have not aborted. If I take the second medication, the duration of my stay at the clinic at the second visit will be approximately four hours, during which time I will be closely monitored by the study team. During this time, there is an 60-80% chance that abortion will occur. If I come to the clinic in a car, I will be sure to arrange for someone else to drive me home from this visit, and understand that I will not drive myself home.

[2]Amendment 2 dated April 27, 1995

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 17 Page 2 of 8

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

I understand that if the abortion does not occur at the clinic, it is likely to occur at home and I may continue to have uterine bleeding for several days. **I understand that the amount of bleeding may be similar to that which occurs during a spontaneous miscarriage (i.e. more than a heavy menstrual period). The risk of heavy bleeding increases after 49 days since the first day of my last menstrual period**[3].** I should use sanitary napkins until the uterine bleeding or spotting ends and not use tampons. As with surgical abortion, I cannot resume douching until the bleeding stops (about 10-12 days). I should not resume sexual intercourse for eight to ten days after taking the prostaglandin, by which time most abortions would have been completed.

I understand that I may see the product of conception on my sanitary napkin or in the toilet. This may happen at the clinic, at home or work. Through the seventh week after conception, this product is called an embryo; it is smaller than a quarter and is usually embedded in a blood clot. Even if I see the products of conception, I will not be able to tell whether the method has been effective as part of the placenta may still remain in the uterus. This is why it is important to return to the clinic for a follow-up, visit 3, so that the clinic staff can determine if the abortion is complete.

A further appointment will be made for me to return to the clinic two weeks after taking the first tablet (visit 3), to ensure that the treatment has been effective. **I understand that I may again be asked for additional blood samples (about 2 teaspoons) to be collected to measure the levels of different substances normally in my blood, and to determine the characteristics of my blood. If I decide not to have additional blood samples taken, I may still continue to participate in the study.*** [4] If the treatment has not been effective, then a surgical procedure called vacuum aspiration or dilatation and curettage will be carried out at that time to complete the abortion. This is the same

[3] Amendment 3 dated May 2, 1995

[4] Amendment 2 dated April 27, 1995

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOGOL NUMBER: 166 A

surgical procedure that would have been used had I elected to undergo surgical abortion in the first instance. I will be sure to have arranged for someone else to drive me home from this visit, and understand that I will not drive myself home. If I notice a vaginal discharge with odor after treatment, this may indicate an infection. I will contact my physician for an appointment.

I understand that bleeding may continue beyond my third visit. If this occurs the clinic will contact me by telephone to determine if it has stopped or if I need additional treatment.

I understand that there are no indications at present that use of an antiprogestin to end a pregnancy has prevented or harmed a woman's ability to have a baby in the future. Women who have taken mifepristone have been able to conceive and subsequently bear a healthy child. Since it is possible to become pregnant again after the abortion, I will be asked to select and use a contraceptive method.

3. Benefits

I understand that an advantage of the mifepristone/misoprostol medical method for pregnancy termination is that it avoids a surgical procedure. There is no anesthesia-related risks or risk of uterine perforation or cervical canal injury which may rarely be observed after surgical termination of pregnancy. Another benefit is the satisfaction of participating in the study that will make mifepristone/misoprostol available to women in the U.S.

4. Risks and discomforts

I understand that drawing blood for the tests at the first **and third visits** may be associated with discomfort, bruising, and possibly infection at the site of withdrawal. I understand that experience gained so far with the combination of drugs and the termination of early pregnancy indicates that this therapy has few side effects. The frequency of short-term complications are comparable to that observed after surgical abortion performed by vacuum aspiration. The most common complaint during treatment (particularly following administration of the second medication) is lower abdominal pain or

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

cramps which are similar to those associated with a very heavy menstrual period. I will receive appropriate medication for pain when required.

I understand that I should not take aspirin, Motrin®, ibuprofen (Advil®) or any other drug known to block the action of prostaglandins. However, I may take Tylenol® and I may receive stronger medications for pain from my doctor. I understand that cramps and abdominal pains are usual and an expected part of the abortive process. Nausea, vomiting, and diarrhea have been observed following administration of the second medication. Therefore, at the second visit it is necessary to remain at the clinic under appropriate medical supervision for approximately four hours before returning home. I **understand that uterine bleeding, similar to that which occurs during a spontaneous miscarriage (i.e. more than a** heavy menstrual period) and lasting at least one week, may be expected. **The risk of heavy bleeding increases after 49 days since the first day of my last menstrual period**[5]** In rare instances very heavy uterine bleeding may occur requiring surgical abortion and/or blood transfusion.

I understand that it is not advisable to allow a pregnancy to continue after taking mifepristone and/or misoprostol, since the full effects of mifepristone on the fetus are not known and misoprostol administration in early pregnancy has been associated with abnormal development of the fetus. I understand that based on prior studies and recently obtained information, abortion after mifepristone/misoprostol is successful in termination of pregnancy in approximately 95% of treated women whose first day of their last menstrual period occurred no more than 49 days before administration of mifepristone. In women whose first day of their last menstrual period occurred from 50 to 63 days before they received mifepristone, this new information suggests that as many as one in four may require some form of surgical procedure.**

[5]Amendment 3 dated May 2, 1995

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

When abortion is incomplete, vacuum aspiration or dilatation and curettage are recommended to terminate bleeding and prevent anemia. *When abortion does not occur, surgical termination of pregnancy is recommended because of the possible risk to the fetus. I have previously agreed to this procedure.*

There have been no serious heart conditions in the 52,000 women using the combination of drugs in the study for pregnancy termination. However, serious cardiovascular complications, including one fatal heart attack occurred during medical abortion using a different drug combination. These heart conditions have occurred usually in women who are heavy smokers or have increased blood fats, diabetes, high blood pressure, or family history of heart disease. This risk also increased in women who are over 35 years of age. These complications have been seen only following an injected prostaglandin and are rare (one in 20,000 cases). To date there is no evidence that the oral prostaglandin (misoprostol) that I will be taking in this study and which has been used widely for prolonged periods of time in the prevention of stomach ulcers, is associated with such cardiovascular side effects.

5. Alternative Statement

I know that my pregnancy could be terminated by a surgically performed abortion procedure (dilatation and curettage or vacuum aspiration). The possible advantages and disadvantages of a surgical rather than a medical termination have been explained to me.

The advantages of surgical termination of pregnancy is that this is a one day procedure.

The risks associated with surgical abortion are minimal. These include the risk of an anesthetic procedure. In the U.S., less than 1% of patients who undergo a surgical abortion experience a major complication associated with the procedure such as a serious pelvic infection, cervical tear, bleeding requiring a blood transfusion or unintended major surgery (for a uterine perforation).

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

6. Physical Injury Statement

If I require medical treatment as a result of physical injury arising from my participation in this study, immediate, essential, short-term medical care and treatment as determined by the doctors in this study will be made available without charge to me. There will be no monetary compensation for any other care, but medical consultation and appropriate referral services are available. Further information on the availability of medical care and treatment for any physical injury resulting from my participation in this study may be obtained from the Investigator, Dr. Suzanne Poppema at 206-546-8891.

7. Whom to Call in an Emergency

I understand that if severe uterine bleeding, or abdominal pain, or any other medical emergency arises in association with this method, I will report immediately to Aurora Medical Services, Inc., P.S., 1207 North 200th Street, Suite 214, Seattle, WA 98133. In addition, I will contact Dr. Poppema, ———————— at 206-546-8891. If he or she cannot be reached in a medical emergency related to the study, I may contact the physician on call at 206-726-2101.

8. Offer to Answer Questions and Freedom to Withdraw from the Study

I have been told that I may withdraw from the study at any time without jeopardy to my present or future medical care from the hospital or clinic. If I withdraw I will be offered a surgical abortion. I have been told to contact Dr. Poppema, ———————— ———— at 206-726-2101 if I have any questions about the research. These physicians may appoint their associates to answer my questions.

I also understand that the Principal Investigator may require me to withdraw from the study, if in his/her medical judgement it is in the best interest of my health or if it becomes impossible for me to follow the experimental procedure of this study.

I understand that, if my tre+atment under the study does not result in an abortion, and I refuse surgical abortion and continue with my pregnancy, I risk, and the infant may risk, complications, including fetal or infant malformation.

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 17 Page 7 of 8

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166 A

9. Confidentiality

I understand that information obtained in this study will be transmitted only in a form hat cannot be identified with me, and that all records will be kept in a locked cabinet. understand that the Population Council or their designated monitors, as well as the U.S. Food and Drug Administration may request access to my medical records.

I understand that I may be asked to be interviewed by a representative of the ponsor. The interview will be conducted in the language that I speak and will verify hat I understand the risks, benefits, procedures, and the experimental nature of the tudy. If I do not agree to be interviewed, this will not affect my present or future edical care from the hospital or the clinic, or my participation in the study. I nderstand that I can change my mind at any time. All information will be kept onfidential.

10. Subject's Statement

I, the undersigned, have had the risks and benefits of this study explained to me in a language that I understand. I agree to participate in this study as a volunteer subject.

_____ _____

Date Signature of Volunteer

11. Investigator's Statement

I, the undersigned, have explained to the volunteer in the language which she speaks the procedures to be followed in this study and the risks and benefits involved.

_____ _____

Date Signature of Investigator

_____ _____

Date Signature of Witness to the Above Signatures and Explanation

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 17 Page 8 of 8

February 26, 1996

Dr. Suzanne T. Poppema
Aurora Medical Services, Inc.
1207 N. 200th, Suite 214
Seattle, WA 98133

Re: "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of up to 63 Days" (#166A)

Dear Dr. Poppema:

In order to verify the total accountability of the study supplies for the above referenced study, final drug accountability was conducted. As is outlined below, the total amount of study drug which was sent to your site, the total amount utilized during the course of the study by the site, and the total returned to the point of distribution [redacted] are summarized.

TOTAL TABLETS SUPPLIED TO SITE	714 TABLETS MIFEPRISTONE 200 MG
TOTAL TABLETS DISPENSED	495 TABLETS
TOTAL TABLETS RETURNED TO OXFORD	219 TABLETS
TABLETS NOT ACCOUNTED FOR	0

One patient received 6 tablets.

Please retain a copy of this letter in your regulatory files.

Sincerely.

/S/

Director
Clinical Research Department

AMS:kan

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 30 Page 1 of 1

FAX: (201) 777-1279
FAX: (201) 777-9847

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 12 1999

Suzanne T. Poppema, M.D.
Aurora Medical Services
1207 N. Street, Suite 214
Seattle, Washington 98133

Dear Dr. Poppema:

Between November 1 and November 5, 1999, [redacted] representing the Food and Drug Administration (FDA), inspected your conduct of a clinical study (Protocol #166A) of the investigational drugs mifepristone and misoprostol. You conducted this study for The Population Council, Inc. This inspection is part of FDA's Bioresearch Monitoring Program, which includes inspections designed to validate clinical studies on which drug approval may be based and to assure that the rights and welfare of the human subjects of these studies have been protected.

From our evaluation of the inspection report and the documents submitted with that report, we conclude that you adhered to the Federal regulations and/or good clinical practices that govern the conduct of clinical studies and the protection of human subjects.

We appreciate the cooperation shown [redacted] during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below.

Sincerely yours,

/S/

[redacted]

Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research,
7520 Standish Place, Suite 103
Rockville, Maryland 20855

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research
Food and Drug Administration
Rockville MD 20857

COMPLIANCE REVIEW

DATE: January 4, 2000

TO: Administrative File Number 09946

FROM: Good Clinical Practice Branch 1
Division of Scientific Investigations

SUBJECT: NDA 20-687

REVIEW OF: Suzanne T. Poppema, M.D.
Aurora Medical Services
1207 N. Street, Suite 214
Seattle, Washington 98133

INSPECTION DATES: November 1 to November 5, 1999

DISTRICT OFFICE/FDA INVESTIGATOR: Seattle Office

DISTRICT CLASSIFICATION: NAI

BACKGROUND:

This was a routine inspection in support of the NDA listed above.

This is the first inspection of Dr. Poppema. She has been involved in a clinical study for 1 IND.

ANALYSIS OF INSPECTION FINDINGS:

This was a routine inspection accompanied by the usual supporting exhibits. Dr. Poppema was issued an NAI letter as neither the inspection itself or the review of the EIR identified any issues of regulatory concern. There were no limitations on the inspection, EIR, and/or interpretation.

CONCLUSION AND RECOMMENDATION:

The letter was classified NAI as no regulatory concerns were identified. No additional regulatory follow-up is needed.

/S/

CONCURRENCE:

Concur: ✓ Date: 1/11/00

Nonconcur: _____ Date: _____
(See attached supervisory comments regarding non-concurrence)

/S/

Good Clinical Practice Branch 1
Division of Scientific Investigations

No 483 was issued.

FINAL CLASSIFICATION: NAI

Distribution:
HFA-224
HFD-45/Reading File
DSI File Number 09946

APPEARS THIS WAY
ON ORIGINAL

File No: 09946 Name: Suzanne Coppens

GCP1

DATE	TO:	ACTION REQUESTED
12-28-99		
1/7/00		1.7.00
1/11/00		SIGNED → DISTRIBUTE
		APPEARS THIS WAY ON ORIGINAL

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
482. EIR. ATTACHMENT, EXHIBITS 1-7

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO
22201 23rd Drive SE
Bothell, Washington 98021-4421

TO

2. NAME AND TITLE OF INDIVIDUAL
Suzanne T. Poppema, M.D.

3. DATE
11/01/99

4. FIRM NAME
Aurora Medical Services

5. HOUR
9:00 a.m. / p.m.

6. NUMBER AND STREET
1207 N. 200th Street, Suite 214

7. CITY AND STATE & ZIP CODE
Seattle, Washington 98133

8. PHONE # & AREA CODE
206-546-8891

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
/S/

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Consumer Safety Officer

[1]Applicable to portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704 (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j))* A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2]Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories and ******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ****** Control of Radiation

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information.

Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such *information is needed by the manufacturer for purposes of section 359, and* (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election *(together with information identifying the notifier and the product)* to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful –

(1) •••

(2) •••

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

•••

Part G – Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgement may be necessary."

APPEARS THIS WAY
ON ORIGINAL

Attachment to Form FDA 482

Resources for FDA Regulated Businesses

The U.S. Food and Drug Administration strives to protect, promote and enhance the health of the American people, while minimizing the regulatory burden on the industries it regulates. You have a right to disagree with any agency decision, action, or operation without fear of retaliation. You also have a right to be treated with appropriate courtesy and respect. If you are dissatisfied with any agency decision or action, you may appeal to the supervisor of the employee who made the decision or took the action. If the issue is not resolved at the first supervisor's level, you may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's chain of command.

To resolve a problem with your company's interaction with FDA, or if you have questions or concerns about FDA rules or procedures, we suggest that you first write or call your district office to explain your concerns. If you are not satisfied with the help provided by the district office, you may take your complaint or concern to the regional office. If that effort is not satisfactory, contact FDA's Office of the Chief Mediator and Ombudsman for further assistance and guidance.

Contact the **District Office** if you have a concern or question about an inspection, an import or export issue, or any other action taken by an FDA field representative. The District Office will provide you with the name and phone number of someone who will review the matter and provide assistance.

District	Telephone
Atlanta	(404) 347-4344
Baltimore	(410) 962-3396
Buffalo	(716) 551-4461
Chicago	(312) 353-5863
Cincinnati	(513) 679-2700
Dallas	(214) 655-5310
Denver	(303) 236-3000
Detroit	(313) 226-6260
Florida	(407) 475-4700
Kansas City	(913) 752-2100
Los Angeles	(949) 798-7600

District	Telephone
Minneapolis	(612) 334-4100
Nashville	(615) 781-5385
New England	(781) 279-1675
New Jersey	(973) 526-6000
New Orleans	(504) 589-6344
New York	(718) 340-7000
Philadelphia	(215) 597-4390
San Francisco	(510) 337-6700
San Juan	(787) 729-6844
Seattle	(425) 486-8788

Contact the **Regional Office** for further help if you were not able to effectively resolve the issue with the assistance of the district office. Telephone numbers for the regional offices and a list of the states covered by each region are on the Internet at http://www.fda.gov/ora/hier/ora_field_names.txt.

Contact the **Office of the Chief Mediator and Ombudsman** at 301-827-3390 if you have been unsuccessful in resolving a problem at the district and regional levels. The office's home page is on the Internet at http://www.fda.gov/oc/ombudsman/homepage.htm.

The Small Business Administration also has an ombudsman. The **Small Business and Agriculture Regulatory Enforcement Ombudsman** and 10 Regional Fairness Boards receive comments from all kinds of small businesses about federal agency enforcement actions and annually evaluate the enforcement activities, rating each agency's responsiveness to small business. If you wish to comment on the enforcement actions of FDA, call 1-888-734-3247. The ombudsman's home page is on the Internet at http://www.sba.gov/regfair.

Small Business Guide to FDA
Internet at http://www.fda.gov/opacom/morechoices/smallbusiness/toc.html

Office of Regulatory Affairs (ORA)
Internet at http://www.fda.gov/ora/ora_home_page.html

Food and Drug Administration (FDA)
Internet at http://www.fda.gov

SITE VISIT RECORD

Protocol No. 166A

Investigator 003 - Poppema Location Seattle, Washington

Visit Date(s)	Signature Personnel	Purpose of Visit	Signature Investigator or Staff
8/16/94		PSV	
11/8/94		initial	
11/30/94		monitoring	
1/5/95		monitoring	
2/6-9/95		monitoring	
3/14-3/16 95		monitoring	
21 March 95		site visit	
4/26-27/95		monitoring	
5/23-25/95		monitoring	
7/12-13/95		monitoring	
9/25/95		Monitoring visit	
9/26/95		monitoring visit	
9/27/95		monitoring visit	
9/28/95		Monitoring visit	
~~FFU~~ 11/15/95		Monitoring visit	
3/18-20/96		Audit	

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 9 Page 1 of 1

Amendment 3
May 5, 1995

CONFIDENTIAL

EVALUATION OF THE EFFICACY, SAFETY AND ACCEPTABILITY OF MIFEPRISTONE AND MISOPROSTOL IN INDUCING ABORTION IN PREGNANT WOMEN WITH AMENORRHEA OF UP TO 63 DAYS

PROTOCOL NUMBER: 166A,B

SPONSOR: The Population Council, Inc.
1230 York Avenue
New York, New York 10021

_____

Signature, Principal Investigator

Protocol approved by The Population Council's IRB on September 14, 1994
Amendment No. 1 approved by The Population Council's IRB on November 2, 1994
Amendment No. 2 and 3 approved by The Population Council's IRB on May 5, 1995

I. INTRODUCTION

Mifepristone is a synthetic steroid currently used for medical abortion in France, Sweden, United Kingdom and China. It acts as a competitive blocker of progesterone and cortisol through binding to their receptors. Because of its antiprogesterone activity, mifepristone has been developed primarily as a medical abortifacient. When used alone in different regimens with total doses ranging from 140 to 1600 mg administered over one to ten days, the success rate of abortion in women with amenorrhea of less than 50 days duration usually varied between 64-85%[1].

Subsequent studies demonstrated that when mifepristone (600 mg) was followed two days later by a prostaglandin analog administered either by the intramuscular route (sulprostone, a prostaglandin E_2 analog), or as a vaginal pessary (gemeprost, a prostaglandin E_1 analog), the efficacy rate for complete abortion increased to 95% and above. Based on these observations, mifepristone has been marketed in France since September 1989 as a medical alternative to surgical abortion for the termination of pregnancies in women with amenorrhea of 49 days or less. Recently, this mifepristone - prostaglandin regimen was approved in the United Kingdom, and in Sweden. In the latter two countries, this combination is used in women with amenorrhea of up to 63 days.

In Europe there is now an accumulated experience with over 150,000 subjects who have received mifepristone together with various prostaglandins. Clinical trials have been conducted in several countries and have confirmed the initial experience. Unlike treatment with mifepristone alone where the success rate decreased with advancing duration of amenorrhea, the combination was effective up to 63 days of amenorrhea and in various published studies, the incidence of abortion induction ranged from 92.7% to 99%[1].

The most comprehensive study published to date comprises 16,369 subjects from over 450 clinics[2]. In this study 0.8% of the cases experienced uterine bleeding significant enough to necessitate vacuum aspiration or dilatation and curettage and in 0.07% (11 women), a blood transfusion was required. Significant cardiovascular side effects were reported in four cases following sulprostone administration. In three of these subjects, there was severe hypotension necessitating infusion of macromolecular solutes and in the final subject, a 38 year-old smoker, there was an acute myocardial infarction. In these four subjects, symptoms commenced within one hour of sulprostone administration and all recovered uneventfully. However, in general use, there was a fatal myocardial infarction in one woman, who was a 31-year-old heavy smoker, following sulprostone[3]. No cardiovascular complications have been reported following gemeprost, but this may be related to the fact that this analog has been used less often than sulprostone. Sulprostone is rapidly absorbed into the circulation following intramuscular injection,

therefore, it is not unreasonable to assume that this prostaglandin carries a higher risk of cardiovascular problems than preparations that are administered orally or vaginally and are absorbed more gradually. Moreover, gemeprost, unlike sulprostone, is an E_1 analog.

As a consequence, parenteral prostaglandins should be used cautiously in women with heart disease, those over 35 years of age or in heavy smokers. The French health authorities have in fact withdrawn sulprostone as one of the prostaglandin preparations which can be given with mifepristone.

Because of the cardiovascular side effects reported with sulprostone as well as the inconvenience of both sulprostone and gemeprost which both require refrigeration, alternate prostaglandin preparations are now being used. Misoprostol, (methyl 11α, 16-dihydroxy-16-methyl-9-oxoprost-13 E-en-1-oate) is a prostaglandin E_1 analog that has been safely used for the prevention of nonsteroidal anti-inflammatory drug-induced gastric ulcers in patients at high risk for complications from gastric ulcers for many years; for this indication, it is given in an oral dose of 200 μg four times daily. Its effects on uterine tone are similar to those of other prostaglandins. Misoprostol is inexpensive, orally active and stable. In a recently published French study in women with amenorrhea of 49 days or less, one group comprising 505 women received 400 μg misoprostol 48 hours after mifepristone; the success rate for termination of pregnancy was 96.9%[4]. A second group of 390 women initially followed the same protocol, but if pregnancy was not terminated within four hours after misoprostol, the women were offered an additional 200 μg dose of misoprostol. In this second group, the overall success rate was 98.7%. These results indicate that the combination of mifepristone and misoprostol is of equal or greater effectiveness than the combination of mifepristone and either parenteral or vaginal prostaglandin for the termination of early pregnancy.[4] No serious cardiovascular side effects have been observed. Other side effects were neither more frequent nor more severe than after either parenteral or vaginal prostaglandin preparations[4].

A study from Britain reported complete abortion in 92 out of 99 women with amenorrhea of less than 57 days who were given 200 mg mifepristone followed 48 hours later by 600 μg misoprostol. There were three on-going pregnancies and four incomplete abortions. Vomiting was exhibited in 24% and diarrhea in 7% of the women. No analgesia was needed in 62% of the women[5].

In the two studies reported above, approximately 60-80% of women aborted during the four hours following prostaglandin administration. A number of side effects have been observed during this four hour period. These include: uterine pain, nausea, vomiting and diarrhea. In one of these studies the incidence of nausea, vomiting and diarrhea were 43%, 17% and 14% respectively[4]. It is for these reasons that it is recommended that women be monitored in the clinic for four hours following prostaglandin administration.

In Europe over 52,000 women have received mifepristone followed 48 hours later by misoprostol without serious heart complications.

2. SUMMARY OF STUDY

The aim of the study is to determine the safety, efficacy, acceptability and feasibility of mifepristone plus misoprostol in inducing abortion, within the U.S. health care system setting, when administered to women exhibiting amenorrhea of varying duration (up to 63 days). The duration of amenorrhea will be defined throughout this document as the number of days from the first day of the last menstrual period. In addition to the large pivotal studies, a small initial pilot study will be conducted to enable the investigators to gain first hand experience with the proposed dosing regimen.

A total of 1,050 pregnant subjects will be enrolled in this and an identical sister protocol, to be conducted simultaneously. Thus a total of 2,100 subjects will be enrolled in the two trials. Three groups of subjects will be examined:

Group 1: Amenorrhea of $\leq$ 49 days
Group 2: Amenorrhea of 50 through 56 days
Group 3: Amenorrhea of 57 through 63 days

Analysis will also be conducted on safety, efficacy and acceptability of all subjects taken as a single group, regardless of the duration of amenorrhea. This will be a multicenter trial utilizing a minimum of six centers in each of the two studies. The centers will all perform pregnancy interruption on a regular basis. The centers will have access to facilities for blood transfusion and routine emergency resuscitation techniques. In all the trial centers, the recruitment of subjects will be such that, as closely as possible, equal numbers of subjects will be enrolled into each of the three groups defined above.

Subjects shall visit the study center three times, unless state law requires an additional, initial informational visit with a mandatory waiting period before the process can begin. At the initial visit (Day 1; after any required statutory waiting period), a full history and physical examination will be performed and the duration of amenorrhea will be determined and the reasons for selecting a medical abortion will all be recorded. At this visit, 600 mg of mifepristone (three 200 mg tablets) will be administered. The subject will return to the study center for the second visit on Day 3 to receive oral misoprostol (400 μg as two 200 μg tablets). The subject will be monitored at the center for at least four hours post the administration of the prostaglandin. The third visit will occur on Day 15. At this visit the completeness of the medical pregnancy termination will be assessed. In the event that the pregnancy is on-going at this time, or if the abortion has been incomplete, either vacuum aspiration or dilation and curettage will be performed. Subjects who undergo a surgical abortion at any time during their enrollment in the study

will return to the center two weeks post the surgical procedure for a follow-up assessment.

3. OBJECTIVE

The objective of this trial is to evaluate the effectiveness, safety, acceptability and feasibility of mifepristone plus misoprostol in inducing abortion when given to women, who have experienced up to 63 days of amenorrhea, within the U.S. health care system setting. Prior to initiation of the pivotal studies, a pilot study comprising 15 women will be performed at each of the selected study centers. The purpose of this pilot trial is to give the investigators exposure to the proposed dosing regimen so they will have first hand experience prior to the initiation of the pivotal studies. The results of the pilot trial will be included in the safety analysis for the product, but the efficacy data will be treated as a subgroup analysis relative to the pivotal trials.

Investigators selected to conduct the trials will be experienced abortion providers and medical investigators. They should have access to an IRB able to review the protocol, and will have malpractice insurance as well as general liability insurance for the clinic, hospital or office where the study will be performed. The investigators should be able to complete the study in six months at a maximum.

The investigators will operate in an appropriate study center; the study center will:

a) Provide routine emergency resuscitation such as O_2, Ambu bag and will be staffed with personnel trained in routine emergency care.

b) Have access on a 24 hour a day basis to blood transfusion, D & C and more elaborate resuscitation procedures.

c) Have space to conduct the study including a room where a woman can be monitored for at least four hours after the prostaglandin administration.

d) Have the physician responsible for the study on call on a 24 hour a day basis, or his/her delegate of equal qualification.

e) Have adequate and sufficient trained personnel for counselling of subjects and conduct of the study.

f) Have transvaginal ultrasound available and personnel trained in the use of the equipment as well as the interpretation of the sonograms for the assessment of gestational age in relation to the reported duration of amenorrhea.

g) Investigators and staff will answer a provided questionnaire at the completion of the study.

4. PATIENT SELECTION

4.1 Patient Sample:

4.1.1 Number of patients: A total of 1,050 patients per each of the identical trials for a total of 2,100 subjects will be enrolled at multiple centers.

4.1.2 Age range: 18 years or older.

4.1.3 Residents of the United States.

4.2 Inclusion Criteria:

4.2.1 Good general health.

4.2.2 Age 18 years or older.

4.2.3 Request termination of pregnancy.

4.2.4 Agree to undergo surgical pregnancy termination in case of failure of the medical abortion method being evaluated.

4.2.5 Have an intrauterine pregnancy of known duration which is less than or equal to 63 days of amenorrhea period. The final determined estimated duration of pregnancy should be less than 64 days of amenorrhea, and as confirmed by uterine size on pelvic examination and ultrasonographic examination.

4.2.6 Have a positive urine pregnancy test.

4.2.7 Willing and able to participate in the study after its precise nature and duration have been explained.

4.2.8 Able and willing to sign an informed consent form.

4.2.9 Resident of the United States.

4.3 Exclusion Criteria:

4.3.1 Evidence of the presence of any disorder which represents a contraindication to the use of mifepristone (e.g., chronic corticosteroid administration, adrenal disease) or misoprostol (e.g., asthma, glaucoma, mitral stenosis, arterial hypotension, sickle cell anemia, or known allergy to prostaglandin).

4.3.2 History of severe liver, respiratory, or renal disease or thromboembolism.

4.3.3 Cardiovascular disease (e.g., angina, valve disease, arrythmia, cardiac failure).

4.3.4 Hypertension being treated on a chronic basis or untreated patients who present with: a blood pressure of > 140 (systolic) or > 90 (diastolic).

4.3.5 Anemia (hemoglobin level below 10 g/dL or hematocrit below 30%) at the Day 1 visit.

4.3.6 A known clotting defect or receiving anticoagulants.

4.3.7 Subjects with an IUD in place.

4.3.8 Insulin dependent diabetes mellitus.

4.3.9 More than 63 days of amenorrhea or results of bimanual pelvic examination or vaginal ultrasound which are inconsistent with 63 days or less of amenorrhea.

4.3.10 Breast-feeding.

4.3.11 Adnexal masses or adnexal tenderness on pelvic examination suggesting pelvic inflammatory disease.

4.3.12 Ectopic pregnancy or threatened abortion.

4.3.13 Women 35 years of age or older who smoke more than 10 cigarettes per day and have another risk factor for cardiovascular disease (e.g., diabetes mellitus, hyperlipidemia, hypertension or family history of ischemic heart diseases).

4.3.14 Unlikely to understand or comply with the protocol requirements.

4.3.15 Women who cannot reach the source of emergency medical care that serves the abortion center within ———— from (a) their home or place of work and (b) the abortion center.

5. STUDY MEDICATION

5.1 Assignment of Study Medication

This is a multicenter trial evaluating the effectiveness, safety and acceptability of mifepristone plus misoprostol in inducing abortion when given to women in one of three groups depending upon the duration of amenorrhea. The three groups are:

Group 1 - Amenorrhea of $\leq$ 49 days
Group 2 - Amenorrhea of 50 through 56 days
Group 3 - Amenorrhea of 57 through 63 days

As closely as is possible, equal numbers of subjects will be enrolled into each of the three groups. There may be differing numbers of patients enrolled from center to center, but the number per group per center should be approximately one third into each of the groups.

5.2 Dosage and Administration

There will be three visits to the study center. At the initial visit (Day 1), a full history and physical examination will be performed and the duration of amenorrhea will be determined and the reasons for selecting a medical abortion will all be recorded. At this visit, 600 mg of mifepristone (three 200 mg tablets) will be administered orally. The subject will return to the study center for the second visit on Day 3 to receive oral misoprostol (400 μg as two 200 μg tablets). The subject will be monitored at the center for at least four hours post the administration of the prostaglandin. The third visit will occur on Day 15. At this visit the completeness of the medical pregnancy termination will be assessed and an acceptability questionnaire administered. In the event that the pregnancy is on-going at this time, or if the abortion has been incomplete, either vacuum aspiration or dilation and curettage will be performed. Subjects who undergo a surgical abortion at any time during their enrollment in the study will return to the center two weeks post the surgical procedure for a follow-up assessment.

5.3 Packaging

A) Mifepristone — Mifepristone will be provided as 200 mg tablets of micronized mifepristone.

B) Misoprostol — Misoprostol will be obtained locally by each investigator as 200 μg tablets of commercially available misoprostol.

All study supplies will be kept in a locked, dry cabinet.

5.4 Labeling

A) Mifepristone — Mifepristone will have a label which will include product identification, expiration date, and drug dose. In addition the following will be printed on the labels: CAUTION: New drug. Limited by Federal Law to Investigational Use. All medication packets will be labelled with the protocol number.

B) Misoprostol — Misoprostol will be obtained locally by each investigator as 200 μg tablets of commercially available misoprostol and dispensed from the center pharmacy.

5.5 Concomitant Medications

No salicylates, indomethacin, or any other drug which inhibits prostaglandin synthesis should be taken. If necessary, analgesics belonging to other pharmacologic classes or spasmolytic drugs may be used. Drugs such as trifluoperazine and related phenothiazines (for treatment of nausea and vomiting) that could increase the risk of hypotension must be avoided as should oxytocin and any other prostaglandin preparation.

The use of concomitant medications during the course of this study will be recorded in the Case Report Form, and these data will be analyzed.

6. STUDY PROCEDURES

Each participating study center will record on a daily basis the number of subjects recruited in each of the three groups. All women approached to participate in the study will be recorded in the study data. Those who refuse to participate in the trial will have a special form completed for the database. These data will be communicated to the sponsor on a weekly basis. At each center, the number of subjects recruited into each of the groups will be equal to one-third the total assigned to the center if possible. When any of the groups has been filled, no further recruitment into that particular group will be conducted. Under no circumstances will any member of the study center staff suggest that a subject appearing at the center, with a duration of amenorrhea consistent with a completed group, be deferred in her request for pregnancy termination to allow for enrollment into an open group at a later time.

6.1 VISIT 1 (Admission, Day 1 of Study)

At the time of the subjects enrollment (Day 1), all the following should be done:

- Counseling.
- Medical, obstetrical and gynecological history.
- Medical examination, including: height, weight, blood pressure, and pulse.
- Bimanual pelvic examination.
- Urine pregnancy test.
- Quantitative Serum ßhCG.
- Vaginal ultrasound.
- Determination of Rh status and where routinely collected, the blood group.
- Hemoglobin or hematocrit determination.

Chemistry Panel (4mL)
Which includes:

Aspartate aminotransferase, Alanine aminotransferase, Alkaline phosphatase, Total Bilirubin, Blood urea nitrogen, Phosphate, Creatinine, 24 hour fasting Glucose, Albumin, Lactate dehydrogenase, Potassium, Sodium, Chloride, Bicarbonate, Uric Acid, Calcium, as well as Cholesterol, Triglycerides, and Total Protein

Hematology Panel (3mL)
Which includes:

Hemoglobin, Hematocrit, RBC, WBC with differential, Platelet count*

Food should be withheld for one hour prior to and one hour post administration of the study drug. At admission to the study, the three tablets of mifepristone (600 mg total) will be swallowed by the subject with no more than 240 mL of water in the presence of a member of the center's study staff who will record the date and time of the administration.

Subjects who smoke will be instructed to refrain from smoking until after the administration of misoprostol at Visit 2, and an appointment will be made for Visit 2.

Subjects will be given a copy of the informed consent and patient diary card describing symptoms which require emergency treatment. These include: heavy bleeding, fever, and severe abdominal pain. The subjects will be given the address and 24 hour telephone number of a medical center (including the name of physicians) which cares for patients on a 24 hour a day basis.

A diary will be provided to each of the subjects for recording medications and symptoms, such as pain, nausea, vomiting and diarrhea. The diary will also be used to record the occurrence of vaginal bleeding on each day. The subject will be instructed to record the bleeding relative to their normal menstrual flow (e.g., lighter, the same as or heavier than normal). If the expulsion takes place before Visit 2, the date and time should be recorded on the subjects diary.

* Amendment 2 dated April 27, 1995

6.2 VISIT 2 (Prostaglandin Administration, Day 3 of Study

Visit 2 will be conducted on Day three (3) of the study. The following will be performed:

- Clinical examination.

- If the patient believes that expulsion occurred prior to Visit 2, the date and time will be recorded on the case report form as they were noted in the subjects diary. Since it is difficult to confirm that an abortion at this time is complete, nearly all subjects will require misoprostol. If however, the physician can verify unequivocally that complete abortion has occurred, the misoprostol will not be administered. If the abortion is incomplete or if there is any uncertainty about the completeness of the abortion, the misoprostol will be administered.

- Brief interview and review of the diary.

- Any adverse events which occurred since Visit 1 will be recorded on the case report form.

- Subject will receive an injection of anti-D globulin if the subject is Rh negative, if indicated.

- Food should be withheld for one hour prior to and one hour post the administration of misoprostol. The two tablets of misoprostol (400 μg total) will be swallowed by the subject with no more than 240 mL of water in the presence of a member of the center's study staff who will record the date and time of the administration.
- The subject will be observed at the study center for the four hour period post the administration of misoprostol at a minimum. The facility should be capable of surgical termination of pregnancy (by vacuum aspiration or dilation and curettage) and have access to blood transfusion and emergency resuscitation.

- During the observation period, the following should be recorded at least hourly:

- Occurrence of nausea, vomiting, or diarrhea. Intensity should be recorded as:

0: none
1: mild
2: moderate
3: severe

Any treatment for these will be recorded as concomitant medications.

- At the onset of any abdominal pain, the following will be recorded:

  Intensity, recorded as: none, mild, moderate, or severe.

  Duration, documenting any treatment as a concomitant medication.

- Blood pressure and heart rate at hourly intervals unless more frequent readings are indicated.

- Time of expulsion, if occurring during the observation period.

- Any unexpected symptom or clinical finding.

The use of intramuscular sulprostone in combination with mifepristone in previous studies has occasionally precipitated an episode of hypotension usually associated with bradycardia. In extremely rare circumstances this previously utilized treatment regimen has been associated with myocardial infarction and ventricular tachycardia. These complications are very unlikely with the combination of misoprostol and mifepristone. However, any significant fall in blood pressure or significant change in heart rate, however transient, following the administration of misoprostol will be recorded and the subject observed for at least three hours after their blood pressure and heart rate have returned to baseline. In case of chest pain, hypotension or cardiac arrhythmia, an ECG should be performed immediately and if required adequate resuscitation should be undertaken.

The cycle immediately following the administration of mifepristone is ovulatory. Therefore, subjects will be counseled to initiate contraception. Barrier contraception may be initiated within three days of misoprostol administration.

- A gynecological examination will be performed to determine if products of conception remain in the vagina or cervix.

- A very active attempt should be made to contact any subject who fails to appear for the Visit 2 appointment. The administration of misoprostol after Day 3 is strongly discouraged. Misoprostol may be administered between 36 and 60 hours after mifepristone administration.

[illegible] center shall retain its records relating to such subject through the date on which she was last seen at the center for a period of thirty (30) years following such date.

6.3 VISIT 3 (Exit Interview, Day 15 of Study)

Visit 3 will be conducted on Day fifteen (15) of the study. At Visit 3 the following will be performed:

- Clinical and gynecological examination.

- Assessment of severity and duration of uterine bleeding. Subjects who experience bleeding post Day 15 should be followed-up via telephone until the bleeding has stopped or intervention is clinically indicated.

- Assessment of hemoglobin or hematocrit if indicated.

- Blood samples will be collected for:

Chemistry Panel (4mL)
Which includes:

Aspartate aminotransferase, Alanine aminotransferase, Alkaline phosphatase, Total Bilirubin, Blood urea nitrogen, Phosphate, Creatinine, 24 hour fasting Glucose, Albumin, Lactate dehydrogenase, Potassium, Sodium, Chloride, Bicarbonate, Uric Acid, Calcium, as well as Cholesterol, Triglycerides, and Total Protein

Hematology Panel (3mL)
Which includes:

Hemoglobin, Hematocrit, RBC, WBC with differential, Platelet count

A total of twelve (12) subjects per each group of amenorrhea duration, for a total of thirty-six (36) per center will be involved in these assessments at six (6) selected centers. Thus, a total of 216 subjects from the entire study population will participate.*

- Verification of any concomitant medications or other therapeutic measures since Visit 2.

*Amendment 2 dated April 27, 1995

- Assessment of expulsion (history, pelvic examination), as well as date and time of occurrence if appropriate.

- Final evaluation of the treatment outcome through the clinical and gynecological examination. If necessary, perform ultrasonography and/or urine pregnancy test.

- In instances where the medical abortion method has failed, either completely or partially, perform the necessary additional surgical procedure. In the subjects for whom a surgical procedure is required, schedule a follow-up visit as per Section 6.6 below.

- Examine the subject's view of her abortion experience including her view of the experience relative to expectations; assessment of discomforts and side effects; timing and place of abortion; satisfaction with the experience; comparison to any previous abortion experience; best and worst features of the method being assessed in the trial; attitude toward self-administration of prostaglandin at home and preference for home or clinic treatment. All responses will be recorded in the case report forms.

- Assure that the subject's case record forms have been completely, accurately and properly filled in.

- A very active attempt should be made to contact any subject who fails to appear for the Visit 3 appointment.

- If the center is aware of any subject who misses Visit 2 and does not appear for Visit 3, or who otherwise determines to carry her pregnancy to term, the center shall retain its records relating to such subject through the date on which she was last seen at the center for a period of thirty (30) years following such date.

6.4 UNSCHEDULED VISITS

At Visits 1 and 2, subjects will be advised that they may return to the study center at any time if they experience medical problems associated with the medical abortion or for any other medical problem. At any unscheduled visits the following will be recorded:

- Reason for the visit.

- Information regarding utilization of any other medical resources.

- Pregnancy status at onset of visit.

- Temperature, blood pressure, heart rate, and hemoglobin.

- Any medication administered during visit as well as any medications prescribed.

- Any procedures conducted during the visit.

- Results of any pathology testing.

Subjects who have a surgical abortion at any unscheduled visit will have the exit interview (As defined in Section 6.3 above) prior to departure from the study center on the day of the surgical abortion, and will not return for the scheduled Visit 3. However, subjects undergoing surgical abortion will be scheduled for a follow-up visit as outlined in Section 6.6 below.

6.5 MEDICAL ADVISORY COMMITTEE

If serious adverse events occur beyond expectation, the decision of whether or not the study should be discontinued or modified will be taken by the Sponsor in consultation with the Medical Advisory Committee.

6.6 FOLLOW-UP

Subjects who are enrolled and receive either or both drugs in the study and undergo surgical abortion at any time during their enrollment will be scheduled for a follow-up visit. This follow-up visit will be scheduled for two weeks post the date of the surgical abortion. At this visit the following will be recorded:

- Brief medical history and clinical examination.

6.7 EARLY WITHDRAWAL FROM THE TRIAL

Subjects may withdraw from the study at any time at their own request. In all cases, the reasons for the subjects withdrawal must be recorded in detail in the case report forms and in the patients medical records. In all cases of withdrawal the subjects must be encouraged to have surgical abortions. If any subject refuses surgical abortion, the investigator must record that the subject understands the