withdraws from the study after ingesting mifepristone and for whom a complete abortion has not been confirmed for a period of at least 30 years following the subject's last visit to the center.

All efforts will be made to contact subjects who fail to return for the necessary visits (telephone, registered mail). The subject will not be given misoprostol if contacted after 60 hours of the study. A subject may not complete the treatment regimen if severe side effects or symptoms develop after mifepristone administration that, in the opinion of the principal investigator, constitute a threat to the woman's health. Any subjects who do not complete the treatment regimen for any reason will be assessed for the completeness of the abortion, if possible. Any subject who has received mifepristone and has at the time of early termination had an incomplete abortion, as described above, will undergo surgical abortion as described in Section 6.3 above, and will be considered a failure.

7. ADVERSE EXPERIENCES

7.1 General Aspects

Adverse Reactions

Subjects will be notified of possible adverse reactions; they will be instructed to immediately report all adverse reactions to the investigator.

Any adverse reaction, noticed by the investigator or reported by the subject, including clinically significant lab abnormalities, will be recorded in the appropriate section of the case report form, regardless of its severity and relationship to study drug.

Serious or unexpected adverse events will be immediately reported by the investigator by telephone to:

Dr. Irving Spitz
Dr. C. Wayne Bardin
The Population Council, Inc.
(800) 327-8730
24 hour answering service outside normal business hours

_____ will notify the sponsor, and ensure FDA notification. All serious ("any experience that is fatal or life-threatening, is permanently disabling, incapacitating, requires inpatient hospitalization, or causes a congenital anomaly, cancer or is due to overdose") and/or unexpected ("any adverse experience that is not identified in nature, severity or frequency in the current investigator's brochure for the study") adverse

and a written report must be submitted to the medical monitor within 24 hours.

The initial telephone contact will be followed within 3 days by a detailed report of the event which will include copies of hospital case reports, autopsy reports and other documents, when applicable. The adverse event must be followed through resolution.

The same applies to all subjects who died during the course of the study or within 30 days of completion of treatment irrespective of whether the adverse reaction was judged as related to treatment. In case of a death, copy of the autopsy report should be sent to the sponsor, if performed.

For each adverse reaction, the following information will be entered in the case report form: description of event, onset date, resolution date, severity (1=mild, awareness of sign or symptom, but easily tolerated; 2=moderate, discomfort enough to cause interference with usual activity; 3=severe, incapacitating with inability to do usual activity), drug cause-effect relationship and the outcome of the event. The investigator will also note if any action was taken regarding the test drug (temporarily or permanently discontinued) and if therapy or hospitalization was required.

ETHICAL ASPECTS

A. Informed Consent Form

The purpose of the study, those adverse reactions that are known to occur with the study drugs and the subject's right to withdraw from the study at any time without prejudice, must be explained to each subject in a language she understands. The subject is then required to sign in the presence of a witness an approved informed consent form in a language she understands containing all the above-mentioned information and a statement that the subject will permit examination of his/her study case report forms by a third party. Willing subjects may be interviewed by a representative of the sponsor about her understanding of the risks, benefits, procedures, and the experimental nature of the study.

B. Institutional Review Board

This study will not be initiated until the protocol and informed consent form have been reviewed and approved by a duly constituted Institutional Review Board (IRB) as required by U.S. FDA regulations. It is the responsibility of the investigator to submit the study protocol with its attachments to the IRB for review and approval.

IRB general assurance number must be given to the Sponsor of the study prior to study initiation, along with a signed and dated statement that the protocol and informed consent form have been reviewed and approved by the IRB.

The investigator is committed, in compliance with FDA regulations, to inform the IRB of any emergent problems, serious adverse reactions or protocol amendments.

C. Protocol Amendments

Any amendment to the protocol will be with mutual agreement between the investigator and the Sponsor. All amendments to the protocol will be submitted to the FDA and to the Institutional Review Board (IRB) concerned for review and, if necessary, approval prior to implementation of the changes.

D. Study Monitoring

A pre-study visit will be made by the monitor to the investigative site in order to review the protocol and to ascertain that the facility is adequate for satisfactory conduct of the study, as well as to discuss the obligations of both the sponsor and the investigator.

The investigator will permit a representative of the sponsor or his designate and the FDA, if requested, to inspect all case report forms and corresponding portion of the study subjects original office and/or hospital medical records, at regular intervals throughout the study. These inspections are for the purpose of assessing the progress of the study, verifying adherence to the protocol, determining the completeness and exactness of the data being entered on the case report forms and assessing the status of study drug storage and accountability. During site visits, case report forms will be examined by the study monitor(s) and verified by comparison with corresponding source data (such as hospital and/or office records).

ADMINISTRATIVE ASPECTS

A. Curricula Vitae

The investigator will provide the Sponsor with copies of the curricula vitae of himself/herself and the co-investigators listed on the FDA Form 1572.

A Case Report Form in triplicate will be provided by the sponsor for each subject to be filled in at each visit. Additional forms will be used for screening of the subjects prior to enrollment. In the event of additional visits, extra case report forms for the unscheduled visits will be filled out. At the visits on Days 1 and 15, acceptability questions will be asked, and the data recorded.

Acceptability questions will be asked on the day of surgical abortion for those having a surgical abortion.

One copy of the forms will be retained by the clinical study site, the other copies will be retrieved by the study monitor at the monitoring visits. All forms will be filled in legibly in black ball point pen. All entries, corrections and alterations are to be initialed and dated by the investigator, co-investigator, or study coordinator making the correction. Corrections will be made by crossing through the incorrect data with a single line so that the incorrect information remains visible, and putting the correct information next to the incorrect data. A reasonable explanation must be given by the investigator for all missing data.

C. Data Retrieval

At intervals during the study and at the conclusion of the study, the study monitor will retrieve signed and dated case report forms from the study site for data entry and analysis. The original and one copy of each page will be retrieved by the monitor. The investigator will keep a copy of all original case report forms and source documents.

D. Records Retention

Except as otherwise explicitly set forth herein, pursuant to applicable federal regulations, the investigator must retain copies of all study records for a period of two (2) years following the date a marketing application is approved for the indication for which the drug is being investigated. If no application is filed or if the application is not approved, the study records must be retained until 2 years after the investigation is discontinued and FDA is notified.

E. Study Termination

Either the investigator or the sponsor may terminate the study at any time for well documented reasons, provided a written notice is submitted at a reasonable time in advance of intended termination.

8.1 Population Analyzed

All subjects to whom mifepristone has been administered will be included in the analyses.

A) Efficacy

Efficacy will be determined by each subject's abortion status and history at Visit 3 (Day 15), two weeks post the administration of mifepristone. The pregnancy/abortion status requires a clinical evaluation, including where necessary ultrasonographic and/or urine pregnancy results.

One measure of success will be defined as a pregnancy termination by Visit 3 (Day 15) without the need for surgical or instrumentation procedures except for forceps extraction of ovular tissue fragments extending through the external cervical os. If pregnancy has not been terminated by Visit 3 (Day 15), this will be considered a failure.

FAILURES

Two categories of failures will be recognized. These will be called medical failures and acceptability failures.

Medical failures are of two types:

i) persisting pregnancy at Visit 3 (Day 15).
ii) medically indicated surgical intervention because of:
    a) incomplete expulsion at Visit 3 (Day 15).
    b) serious adverse advents that warrant early surgical interruption of pregnancy.

Acceptability failures are deemed to have occurred when subjects request surgical interruption of a persisting pregnancy before Visit 3 (Day 15) without medical necessity.

In consequences of this distinction between types of failure, there will be two evaluations of success and failure rates.

[illegible] will be determined by life table analysis on a day to day basis from Visit 1 (Day 1) through Visit 3 (Day 15). Women who request surgical abortions before Visit 3 (acceptability failures) will be considered as censored as of mid-day on the day of the surgical abortion. Persisting pregnancies as of Visit 3 are considered failures. The method success rate is 1-MFR for any day or cumulative analysis. Women with persisting pregnancies of less than two weeks post the administration of mifepristone when last observed (e.g., lost to follow-up) will be treated as censored in mid-day of the last observation in the calculation of gross rates.

The *total failure rate* (TFR) will also be determined by life table techniques using the assumption that some of the subjects with persisting pregnancies are last observed before two weeks post the administration of mifepristone. Daily total failure rates are computed under the assumption that subjects with continuing pregnancies last observed before Visit 3 were last observed in the middle of the day of last observation.

Data will be recorded in the case report forms to allow for the distinction between medical and acceptability failures.

All failures will undergo vacuum aspiration or dilation and curettage. Material will be submitted for pathological examination.

B) Safety

Safety will be assessed utilizing the following parameters:

- Duration and severity of uterine bleeding; data obtained from subject diary, determination of hemoglobin, by treatment (e.g., transfusion, surgical procedure) necessary secondary to heavy and prolonged uterine bleeding.

- Occurrence of any adverse event or abnormal clinical finding (e.g., signs of pelvic infection).

- Adverse events linked to drug administration and abortion (e.g., nausea, vomiting, diarrhea, painful uterine contractions).

- Assessment of heart rate and blood pressure during the observation period following the administration of misoprostol.

Safety data will include all safety parameters at all visits both scheduled and unscheduled, as well as data collected in the subject's diary, of all subjects to whom mifepristone has been administered.

Acceptability will be measured by patient interviews at the final discharge visit. The assessments will be made on the basis of answers to questions concerning:

- satisfaction with the information and counseling,
- satisfaction with the procedure,
- comparison to previous abortion experience, where applicable,
- willingness to choose the method again, and,
- willingness to recommend the method to others.

All these variables will be assessed in light of the level of complications, discomforts, and side effects recorded for each patient on both the questionnaire and symptomatology diary.

Acceptability of the regimen will also be determined through a questionnaire for providers.

D) Feasibility of Use in the U.S. Health Care System

Variability is built into the study with regard to: Type of abortion site (hospital clinic, Planned Parenthood clinic, feminist health clinic, private practice, free-standing abortion clinic), ethnicity of patient, socioeconomic status (Medicare, self-pay, insurance, help fund, etc.), and location in inner city, small city, suburb, or rural area. The association of these factors with:

- adherence to the protocol
- complications and side effects
- failure (and type of failure)
- patient satisfaction with medical abortion
- provider comfort with medical abortion

will be analyzed.

8.2 ANALYTIC METHODS

8.2.0. A detailed plan, outlining in advance the statistical evaluation of each baseline, safety and efficacy variable, will be submitted to file prior to statistical examination of the data. Essential features of this plan, as presently anticipated, are described below.

[illegible] administration of mifepristone will be summarized. All variables pertaining to safety, efficacy and acceptability will be summarized.

8.2.2. Lifetable Analysis of Efficacy: Single and multiple decrement failure rates for each type of failure and for the total failure rate will be analyzed for each amenorrhea duration, and all durations. Failure rates, by duration of amenorrhea, for age, ethnic group, payment status, and service delivery groups will be determined.

8.2.3. Efficacy Analysis: Multinomial logistic models will be employed to evaluate efficacy. Successful abortion, incomplete expulsion, early surgical interruption due to medical necessity and early surgical interruption at the patient's request (no medical necessity) will serve as the outcome categories used to form response vectors for the models. In one model, the response vector will be comprised of the cumulative log odds over the three types of failure (i.e., incomplete expulsion, medical interruption and requested interruption). In another model, the response vector will be the log odds of these individual types of failure *per se*. In all models, the independent vector will be amenorrhea duration ($\leq$ 49 days, 50-56 days and 57-63 days).

The models will be used to test the overall (omnibus) effect of amenorrhea status. Additionally, pairwise contrasts among the amenorrhea groups will be evaluated. Both the overall effect and pairwise effects will be examined using traditional hypothesis tests to assess the *complete response vector* (i.e. all failure categories considered simultaneously). However, *individual response categories* will be examined in two ways. First, a traditional hypothesis test will be used to conduct a test of the overall affect of amenorrhea. Second, the examination of pairwise amenorrhea group contrasts will take the form of an equivalency test.

All traditional tests will be evaluated using a type I error rate of 0.05. Equivalence tests will be performed using 90% confidence intervals (which mathematically correspond to a type I error rate of 0.05) and an equivalence interval of $\pm$ 5 percentage points.

Single and or multiple decrement life table techniques, as appropriate, will be used to display failure rate probabilities by time, for individual amenorrhea group and all groups combined. The various effects examined using the multinomial logistic models will also be exhibited in tables and/or figures.

abortion (Days 4-13) [illegible] will be undertaken by a variety of multivariate techniques. This analysis pertains to aspects of efficacy, safety and acceptability.

8.2.5. Baseline/Safety Analysis. Qualitative baseline and safety variables will be systematically summarized in appropriate patient groupings for examination by the medical reviewer. Descriptive statistics for baseline and safety variables that are suitable for quantitative analysis will be displayed in tables and figures. Furthermore, these variable will be evaluated across amenorrhea groups using linear models, applied to continuous or categorical variables. Continuous variables expected to markedly deviate from normality will be rank transformed to obtain nonparametric tests of significance. Any baseline variable found to exhibit a meaningful difference across amenorrhea groups, will be considered for use as covariate or blocking factor in the efficacy analysis. As a conservative measure to increase statistical power, variables exhibiting p-values of 0.20 or less will be singled out to assess their potential relevance to the safety and efficacy of the study drug.

Analysis of variables associated with need for transfusion and with severe cardiovascular adverse events will be undertaken.

8.2.6. Acceptability Analysis: Analysis of variables associated with acceptability within each duration of amenorrhea and overall shall be undertaken using both univariate and multivariate techniques.

9. RISK-BENEFIT ASSESSMENT

Experience gained to date with the use of mifepristone and prostaglandin for the termination of early pregnancy indicates that this has few side effects and a frequency of short-term complications that is comparable to that observed after vacuum aspiration. The most common complaints during treatment, particularly following administration of the prostaglandin, are lower abdominal pain, nausea, vomiting and diarrhea. In addition, bleeding for several days is common. For these complaints, appropriate medication can be prescribed when required. Occasionally, heavy uterine bleeding may necessitate emergency curettage and, very rarely, blood transfusion.

subjects in this trial treated up to 49 days of amenorrhea will be adequate to undergo surgical termination of pregnancy. It is possible the failure rate will be higher in the older pregnancies. Recently obtained information supports the statement that mifepristone plus misoprostol cause abortion in approximately 95 percent of women with amenorrhea of no more than 49 days before administration of mifepristone. In women with amenorrhea of 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. This excess bleeding may be similar to that which occurs during a spontaneous miscarriage (i.e. more than a heavy menstrual period). The possibility of experiencing excess bleeding increases with increasing duration of amenorrhea** .

Following a treatment regimen involving the intramuscular injection of the prostaglandin analog sulprostone, in a very low percentage of cases (one in 20,000), serious cardiovascular complications have been observed, including one case of fatal myocardial infarction. These complications have been most often associated with subjects who were heavy smokers, and still these complications are extremely rare. There is no evidence that misoprostol, a different class of prostaglandin, which is widely prescribed for longterm use in the prevention and treatment of peptic ulcer disease, is associated with any such cardiovascular side effects.

All subjects will be informed as to the potential complications. Centers participating in the trial will ensure that qualified personnel and necessary equipment and supplies are available at all time to deal with any complications.

Studies conducted in mice and rats have shown that mifepristone does not have any teratogenic effects. There are insufficient data to evaluate the effects of mifepristone on the human fetus. In one subject in France who took mifepristone and failed to abort, pregnancy was terminated at 18 weeks because of fetal abnormalities. The precise relationship to mifepristone could not be established[5]. Thus, in the event of a continuing pregnancy, surgical abortion should be performed. Misoprostol has been reported to be teratogenic and is reported to be associated with malformations of the scalp, cranium and other abnormalities[7].

The benefits of this form of medical termination of pregnancy are that most women participating in the study can be expected to have a complete abortion and will not be exposed to the risks associated with surgical abortion, particularly the risks of physical trauma (e.g., cervical laceration, uterine perforation, etc). Nor does medical abortion carry any anesthetic-related risk.

No financial renumeration will be offered to potential study participants.

** Amendment 3 dated May 2, 1995

10. SIGNATURES

I have read the forgoing protocol and agree to conduct the study as outlined.

_____ ___/___/___

Signature of Investigator M D Y

_____ ___/___/___

Signature of Sponsor M D Y

Table 1

	Visit 1	Visit 2	Visit 3
Counseling	X		
Medical, OB-GYN History	X		
Medical Examination	X	X	X
Pelvic Examination	X	X	X
Urine Pregnancy Test	X		X*
Quant. Serum ßhCG	X		X*
Vaginal Ultrasound	X	X*	X*
Blood Typing including Rh	X		
Hemoglobin or Hematocrit Determination	X		X*
Administration of Mifepristone	X		
Administration of anti-D globulin		X*	
Administration of Misoprostol		X	
Interview and Review of Diary		X	X

* - To be conducted if indicated

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APPENDIX I

PROTOTYPE INFORMED CONSENT

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 B

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** 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.

**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 B

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*** . 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.

* 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

PROTOCOL NUMBER: 166 B

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**** . 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.*** 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

** Amendment 3 dated May 2, 1995

* Amendment 2 dated April 27, 1995

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 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** 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.**

**Amendment 3 dated May 2, 1995

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).

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. _____ (telephone:_____).

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 (institute, address, telephone no.) In addition, I will contact Dr. _____

(telephone:_____). If he or she cannot be reached in a medical emergency related to the study, I may contact Dr. _____ (telephone:_____).

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. _____(telephone:_ _____ or Dr. _____ (telephone:_____ 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 I refuse surgical abortion and continue with my pregnancy, I risk, and the infant may risk, complications, including fetal or infant malformation.

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.

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

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

Protocol:

Cover Sheet:	Change:	The Population Council to The Population Council, Inc.
	Change:	Written authorization from The Population Council, to written authorization **of** The Population Council
Table of Contents: 6.5:	Change:	SAFETY ASSESSMENT COMMITTEE to MEDICAL ADVISORY COMMITTEE
P. 3: First paragraph:	The word either was added in reference to parenteral or vaginal prostaglandins in combination with mifepristone	
P. 3: Last paragraph:	Change:	heart condition **to** heart complications
P. 4: Third paragraph:	Change:	as close as possible to as **closely** as possible
P. 4: Last paragraph:	Add:	Subject 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.**
	Add:	At the initial visit (Day 1); **after any required statutory waiting period.**
P. 5: second paragraph:	Change:	institutional insurance **to** general liability insurance
P. 6:	Add: 4.1.3	**Residents of the United States**
P. 6:	Add: 4.2.9	**Resident of the United States**
P. 7: 4.3.2	delete	~~—————~~
P. 7: 4.3.5	Add:	**or hematocrit below 30%**
P. 7: 4.3.7	Delete	~~————————————————————~~
	Add:	**Subjects with an IUD in place.**
P. 7: 4.3.15	Change to:	Women who cannot reach the source of emergency medical care that serves the abortion center within ~~————~~ from (a) their home or place or work and (b) the abortion center.

P. 8: Section 5.2		Change [illegible] orally:	
P. 9: Section 5.3	A)	Change to	Mifepristone will be provided as 200 mg tablets of micronized mifepristone
	B)	Change to:	Misoprostol will be obtained locally be each investigator as 200 µg tablets of commercially available misoprostol.
P. 9: Section 5.4:	A)	Change to:	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)	Change to:	Misoprostol will be obtained locally by each investigator as 200 µg tablets of commercially available misoprostol and dispensed from the center pharmacy.
P. 9: Section 5.5 paragraph 1		Change:	hypertension to hypotension
		Change:	should be avoided to **must** be avoided
P. 10: Section 6.1:		Change:	Serum βhCG test to quantitative serum βhCG.
		Change:	Determination of blood group and Rh status to Determination of Ph status and where routinely collected, the blood group.
P. 10: Last paragraph:		Add:	**No more than** 240 ml.
P. 11: Second paragraph:		Change:	Subjects will be given written information **to** Subjects will be given a copy of the informed consent and patient diary card.
		Change:	.... which receives patients ..... **to which cares** for patients.
Section 6.2:		Add:	**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.
	Last paragraph:	Delete:	~~———~~
		Add:	**, if indicated.**
P. 12:	First paragraph:	Add:	**No more than** 240 ml
	Second paragraph: Last sentence	Delete:	~~———~~
P. 13:	Section 6.2: Second to Last paragraph	9/6/94 last paragraph Change to:	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.
P. 13:	Section 6.2:	Add:	**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.**
P. 13:	Section 6.3:	Add:	**Subjects who experience bleeding post Day 15 should be followed-up via telephone until the bleeding has stopped or intervention is clinically indicated.**
P. 14:	after last paragraph:	Add:	**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.**
P. 15:	Section 6.5:	Change Heading:	Safety Assessment Committee to Medical Advisory Committee.
		Change Body:	Safety Assessment Committee to Medical Advisory Committee

P. 15	Section 6.7: first paragraph	Add:	A center must retain its records with respect to a subject who withdraws from the study after ingesting mifepristone and for whom a complete abortion has not been confirmed for a period of **at least 30 years following the subject's last visit to the center.**
P. 16:	Section 6.7: Second paragraph	Change:	Day 6 to 60 hours
P. 18:	Section A:	Change:	study drug to study drugs.
P. 20:	Section D:	Add:	**Except as otherwise explicitly set forth herein,**
P. 21:	Seventh paragraph:	Change:	submitted for histological examination to submitted for pathological examination
P. 27:		Add:	**Hemoglobin or Hematocrit Determination, Quant. Serum βhCG**
		Change:	Administration of ——— to Administration of anti-D globulin

Informed Consent:

Section 1	Change:	Approximately ——— to over 150,000
Section 2 Clinic Visits: Second paragraph last sentence:	Change:	or third visit to, visit 3,
Section 2 Clinic Visits:	Add:	paragraph 4

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.

Section 8: After last paragraph

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

The protocol is being amended in order to determine if any changes occur in the blood chemistry or hematology parameters of subjects following the administration of mifepristone and/or misoprostol. Blood samples will be collected as outlined below.

The following additions to the protocol are indicated.

Blood samples will be collected prior to the administration of mifepristone at Visit 1 for the following: ***(page 10 of protocol)***

Chemistry Panel (4m*L*)
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 (3m*L*)
Which includes:

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

Blood samples will again be collected at Visit 3 (Day 15) for the ***same measurements listed (page 13 of protocol)*** above.

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.

The notification process (contact and telephone number) Section 7.1 is modified to remove ~~telephone number~~ and

insert: **Dr. Irving Spitz or Dr. C. Wayne Bardin**
The Population Council, Inc.
(800) 327-8730

The informed consent text was modified to reflect the additional blood collections for chemistry and hematology. *(on pages 30, 31, 32)*.

Section 2 Clinic Visits

1st paragraph

..... 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.* In order to.....

3rd paragraph

..... 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.* If the treatment.....

Section 4 Risks and Discomforts

1st paragraph, 1st sentence

..... for the tests at the first *and third visits* may be.....

The protocol is being amended in order to reflect the recent data indicating an increased need for surgical procedures in Groups 2 and 3.

The additions to the protocol and informed consent are indicated.

Informed Consent

Page 25 add:

Recently obtained information supports the statement that mifepristone plus misoprostol cause abortion in approximately 95 percent of women with amenorrhea of no more than 49 days before administration of mifepristone. In women with amenorrhea of 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. This excess bleeding may be similar to that which occurs during a spontaneous miscarriage (i.e. more than a heavy menstrual period). The possibility of experiencing excess bleeding increases with increasing duration of amenorrhea.

Page 29 delete:

During the early stages of pregnancy, mifepristone plus misoprostol cause abortion in approximately 95 percent of women.

Page 29 add:

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.

Page 31: Section 2

Add:

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.

Page 33: Section 4

Add:

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.

last paragraph

Add:

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.

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

Center Number: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
001	11/08/94	11/10/94	11/22/94	CRAMPS	11/08/94	11/10/94	2	1	3	1
				THIRST	11/08/94	11/08/94	2	1	2	1
				NAUSEA	11/09/94	11/10/94	2	1	2	1
				CHILLS	11/09/94	11/09/94	2	1	2	1
				STOMACHACHE	11/09/94	11/09/94	2	1	2	1
				LEG CRAMPS	11/10/94	11/10/94	2	1	4	1
				HUNGER	11/10/94	11/10/94	2	1	1	1
				DIZZINESS	11/10/94	11/14/94	3	1	6	1
				COLD	11/30/94	12/09/94	1	1	1	1
				ENDOMETRITIS	12/02/94	12/23/94	1	2	1	1
				HEADACHES (INTERMITTENT)	12/14/94	12/23/94	1	1	1	1
				CRAMPS (INTERMITTENT)	12/14/94	12/23/94	1	1	1	1
				YEAST INFECTION	12/23/94	Ongoing	2	2	1	3
002	11/08/94		11/22/94	CRAMPING	11/10/94	11/10/94	1	2	3	1
				HEADACHE	11/10/94	11/10/94	2	2	2	1
003	11/09/94	11/11/94	11/22/94	CRAMPS	11/09/94	11/09/94	1	1	2	1
				CRAMPS	11/10/94	11/10/94	3	1	2	2
				CRAMPS	11/11/94	11/12/94	1	1	7	1
				CRAMPS	11/11/94	11/11/94	3	2	5	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
004	11/09/94	11/11/94	11/22/94	NAUSEA	11/09/94	11/09/94	1	1	2	1
				CRAMPS	11/10/94	11/10/94	2	1	2	1
				LIGHT-HEADEDNESS	11/10/94	11/10/94	1	1	1	1
005	11/15/94	11/17/94	11/30/94	HEADACHE	11/16/94	11/16/94	1	2	1	1
				CRAMPS	11/17/94	11/23/94	3	2	5	2
				CRAMPS	11/24/94	11/25/94	2	2	5	1
006	11/15/94	11/17/94	11/30/94	CRAMPS	11/15/94	11/16/94	1	1	2	4
				DIZZINESS	11/16/94	11/17/94	3	1	2	2
				WEAKNESS	11/16/94	11/17/94	3	1	2	2
				FATIGUE	11/16/94	11/17/94	3	1	2	1
				NAUSEA	11/16/94	11/17/94	3	1	1	2
				STOMACH PAIN	11/16/94	11/17/94	2	1	2	1
				CRAMPS	11/16/94	11/17/94	2	1	3	1
				CRAMPS	11/17/94	11/17/94	3	2	5	2
				WEAKNESS	11/17/94	11/22/94	2	1	6	1
				DIZZINESS	11/17/94	11/22/94	2	1	6	1
				NAUSEA	11/17/94	11/19/94	2	1	6	1
				CRAMPS	11/18/94	11/24/94	2	2	7	1
007	11/15/94	11/17/94	11/30/94	NAUSEA	11/15/94	11/17/94	3	1	2	1
				DEPRESSION	11/15/94	11/17/94	2	1	1	1
				CRAMPS	11/15/94	11/15/94	1	2	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
007 (Cont.)				HEADACHE	11/16/94	11/17/94	1	2	2	1
				CRAMPS	11/17/94	11/18/94	2	2	5	1
008	11/15/94	11/17/94	12/01/94	CRAMPS	11/15/94	11/17/94	1	1	2	1
				STOMACHACHE	11/15/94	11/17/94	1	1	2	1
				BACTERIAL VAGINOSIS	11/15/94	Ongoing	2	2	1	3
				CRAMPS	11/17/94	11/20/94	1	1	7	1
009	11/16/94	11/18/94	11/30/94	CRAMPS	11/16/94	11/18/94	2	2	2	4
				NAUSEA	11/16/94	11/18/94	1	1	2	1
				VOMITING	11/16/94	11/18/94	1	1	2	1
				TWITCHINESS (WITH CRAMPS)	11/16/94	11/18/94	2	1	1	1
				HEADACHES	11/18/94	11/23/94	2	2	6	1
				CRAMPS	11/18/94	11/23/94	3	2	7	1
				NAUSEA	11/18/94	11/25/94	1	1	6	1
010	11/16/94	11/18/94	11/30/94	CRAMPS	11/17/94	11/17/94	1	2	3	1
				ABD. PAIN	11/19/94	11/20/94	2	1	6	1
				CRAMPS	11/21/94	11/22/94	1	1	7	1
011	11/16/94	11/18/94	11/30/94	NAUSEA	11/16/94	11/18/94	3	2	3	1
				HEADACHES	11/16/94	11/18/94	2	2	3	1
				CRAMPS	11/16/94	11/29/94	2	2	3	1
				DIARRHEA	11/16/94	11/18/94	2	1	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
011 (Cont.)				VOMITING	11/16/94	11/18/94	3	2	3	1
				CRAMPS	11/30/94	12/13/94	1	1	1	1
012	11/21/94	11/23/94	12/07/94	CRAMPS	11/22/94	11/23/94	1	1	2	1
013	11/21/94	11/23/94	12/07/94	CRAMPS	11/21/94	11/23/94	1	2	3	3
				NAUSEA	11/21/94	11/23/94	1	1	2	1
				CRAMPS	11/23/94	11/26/94	1	2	7	1
014	11/30/94	12/02/94	12/15/94	THICK CLEAR DISCHARGE	11/30/94	11/30/94	1	1	1	1
				CRAMPS	11/30/94	11/30/94	1	1	3	1
				CRAMPS	12/01/94	12/01/94	3	2	3	1
				NAUSEA	12/02/94	12/02/94	1	1	7	1
				CRAMPS	12/04/94	12/04/94	3	2	7	1
015	11/30/94	12/02/94	12/14/94	CRAMPS	12/02/94	12/02/94	2	1	7	1
016	11/30/94	12/02/94	12/14/94	PRESSURE IN LOWER BACK	11/30/94	12/02/94	3	1	2	2
				NERVOUS, FLU-LIKE STOMACHACHE	11/30/94	12/02/94	2	1	2	2
				CRAMPS	11/30/94	11/30/94	1	1	2	4
				CRAMPS	12/01/94	12/01/94	2	1	2	4
				CRAMPS	12/02/94	12/05/94	3	1	7	2
				COLD/CHILLS	12/02/94	12/02/94	2	1	1	1
				PRESSURE IN LOWER BACK	12/03/94	Ongoing	2	1	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
016 (Cont.)				NERVOUS, FLU-LIKE STOMACHACHE	12/03/94	Ongoing	1	1	1	3
				CRAMPS	12/06/94	12/09/94	2	1	7	4
				CRAMPS	12/10/94	12/15/94	3	1	1	2
				EXCESSIVE BLEEDING	12/12/94	12/14/94	3	1	7	1
				ENDOMETRITIS	12/14/94	Ongoing	2	2	7	3
				CRAMPS	12/16/94	12/16/94	1	1	1	1
017	11/30/94	12/02/94	12/15/94	NAUSEA	11/30/94	12/02/94	3	1	3	1
				HEADACHES	11/30/94	12/02/94	1	2	2	1
				DIZZINESS	12/02/94	12/02/94	2	1	6	1
				CRAMPS	12/02/94	12/06/94	2	1	7	1
018	11/30/94	12/02/94	12/14/94	CRAMPS	11/30/94	11/30/94	1	2	3	4
				CRAMPS	12/01/94	12/02/94	3	2	3	1
				VOMITING	12/01/94	12/01/94	1	1	2	4
				NAUSEA	12/01/94	12/01/94	1	2	2	1
				NAUSEA	12/02/94	12/13/94	3	2	6	1
				VOMITING	12/02/94	12/03/94	3	1	6	1
				CRAMPS	12/06/94	12/06/94	1	1	1	1
019	11/30/94	12/02/94	12/14/94	CRAMPS	11/30/94	11/30/94	2	1	1	4
				CRAMPS	12/01/94	12/02/94	3	2	3	2
				CRAMPS	12/03/94	12/06/94	2	2	7	2
				HEADACHE	12/04/94	12/08/94	2	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
019 (Cont.)				CRAMPS	12/07/94	12/07/94	1	2	7	1
020	11/30/94	12/02/94	12/15/94	NAUSEA	11/30/94	12/04/94	3	1	1	1
				HEADACHE	11/30/94	11/30/94	2	2	1	1
				ARM PAIN FROM BLD DRAW	11/30/94	11/30/94	2	2	1	1
				BREAST ENLARGEMENT	11/30/94	01/06/95	2	1	1	1
				CRAMPS	12/01/94	12/02/94	2	2	3	2
				CRAMPS	12/03/94	12/04/94	1	2	5	1
				ANEMIA	12/15/94	Ongoing	2	2	7	3
				CRAMPS	01/06/95	03/02/95	3	2	1	1
				EXCESSIVE BLDG.	01/06/95	01/06/95	2	2	7	1
				PINCHING ON LOWER (L) SIDE	02/09/95	02/09/95	2	1	1	1
				FATIGUE	02/11/95	03/02/95	2	1	1	1
				LIGHTHEADEDNESS	02/11/95	03/02/95	2	1	1	1
				EXCESSIVE BLDG.	02/17/95	02/17/95	2	2	1	1
021	11/30/94	12/02/94	12/14/94	NAUSEA	11/30/94	12/03/94	1	1	1	1
				HEADACHE	11/30/94	12/01/94	2	2	2	1
				DIARRHEA	12/01/94	12/02/94	3	1	3	1
				CRAMPS	12/02/94	12/06/94	3	2	7	2
				CRAMPS	12/07/94	12/11/94	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
022	12/07/94	12/09/94	12/23/94	NAUSEA	12/07/94	12/07/94	2	1	2	1
				DIARRHEA	12/16/94	12/16/94	2	1	1	1
				ABDOMINAL CRAMPS	12/16/94	12/16/94	2	1	1	1
				HEADACHE	12/16/94	12/16/94	2	2	1	1
023	12/07/94	12/09/94	12/21/94	NAUSEA	12/07/94	12/07/94	1	1	2	1
				CRAMPS	12/08/94	12/08/94	1	1	3	1
				NAUSEA	12/08/94	12/08/94	3	1	3	1
				WEAK	12/08/94	12/08/94	3	1	1	1
				DIZZY	12/08/94	12/08/94	3	1	2	2
				DIZZY	12/09/94	12/09/94	2	1	6	1
				SWEATING	12/09/94	12/09/94	3	1	6	1
				VOMITING	12/09/94	12/09/94	2	1	5	1
				STUFFY NOSE	12/09/94	12/09/94	1	1	1	1
				THROBBING UTERINE PAIN	12/11/94	12/12/94	2	2	6	1
				FEVER	12/11/94	12/12/94	2	1	1	1
				INFECTION (ENDOMETRITIS)	12/11/94	12/21/94	2	2	6	1
024	12/07/94	12/09/94		NAUSEA	12/07/94	12/09/94	3	1	3	1
				CRAMPS	12/08/94	12/08/94	1	1	2	1
				DIARRHEA	12/08/94	12/08/94	1	1	2	1
				EMESIS	12/09/94	12/09/94	2	1	4	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
025	12/07/94	12/09/94	12/20/94	FEVERISH	12/07/94	12/10/94	2	1	1	4
				FATIGUE	12/07/94	12/13/94	2	1	1	1
				NAUSEA	12/07/94	12/07/94	1	1	2	1
				CRAMPS	12/08/94	12/08/94	1	2	3	4
				NAUSEA	12/08/94	12/08/94	2	1	2	4
				NAUSEA	12/09/94	12/11/94	3	1	6	1
				CRAMPS	12/09/94	12/12/94	3	2	7	2
				FEVER	12/11/94	12/13/94	3	1	1	1
				VOMITING	12/11/94	12/11/94	2	1	1	1
				CRAMPS	12/13/94	12/13/94	2	2	7	2
				CRAMPS	12/14/94	12/16/94	1	1	7	1
				ANEMIA	12/20/94	Unknown	2	2	2	[5]
026	12/07/94	12/09/94	12/22/94	UPPER ABDOMINAL PAIN	12/07/94	12/07/94	1	1	3	1
				CRAMPING	12/07/94	12/07/94	2	1	3	1
				VOMITING	12/08/94	12/09/94	3	1	3	1
				CHILLS	12/08/94	12/09/94	1	1	3	1
				NAUSEA	12/08/94	12/09/94	3	1	2	1
				DIARRHEA	12/08/94	12/08/94	3	2	1	1
				FEVERISH	12/08/94	12/08/94	2	2	1	1
				SWOLLEN LIP	12/09/94	Ongoing	1	1	1	3
				CRAMPING	12/09/94	12/09/94	3	2	5	2
				CRAMPING	12/10/94	12/11/94	1	2	7	1
				CRAMPING	12/12/94	12/13/94	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
026 (Cont.)				HEADACHE	12/12/94	12/12/94	2	2	1	1
027	12/07/94	12/09/94	12/22/94	NAUSEA	12/07/94	12/09/94	3	1	3	1
				CHILLS	12/07/94	12/08/94	1	1	2	1
				CRAMPS	12/09/94	12/22/94	3	2	7	2
				CRAMPS	12/23/94	12/24/94	2	1	6	1
				CRAMPS	12/25/94	12/30/94	1	1	6	1
				VAGINAL SORENESS	01/14/95	01/19/95	2	2	1	1
				VAGINAL BURNING	01/14/95	01/19/95	2	2	1	1
				PELVIC PAIN	01/14/95	01/19/95	2	2	1	1
				ENDOMETRITIS	01/14/95	01/26/95	2	2	6	1
				DISCHARGE	01/16/95	01/18/95	1	1	6	1
				BACK PAIN	01/21/95	02/01/95	2	2	1	1
				PELVIC PAIN	01/21/95	02/01/95	2	2	1	1
				VAGINAL BURNING	01/30/95	02/01/95	2	1	1	1
028	12/07/94	12/09/94	12/22/94	HEADACHE	12/08/94	12/08/94	1	2	2	1
				CHILLS	12/09/94	12/09/94	2	1	1	1
				CRAMPS	12/10/94	12/11/94	2	2	7	1
				HEADACHE	12/12/94	12/12/94	3	2	1	2
				HEADACHE	12/13/94	12/16/94	2	2	1	1
				CRAMPS	12/13/94	12/15/94	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
029	12/14/94	12/16/94	12/29/94	CHILLS	12/16/94	12/16/94	3	1	1	1
030	12/14/94	12/16/94	12/29/94	NAUSEA	12/15/94	12/15/94	1	1	2	1
				CRAMPS	12/15/94	12/15/94	1	2	2	1
				CRAMPS	12/16/94	12/17/94	2	2	7	1
031	12/14/94	12/16/94	12/28/94	NAUSEA	12/15/94	12/15/94	1	1	2	1
				CHILLS	12/16/94	12/16/94	3	1	1	1
				CRAMPS (ABD PAIN)	12/16/94	12/18/94	2	2	7	2
				TRANSIENT HYPOTENSION	12/16/94	12/16/94	2	1	5	1
				CRAMPS	12/19/94	12/19/94	1	1	7	1
032	12/20/94	12/22/94		NAUSEA	12/21/94	12/22/94	1	1	2	1
				VOMITING	12/21/94	12/22/94	1	1	2	1
				CRAMPS	12/22/94	Ongoing	2	1	7	3
033	12/21/94	12/23/94	01/18/95	DIZZINESS	12/21/94	12/23/94	2	1	1	1
				HEADACHE	12/21/94	12/21/94	2	2	2	1
				NAUSEA	12/21/94	12/21/94	2	1	2	1
				CRAMPS	12/23/94	12/24/94	2	2	7	1
				EXCESSIVE BLEEDING *SEE ATTACHED REPORT	12/29/94	12/29/94	3	3	7	1
				MIGRAINES	12/29/94	01/03/95	3	2	1	1
				SYNCOPE	12/29/94	12/29/94	3	3	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
033 (Cont.)				ANEMIA	12/29/94	Ongoing	2	2	7	2
034	12/21/94	12/23/94	01/05/95	NAUSEA	12/21/94	12/22/94	3	1	2	2
				NAUSEA	12/22/94	12/23/94	2	1	2	1
				CRAMPING	12/23/94	12/24/94	2	1	7	2
				CRAMPING	12/25/94	12/28/94	1	1	7	1
035	12/21/94	12/23/94	01/04/95	NAUSEA	12/21/94	12/23/94	3	1	2	1
				CRAMPING	12/21/94	12/23/94	1	1	2	3
				CRAMPING	12/23/94	12/27/94	3	2	7	1
				CRAMPING	12/29/94	12/30/94	1	1	6	1
037	12/21/94	12/23/94	01/06/95	CRAMPS	12/21/94	12/23/94	1	1	3	1
				NAUSEA	12/22/94	12/24/94	2	1	2	2
				LIGHTHEADEDNESS	12/23/94	12/23/94	3	1	1	1
				FATIGUE	12/23/94	12/23/94	3	1	1	1
				WEAKNESS	12/23/94	12/23/94	3	1	1	1
				SYNCOPE	12/23/94	12/23/94	2	1	1	1
				HEADACHE	12/24/94	12/31/94	1	2	1	1
				NAUSEA	12/25/94	12/31/94	1	1	1	1
				LIGHTHEADEDNESS	12/26/94	12/31/94	1	1	1	1
				FEVER	01/11/95	01/11/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
038	12/21/94	12/23/94	01/25/95	CRAMPS	12/21/94	12/23/94	1	1	2	1
				NAUSEA	12/21/94	12/22/94	2	1	2	4
				NAUSEA	12/22/94	12/23/94	3	1	2	1
				HEADACHE	12/22/94	12/22/94	2	2	1	1
039	12/27/94	12/29/94	01/12/95	CRAMPS	12/27/94	12/29/94	2	2	3	1
				STREP THROAT	01/03/95	01/11/95	2	2	1	1
				FATIGUE	01/03/95	01/11/95	2	1	1	1
040	12/27/94	12/29/94	01/13/95	CRAMPS	12/27/94	12/29/94	1	1	3	4
				COUGH	12/28/94	12/28/94	2	1	1	1
				CRAMPS	12/29/94	12/30/94	3	2	7	2
				HEAVY BLEEDING	12/29/94	12/29/94	3	2	7	1
				CRAMPS	12/31/94	01/17/95	1	1	7	1
041	12/27/94	12/29/94	01/12/95	FATIGUE	12/27/94	12/31/94	2	1	1	1
				GENERAL ACHINESS	12/27/94	12/31/94	2	2	1	1
				HEADACHES	12/27/94	12/31/94	2	2	2	1
				CRAMPS	12/29/94	01/02/95	3	2	7	2
				CRAMPS	01/03/95	01/03/95	2	1	7	1
				SINUS ACHE	01/10/95	01/11/95	1	2	1	1
				CRAMPS	01/12/95	01/12/95	2	1	7	2
				CRAMPS	01/13/95	01/13/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
042	12/27/94	12/29/94	01/13/95	VOMITING	12/27/94	12/28/94	2	1	2	1
				NOSE BLEED	12/27/94	12/27/94	3	1	1	1
				CRAMPS	01/01/95	01/01/95	3	2	7	1
				BACK PAIN	01/01/95	01/01/95	3	2	6	1
				HEADACHE	01/02/95	01/02/95	2	2	6	1
043	01/04/95	01/06/95	01/19/95	YEAST INFECTION *	01/04/95	01/19/95	1	2	1	1
				CRAMPS	01/05/95	01/06/95	2	2	3	2
				CRAMPS	01/06/95	01/08/95	1	2	7	1
				HEADACHE	01/14/95	01/15/95	2	2	1	1
				DIARRHEA	01/18/95	01/19/95	2	2	1	1
				FEVER	01/18/95	01/19/95	2	2	1	1
				VIRUS	02/08/95	02/12/95	2	2	1	1
044	01/04/95	01/06/95	01/19/95	DIARRHEA	01/04/95	01/04/95	1	1	2	1
				DEPRESSION	01/05/95	01/05/95	2	1	1	1
				NAUSEA	01/09/95	01/10/95	1	1	6	1
				VOMITING	01/09/95	01/10/95	1	1	6	1
045	01/04/95	01/06/95	01/19/95	NAUSEA	01/04/95	01/05/95	2	1	2	1
				VOMITING	01/04/95	01/05/95	2	1	2	1
				CRAMPS	01/05/95	01/05/95	1	2	3	1
				YELLOWISH DISCHARGE	01/05/95	01/06/95	1	1	1	1
				LOW BACK PAIN/PRESSURE	01/06/95	01/10/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
045 (Cont.)				HEADACHES	01/19/95	01/26/95	2	1	1	1
046	01/04/95	01/06/95	01/20/95	CRAMPS	01/04/95	01/05/95	2	2	3	1
				EYES ACHING (BACK OF EYES)	01/04/95	01/04/95	2	1	1	1
				DIZZINESS	01/06/95	01/06/95	2	1	1	1
				CRAMPS	01/06/95	01/07/95	3	2	7	1
047	01/04/95	01/06/95	01/19/95	DIZZINESS	01/05/95	01/05/95	2	1	1	1
				NAUSEA	01/05/95	01/06/95	2	1	6	1
				VOMITING	01/06/95	01/06/95	2	1	6	1
				CRAMPS	01/06/95	01/06/95	2	2	7	4
				FATIGUE	01/06/95	01/06/95	2	1	1	1
				CRAMPS	01/07/95	01/08/95	3	2	7	1
				DIARRHEA	01/07/95	01/08/95	3	1	6	1
				CONSTIPATION	01/13/95	01/13/95	3	1	1	1
				CONSTIPATION	01/17/95	01/17/95	1	1	1	1
048	01/04/95	01/06/95		HEADACHES	01/04/95	01/06/95	3	2	2	2
				CRAMPS	01/04/95	01/06/95	1	2	3	4
				CRAMPS	01/06/95	Ongoing	2	[5]	7	3
				HEADACHES	01/06/95	Ongoing	2	[5]	6	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
049	01/11/95	01/13/95	01/27/95	HEADACHE	01/12/95	01/12/95	1	1	2	1
				CHILLS	01/13/95	01/13/95	2	1	1	1
				CRAMPS	01/13/95	01/14/95	[5]	1	7	1
				BACKACHE	01/15/95	01/15/95	1	1	6	1
				CRAMPS	01/16/95	01/16/95	[5]	1	7	1
				ENDOMETRITIS	01/27/95	02/22/95	2	2	7	1
050	01/11/95	01/13/95	01/25/95	HEADACHE	01/11/95	01/11/95	2	1	2	1
				NAUSEA	01/11/95	01/11/95	1	1	2	1
				CRAMPING	01/11/95	01/12/95	1	1	3	1
				NAUSEA	01/12/95	01/12/95	2	1	2	1
				BACKACHE	01/13/95	01/13/95	2	1	6	1
				CRAMPING IN THIGHS	01/13/95	01/17/95	2	1	6	1
				NAUSEA	01/13/95	01/13/95	1	1	6	1
				VOMITING	01/13/95	01/13/95	3	1	6	1
				FAINTNESS/PASSING OUT	01/13/95	01/13/95	3	3	1	1
				EXCESSIVE BLEEDING	01/13/95	01/13/95	3	3	7	1
				HEADACHE	01/15/95	01/23/95	3	2	1	1
051	01/11/95	01/13/95	01/27/95	CRAMPS	01/12/95	01/12/95	2	1	2	1
				CRAMPS	01/13/95	01/13/95	1	1	7	4
				CRAMPS	01/13/95	01/14/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
052	01/11/95	01/13/95	01/25/95	NAUSEA	01/11/95	01/12/95	1	1	2	1
				HEADACHE	01/24/95	01/25/95	1	2	1	1
053	01/18/95	01/20/95	02/01/95	NAUSEA	01/18/95	01/19/95	2	1	2	1
				CRAMPS	01/18/95	01/18/95	1	1	3	1
				CRAMPS	01/20/95	01/20/95	2	1	5	1
				DIZZINESS	01/20/95	01/20/95	3	1	6	1
				SYNCOPE	01/20/95	01/20/95	1	1	1	1
				CRAMPS	02/01/95	02/01/95	2	1	6	1
054	01/18/95	01/20/95	02/01/95	CRAMPS	01/19/95	01/19/95	1	1	3	1
				DIZZINESS	01/20/95	01/20/95	1	1	1	1
				CRAMPS	01/20/95	01/20/95	2	1	7	2
				FEVER	01/20/95	01/21/95	2	2	1	1
				CRAMPS	01/21/95	01/25/95	1	1	7	1
055	01/18/95	01/20/95	02/03/95	NAUSEA	01/18/95	01/18/95	2	1	3	1
				NAUSEA (PRE-MIS)	01/20/95	01/20/95	3	1	2	1
				VOMITING (PRE-MIS)	01/20/95	01/20/95	3	1	2	1
				CRAMPS	01/20/95	01/24/95	2	2	7	2
				CRAMPS (PRE-MIS)	01/20/95	01/20/95	1	1	3	2
				CRAMPS	01/25/95	01/25/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
056	01/18/95	01/20/95	02/01/95	HOT FLASHES	01/18/95	01/18/95	3	1	1	1
				SHAKINESS	01/19/95	01/20/95	2	1	1	1
				LIGHTHEADEDNESS	01/19/95	01/20/95	2	1	1	1
				HEARTBURN	01/20/95	01/20/95	1	1	1	1
				EXCESSIVE BLEEDING	01/20/95	01/20/95	3	2	5	1
				HEADACHE	01/20/95	01/20/95	2	2	6	1
				CRAMPS	01/24/95	01/24/95	1	1	7	1
057	01/18/95	01/20/95	02/01/95	NAUSEA	01/18/95	01/19/95	2	1	2	1
				VOMITING	01/18/95	01/19/95	2	1	2	1
				CRAMPS	01/19/95	01/19/95	3	1	3	2
				CRAMPS	01/20/95	01/24/95	1	2	7	1
058	01/25/95	01/27/95	02/10/95	NAUSEA	01/25/95	01/27/95	2	2	2	1
				CRAMPS	01/25/95	01/26/95	1	2	3	4
				TINGLING FINGERS	01/27/95	01/27/95	2	1	1	1
				(L) LEG NUMB	01/27/95	01/27/95	2	1	1	1
				CRAMPS	01/27/95	01/27/95	3	2	5	2
				CRAMPS	01/28/95	02/01/95	2	2	7	1
059	01/25/95	01/27/95	02/08/95	CRAMPS	01/25/95	01/26/95	1	1	3	1
				HEADACHE	01/25/95	01/25/95	1	1	2	4
				HEADACHE	01/26/95	01/26/95	2	1	2	1
				PAIN/CRAMPS	01/28/95	02/03/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
060	01/25/95	01/27/95	02/10/95	NAUSEA	01/26/95	01/26/95	3	1	2	1
				CRAMPS	01/27/95	01/31/95	1	1	7	1
				HEADACHE	01/30/95	01/30/95	2	2	1	1
				HEADACHE	02/09/95	02/09/95	2	2	1	1
061	01/25/95	01/27/95	02/08/95	CRAMPS	01/27/95	01/27/95	2	1	5	1
				CRAMPS	01/29/95	01/29/95	1	1	7	1
062	02/01/95	02/03/95	02/15/95	CRAMPS	02/02/95	02/03/95	2	2	3	4
				CRAMPS	02/03/95	02/03/95	3	2	5	2
				CRAMPS	02/03/95	02/07/95	2	2	7	1
				CHILLS	02/03/95	02/03/95	2	1	4	1
				WEAK	02/04/95	02/04/95	1	1	7	1
				LIGHT-HEADED	02/04/95	02/04/95	1	1	7	1
063	02/01/95	02/03/95	02/16/95	BACTERIAL VAGINOSIS (PRE-STUDY)	02/01/95	02/16/95	2	2	1	1
				NAUSEA	02/01/95	02/01/95	1	1	3	1
				CRAMPS	02/03/95	02/06/95	3	2	7	1
064	02/01/95	02/03/95	02/16/95	NAUSEA	02/02/95	02/02/95	1	1	2	1
				CRAMPS	02/02/95	02/02/95	2	1	3	1
				CRAMPS	02/03/95	02/04/95	2	1	5	2
				CRAMPS	02/05/95	02/16/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
065	02/01/95	02/03/95	02/15/95	YEAST INFECTION (PRE-STUDY)	02/01/95	02/15/95	2	1	1	1
				CRAMPS	02/02/95	02/06/95	1	2	3	1
				DISCHARGE	02/09/95	Ongoing	1	1	1	3
066	02/08/95	02/10/95	02/23/95	CRAMPS	02/10/95	02/10/95	2	2	7	2
				CRAMPS	02/11/95	02/15/95	1	1	7	1
067	02/08/95	02/10/95	02/22/95	NAUSEA	02/08/95	02/08/95	2	1	2	2
				CRAMPS	02/08/95	02/08/95	2	1	3	2
				NAUSEA	02/09/95	02/09/95	1	1	2	4
				CRAMPS	02/09/95	02/09/95	1	1	3	1
				NAUSEA	02/10/95	02/10/95	3	1	1	1
				COLD (SNEEZING, RUNNY NOSE, SORE THROAT)	02/11/95	02/12/95	1	2	1	1
				CRAMPS	02/12/95	02/12/95	1	1	7	1
				HEADACHE	02/12/95	02/12/95	2	2	1	1
068	02/08/95	02/10/95	02/22/95	CRAMPS	02/08/95	02/10/95	1	1	3	1
				HEADACHE	02/19/95	02/19/95	2	2	1	1
				COLD	02/19/95	Ongoing	2	2	1	2
069	02/08/95	02/10/95	02/22/95	CRAMPS	02/08/95	02/10/95	2	2	2	3
				HEADACHE	02/08/95	02/09/95	2	2	2	2
				NAUSEA	02/08/95	02/10/95	2	1	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
069 (Cont.)				DIARRHEA	02/09/95	02/09/95	2	1	2	1
				CRAMPS	02/10/95	02/17/95	2	2	7	4
				HEADACHE	02/10/95	02/10/95	1	2	4	4
				NAUSEA	02/11/95	02/11/95	3	1	6	1
				HEADACHE	02/11/95	02/11/95	2	2	4	2
				HEADACHE	02/12/95	Ongoing	1	2	1	3
				CRAMPS	02/18/95	02/19/95	3	2	7	2
				CRAMPS	02/20/95	02/22/95	2	2	7	1
				HOT/COLD SWEATS	02/20/95	02/25/95	3	1	1	1
				FEVERISH	02/20/95	02/25/95	3	2	1	1
				ENDOMETRITIS	02/22/95	03/02/95	2	2	7	1
				CRAMPS	02/24/95	02/26/95	1	2	1	1
				EXCESSIVE BLEEDING	03/03/95	03/04/95	3	4	7	1
070	02/08/95	02/10/95	02/22/95	FATIGUE	02/01/95	02/10/95	2	1	1	1
				NAUSEA	02/08/95	02/08/95	3	2	2	2
				VOMITING	02/08/95	02/08/95	3	2	2	1
				HEADACHE	02/09/95	02/09/95	2	1	2	1
				NAUSEA	02/09/95	02/09/95	2	1	2	1
				HEADACHE	02/10/95	02/10/95	3	1	6	1
				WEAKNESS	02/10/95	02/10/95	3	1	1	1
				BACK PAIN	02/10/95	02/10/95	3	1	4	1
				CHILLS	02/10/95	02/10/95	2	1	4	1
				CRAMPS (UTERINE)	02/10/95	02/10/95	2	1	5	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
070 (Cont.)				MUSCLE SPASMS IN LEGS/RECTUM	02/10/95	02/11/95	3	1	6	2
				CRAMPS (UTERINE)	02/12/95	02/12/95	2	1	7	1
				MUSCLE SPASMS IN RECTUM/LEGS	02/12/95	02/16/95	2	1	6	2
				CRAMPS (UTERINE)	02/14/95	02/15/95	3	1	7	1
				COLD SORE	02/16/95	02/19/95	2	2	1	1
				MUSCLE SPASMS IN RECTUM/LEGS	02/17/95	Ongoing	1	1	6	3
071	02/15/95	02/17/95	03/03/95	HEADACHE	02/15/95	02/15/95	1	1	2	1
				CRAMPS	02/15/95	02/15/95	1	1	3	4
				FATIGUE	02/15/95	02/15/95	1	1	1	4
				CRAMPS	02/16/95	02/16/95	2	2	2	4
				CHILLS	02/16/95	02/16/95	1	1	1	1
				FEVERISH	02/16/95	02/16/95	1	1	1	1
				FATIGUE	02/16/95	02/16/95	2	1	1	1
				CRAMPS	02/17/95	02/17/95	3	2	5	2
				CRAMPS	02/18/95	02/18/95	2	2	7	2
				HEADACHE	02/18/95	02/18/95	2	2	1	1
				CRAMPS	02/19/95	02/19/95	1	2	7	1
				FATIGUE	02/19/95	02/19/95	2	1	1	2
				FATIGUE	02/20/95	Ongoing	1	1	1	3
				FEVER	02/21/95	02/21/95	1	1	1	1
				ABD. PAIN	02/22/95	03/01/95	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.

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

Center Number: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
072	02/15/95	02/17/95	04/26/95	NAUSEA	02/15/95	02/17/95	2	1	4	1
				CRAMPING	02/16/95	02/16/95	[5]	1	7	1
				BACKACHE	02/16/95	02/16/95	[5]	1	6	1
				CRAMPING	02/17/95	Ongoing	2	[5]	7	[5]
				EXCESSIVE BLDG	02/17/95	03/15/95	2	1	7	1
				ENDOMETRITIS/SALPINGITIS	04/26/95	05/02/95	1	2	7	1
				INGUINAL LYMPHADENOPATHY	04/26/95	Ongoing	[5]	1	1	3
073	02/15/95			VOMITING	02/15/95	02/16/95	3	3	2	1
				NAUSEA	02/15/95	02/16/95	3	3	2	1
				STOMACH UPSET (DUE TO DOXY PER PT.)	02/16/95	02/20/95	2	1	1	1
074	02/15/95	02/17/95	03/02/95	BLOATED	02/15/95	02/15/95	2	1	1	1
				CRAMPS	02/15/95	02/15/95	1	1	3	4
				NAUSEA	02/16/95	02/16/95	2	1	2	1
				CRAMPS	02/16/95	02/16/95	2	1	2	1
				LIGHTHEADED SECONDARY TO BLDG.	02/17/95	02/17/95	1	1	5	1
				CRAMPS	02/17/95	02/17/95	3	2	5	2
				CONSTIPATED	02/17/95	02/17/95	1	1	1	1
				ANEMIA	02/17/95	03/02/95	1	2	6	1
				CRAMPS	02/18/95	02/18/95	1	2	7	4
				HEADACHE	02/18/95	02/18/95	[5]	2	1	1
				CRAMPS	02/19/95	02/19/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
074 (Cont.)				HEADACHE	02/24/95	02/24/95	[5]	2	1	1
075	02/15/95	02/17/95	03/02/95	DIARRHEA	02/16/95	02/16/95	2	1	1	1
				CRAMPS	02/16/95	02/17/95	1	1	2	3
				CRAMPS	02/17/95	02/18/95	1	1	7	1
				STREP THROAT	02/27/95	Ongoing	3	2	1	3
076	02/22/95	02/24/95		NAUSEA (PRE-MIS)	02/22/95	02/24/95	2	1	2	4
				CRAMPS (PRE-MIS)	02/23/95	02/24/95	3	1	3	3
				CRAMPS (POST-MIS)	02/24/95	Unknown	3	2	7	[5]
				NAUSEA (POST-MIS)	02/24/95	Unknown	3	[5]	4	[5]
077	02/22/95	02/24/95	03/09/95	STOMACH PAIN	02/22/95	02/22/95	1	1	2	4
				WEAKNESS	02/22/95	02/22/95	3	1	1	1
				DIZZINESS	02/22/95	02/22/95	3	1	1	1
				STOMACH PAIN	02/23/95	02/23/95	2	1	2	4
				CRAMPS	02/24/95	02/24/95	3	2	5	1
078	02/22/95	02/24/95	03/10/95	NAUSEA	02/22/95	02/22/95	3	1	2	2
				FATIGUE	02/22/95	02/25/95	2	1	1	1
				VOMITING (VOMITED MIFEPRISTONE)	02/22/95	02/22/95	2	2	3	1
				NAUSEA	02/22/95	02/24/95	1	2	3	1
				CRAMPS	02/24/95	02/24/95	1	1	5	1
				FEVER (PT. SAYS DUE TO FLU)	03/08/95	03/10/95	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
078 (Cont.)				FLU SX	03/08/95	03/10/95	2	1	1	1
079	02/22/95	02/24/95	03/17/95	NAUSEA	02/22/95	02/24/95	1	1	2	1
				CRAMPS	02/22/95	02/24/95	2	1	5	3
				CRAMPS	02/24/95	02/25/95	2	2	7	1
080	02/22/95	02/24/95		NAUSEA	02/23/95	02/24/95	2	1	2	1
				DIZZINESS	02/24/95	02/24/95	1	1	6	1
081	02/22/95	02/24/95	03/16/95	NAUSEA	02/22/95	02/24/95	2	1	2	3
				HEADACHE	02/22/95	02/22/95	1	2	2	1
				CRAMPS	02/24/95	02/26/95	3	2	7	2
				NAUSEA	02/24/95	03/03/95	2	1	6	1
				CRAMPS	02/27/95	03/01/95	1	2	7	1
				VAGINAL DISCHARGE	03/16/95	04/12/95	1	1	1	1
				CRAMPS	03/31/95	04/07/95	2	1	7	1
082	02/22/95	02/24/95		NAUSEA	02/23/95	02/23/95	1	1	2	1
				DEPRESSION	02/23/95	02/23/95	2	1	1	1
				CRAMPS	02/24/95	Unknown	3	2	5	[5]
083	03/01/95	03/03/95	03/17/95	HEADACHE	03/01/95	03/01/95	1	2	2	1
				NAUSEA	03/01/95	03/01/95	3	1	2	1
				CRAMPS	03/01/95	03/02/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
083 (Cont.)				CRAMPS	03/03/95	03/03/95	3	2	5	2
				CRAMPS	03/04/95	03/05/95	2	2	7	2
				HEADACHE	03/05/95	03/05/95	1	2	1	1
				CRAMPS	03/07/95	03/07/95	2	1	7	1
				CRAMPS	03/21/95	03/22/95	2	1	1	1
				HEADACHE	03/21/95	03/21/95	2	2	1	1
				CRAMPS	04/11/95	04/11/95	3	1	1	1
084	03/01/95	03/03/95		NAUSEA (PRE-MIS)	03/02/95	03/03/95	1	1	1	1
				NAUSEA (AFTER-MIS)	03/03/95	03/03/95	1	1	2	1
085	03/01/95	03/03/95	03/21/95	NAUSEA	03/01/95	03/03/95	3	2	1	2
				CRAMPING	03/01/95	03/03/95	1	1	3	4
				FATIGUE	03/01/95	03/05/95	2	1	1	1
				LOW BACK PAIN	03/01/95	03/05/95	2	1	2	1
				NAUSEA	03/03/95	03/05/95	1	1	6	1
				CRAMPING	03/03/95	03/03/95	3	2	5	2
				CRAMPING	03/03/95	03/05/95	2	2	7	1
086	03/01/95	03/03/95	03/21/95	NAUSEA	02/22/95	03/03/95	3	1	1	1
				CHILLS	03/03/95	03/03/95	1	1	4	1
				CRAMPS	03/03/95	03/05/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
087	03/01/95	03/03/95	04/04/95	CRAMPING	03/01/95	03/01/95	1	1	3	1
				FATIGUE	03/01/95	03/01/95	2	1	1	1
				EXCESSIVE BLEEDING	03/03/95	03/03/95	2	2	7	1
				CRAMPS / ABD. PAIN	03/03/95	03/03/95	3	2	5	2
				CRAMPS	03/03/95	03/03/95	1	2	5	1
088	03/01/95	03/03/95	03/24/95	NAUSEA	02/07/95	03/03/95	1	1	1	1
				WEAKNESS	02/07/95	03/01/95	2	1	1	4
				HEADACHE	03/01/95	03/03/95	1	1	2	1
				SLEEPINESS	03/01/95	03/01/95	3	1	1	1
				WEAKNESS	03/02/95	03/02/95	3	1	1	1
				WEAKNESS	03/02/95	03/03/95	3	1	1	1
				CHILLS	03/03/95	03/03/95	2	1	4	1
				CRAMPS	03/03/95	03/05/95	3	2	7	2
				CRAMPS	03/06/95	03/06/95	2	1	7	1
089	03/01/95	03/03/95		HEADACHE	03/02/95	03/02/95	1	1	1	1
090	03/08/95	03/10/95	03/24/95	CRAMPS	03/08/95	03/10/95	2	2	3	1
				CRAMPS	03/10/95	03/14/95	2	2	7	1
				NAUSEA	03/10/95	03/10/95	2	1	5	1
				HEADACHE	03/12/95	03/12/95	2	2	1	1
				CRAMPS	04/04/95	04/04/95	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
091	03/08/95	03/10/95	03/30/95	CRAMPING	03/08/95	03/09/95	1	2	3	1
				WEAK	03/10/95	03/10/95	1	1	5	1
				TIRED	03/10/95	03/10/95	1	1	5	1
				CRAMPING	03/14/95	03/14/95	1	2	7	1
				COLD	03/14/95	03/14/95	1	2	1	1
				HEADACHE	03/21/95	03/21/95	1	2	1	1
092	03/08/95	03/10/95	03/29/95	CRAMPS	03/08/95	03/08/95	1	1	3	1
				CRAMPS	03/09/95	03/09/95	2	1	3	1
				CRAMPS	03/10/95	03/10/95	2	1	7	1
				BLOATED	03/12/95	03/12/95	3	1	1	1
				CRAMPS	03/12/95	03/12/95	2	1	7	1
093	03/08/95	03/10/95	03/23/95	CRAMPS	03/13/95	03/15/95	3	2	7	1
094	03/08/95	03/10/95	03/29/95	HEADACHES	03/08/95	03/08/95	1	2	1	1
				HEADACHE	03/14/95	03/17/95	1	2	1	1
				CRAMPS	03/14/95	03/17/95	1	2	1	1
				ALLERGIES	03/24/95	Ongoing	2	2	1	3
				SINUS PROBS	03/24/95	Ongoing	2	2	1	3
095	03/08/95	03/10/95		CRAMPING	03/08/95	03/09/95	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
096	03/15/95	03/17/95	03/31/95	NAUSEA	03/15/95	03/17/95	2	1	2	1
				VOMITING	03/15/95	03/17/95	2	1	2	1
				CRAMPS	03/18/95	03/18/95	1	1	7	1
097	03/15/95	03/17/95	04/04/95	CRAMPS	03/17/95	03/20/95	1	1	7	1
				CRAMPS	03/23/95	03/23/95	3	1	7	1
098	03/15/95	03/17/95	03/30/95	TWINGES ("NOT REALLY CRAMPS")	03/16/95	03/16/95	1	1	2	1
				LOWER BACK SORENESS	03/17/95	03/17/95	2	1	1	1
				CRAMPS	03/17/95	03/17/95	2	1	5	1
099	03/15/95	03/17/95	04/04/95	BREAST TENDERNESS	03/08/95	03/19/95	3	1	1	2
				CRAMPS	03/15/95	03/16/95	1	2	3	4
				ANXIETY/RACY HEART	03/15/95	03/16/95	1	1	1	1
				MUSCLE TENSION - BURNING PAIN IN JAW & THIGHS	03/15/95	03/17/95	1	2	1	4
				DEHYDRATION	03/15/95	03/17/95	2	1	1	1
				BACK PAIN	03/15/95	03/19/95	1	2	1	4
				LOW-GRADE FEVER	03/15/95	04/03/95	1	1	6	1
				NAUSEA	03/15/95	03/16/95	1	1	2	1
				CRAMPS	03/17/95	03/17/95	3	2	5	1
				BURNING/SHOOTING PAINS UP THIGH & ALL OVER BODY & ABD. AREA	03/17/95	03/22/95	3	2	1	1
				NAUSEA	03/17/95	03/17/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
099 (Cont.)				CRAMPS	03/20/95	03/21/95	3	2	7	1
				BACK PAIN	03/20/95	03/21/95	3	2	1	2
				HOT FLASHES	03/20/95	03/22/95	3	1	1	1
				NAUSEA	03/20/95	03/22/95	1	1	6	1
				BREAST TENDERNESS	03/20/95	03/20/95	2	1	1	2
				BREAST TENDERNESS	03/21/95	03/22/95	1	1	1	1
				BACK PAIN	03/22/95	04/03/95	1	1	1	1
100	03/15/95	03/17/95		LOWER BACK ACHE	03/16/95	03/17/95	2	1	1	1
				CRAMPING	03/17/95	Unknown	2	2	5	[5]
101	03/22/95	03/24/95	04/05/95	NAUSEA (PRE-STUDY X 3-1/2 WKS)	03/22/95	03/24/95	1	1	1	1
				BACTERIAL VAGINOSIS (PRE-STUDY)	03/22/95	04/05/95	2	2	1	1
				POSS. ENDOMETRITIS (PRE-STUDY)	03/22/95	04/05/95	1	2	1	1
				PELVIC TENDERNESS (& WITH PRE-STUDY U/S)	03/22/95	04/05/95	1	1	1	1
				CRAMPS (PRE-MIS)	03/23/95	03/23/95	1	1	3	4
				HEADACHE	03/23/95	03/26/95	2	2	2	1
				CRAMPS (AFTER-MIS)	03/24/95	03/24/95	2	2	5	2
				CRAMPS	03/25/95	03/25/95	1	2	7	1
102	03/22/95	03/24/95	04/06/95	BACKACHE (LOWER BACK PAIN)	03/22/95	03/24/95	1	1	1	4
				CRAMPS	03/22/95	03/24/95	1	1	3	1
				NAUSEA	03/22/95	03/24/95	1	1	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
102 (Cont.)				VOMITING (PRE-MIS)	03/24/95	03/24/95	2	1	1	1
				HEADACHE	03/24/95	04/04/95	2	2	1	1
				BACKACHE	03/24/95	03/24/95	2	2	4	1
				NAUSEA	03/24/95	03/24/95	3	1	4	1
				CRAMPS	04/04/95	04/05/95	2	2	1	1
				ABD. PAIN	04/04/95	04/05/95	2	2	1	1
				BACKACHE	04/04/95	04/04/95	2	2	1	2
				PELVIC PAIN	04/04/95	04/05/95	2	2	1	1
				BACKACHE	04/05/95	04/20/95	1	2	1	1
103	03/22/95	03/24/95	04/07/95	NAUSEA	03/22/95	03/24/95	3	2	2	1
				VOMITING	03/22/95	03/24/95	3	2	2	2
				EXCESSIVE BLEEDING	03/24/95	03/24/95	2	2	7	1
				VOMITING	03/24/95	03/24/95	2	2	6	1
				CRAMPS	03/24/95	03/24/95	1	1	5	1
				ORTHOSTATIC HYPOTENSION	03/24/95	03/24/95	2	1	4	1
				ANKLES SWOLLEN	03/28/95	03/30/95	1	1	1	1
				TOOTHACHE	04/03/95	Ongoing	2	2	1	3
104	03/29/95	03/31/95		NAUSEA	03/30/95	03/31/95	2	1	2	1
				VOMITING	03/30/95	03/31/95	2	1	2	1
				CRAMPS	03/30/95	03/30/95	2	2	2	1
				CRAMPING	03/31/95	Unknown	3	2	5	[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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
105	03/29/95	03/31/95	04/12/95	CRAMPS	03/29/95	03/29/95	2	1	3	2
				GAS/DIARRHEA	03/29/95	03/29/95	2	1	2	1
				CRAMPS	03/30/95	03/31/95	3	2	3	3
				CRAMPS	03/30/95	03/30/95	1	2	3	4
				FATIGUE	03/30/95	03/30/95	1	1	1	1
				CRAMPS	03/31/95	04/07/95	3	2	7	1
				HEADACHE	03/31/95	04/01/95	1	1	6	1
				DIARRHEA	04/01/95	04/01/95	2	1	4	1
				DIARRHEA	04/03/95	04/03/95	1	1	4	1
106	03/29/95	03/31/95	04/18/95	VOMITING	03/29/95	03/30/95	2	1	2	1
				NAUSEA	03/29/95	03/29/95	1	1	2	1
				TENSION (R) HIP AREA	03/30/95	03/30/95	1	1	1	1
				NAUSEA	03/31/95	03/31/95	2	1	6	1
				CRAMPS	03/31/95	04/01/95	2	2	5	4
				CRAMPS	04/02/95	04/03/95	3	2	7	2
				CRAMPS	04/04/95	04/05/95	2	2	7	2
				CRAMPS	04/06/95	04/06/95	1	2	7	1
				COLD/CONGESTION	04/14/95	04/14/95	1	2	1	1
107	03/29/95	03/31/95	04/28/95	CRAMPS	03/31/95	04/02/95	1	2	5	1
				VOMITING	04/01/95	04/01/95	3	1	6	1
				CRAMPS	04/06/95	04/07/95	1	1	1	1
				CRAMPS	04/10/95	04/10/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
108	03/29/95	03/31/95	04/14/95	CONGESTION	03/29/95	03/31/95	2	2	1	1
				CRAMPING	03/30/95	03/31/95	1	1	3	3
				COUGH	03/30/95	03/30/95	1	2	1	4
				CRAMPING	03/31/95	03/31/95	1	1	5	1
				COUGH	03/31/95	03/31/95	2	2	1	4
				FEVER	03/31/95	04/01/95	3	2	1	2
				MACULAR RASH ON CHEEKS	03/31/95	03/31/95	2	1	2	2
				MACULAR RASH ON CHEEKS	03/31/95	04/02/95	1	2	2	1
				BACKACHE	03/31/95	04/14/95	1	2	1	1
				HEADACHE	03/31/95	04/02/95	3	2	1	1
				COUGH	04/01/95	04/01/95	3	2	1	2
				COUGH	04/02/95	04/08/95	1	2	1	1
				FEVER	04/02/95	04/03/95	1	2	1	1
				CRAMPING	04/03/95	04/04/95	1	1	7	1
				CRAMPING	04/20/95	04/20/95	1	1	7	1
				YELLOWISH D/C	05/02/95	Ongoing	1	1	1	3
109	03/29/95	03/31/95	04/18/95	CRAMPS	03/30/95	03/31/95	1	1	3	4
				CRAMPS	03/31/95	04/02/95	3	2	7	1
110	03/29/95	03/31/95	04/20/95	CRAMPS	03/29/95	03/31/95	1	1	3	4
				QUEASY (NAUSEOUS)	03/29/95	03/29/95	1	1	2	1
				CRAMPS	04/01/95	04/01/95	2	1	7	4
				CRAMPS	04/02/95	04/04/95	3	1	7	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
110 (Cont.)				CRAMPS	04/05/95	04/05/95	2	1	7	2
				CRAMPS	04/07/95	04/07/95	2	1	7	2
				CRAMPS	04/08/95	04/10/95	1	1	7	1
				CRAMPS	04/12/95	04/12/95	1	1	7	1
111	04/05/95	04/07/95	04/20/95	NAUSEA	04/05/95	04/05/95	2	1	2	2
				CRAMPS	04/06/95	04/07/95	2	1	2	3
				CRAMPS	04/07/95	04/13/95	2	2	7	1
				HEADACHE	04/12/95	04/13/95	2	2	1	1
112	04/05/95	04/07/95	04/25/95	HEADACHE (PRE STUDY X 1-2 WKS)	04/01/95	04/07/95	1	1	1	1
				CRAMPS	04/06/95	04/06/95	1	1	2	1
				CRAMPS (AFTER - MIS)	04/07/95	04/07/95	1	1	5	1
				CRAMPS (AFTER - MIS)	04/07/95	04/07/95	3	1	5	2
113	04/05/95	04/07/95		CRAMPS (PRE-MIS)	04/06/95	04/07/95	2	1	1	3
				HEADACHE	04/07/95	04/11/95	3	2	6	1
				CRAMPS (AFTER-MIS)	04/07/95	04/10/95	2	1	5	4
				CRAMPS (AFTER-MIS)	04/07/95	04/07/95	3	1	5	2
				CRAMPS	04/11/95	04/11/95	3	2	7	1
114	04/05/95	04/07/95	04/20/95	FATIGUE	04/05/95	04/10/95	1	1	1	1
				NAUSEA	04/05/95	04/06/95	2	1	2	1
				CRAMPS	04/05/95	04/07/95	1	1	3	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
114 (Cont.)				CRAMPS	04/07/95	04/09/95	1	1	7	1
				CRAMPS	04/07/95	04/07/95	3	1	5	2
115	04/05/95	04/07/95	04/28/95	CRAMPS	04/06/95	04/06/95	3	2	3	1
				NAUSEA	04/06/95	04/06/95	2	1	2	1
				EXCESSIVE BLEEDING WITH CLOTS	04/25/95	04/26/95	3	1	6	1
116	04/05/95	04/07/95	04/18/95	NAUSEA	04/05/95	04/05/95	3	1	2	1
				CRAMPS	04/06/95	04/06/95	3	1	3	1
				NAUSEA	04/07/95	04/08/95	3	1	4	1
				CRAMPS (AFTER MIS)	04/07/95	04/07/95	3	2	5	1
				EXCESSIVE BLDG.	04/07/95	04/07/95	3	2	5	1
				FEVER	04/08/95	04/08/95	2	1	1	1
				HEADACHES	04/11/95	04/17/95	3	2	1	2
				HEADACHE	04/18/95	Ongoing	1	1	1	3
117	04/12/95	04/14/95	06/16/95	DIZZINESS	04/13/95	04/13/95	1	1	1	1
				NAUSEA	04/14/95	04/14/95	1	1	4	1
				CRAMPS	04/14/95	04/14/95	1	1	5	1
118	04/12/95	04/14/95		FATIGUE	04/12/95	04/14/95	2	1	2	1
				INSOMNIA	04/12/95	04/14/95	2	1	1	1
				NAUSEA	04/12/95	04/14/95	2	1	2	1
				CRAMPS	04/13/95	04/13/95	2	2	3	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
118 (Cont.)				CRAMPS	04/14/95	04/14/95	3	1	5	1
119	04/12/95	04/14/95	05/03/95	NAUSEA	04/12/95	04/13/95	2	1	2	1
				VOMITING	04/12/95	04/13/95	3	1	2	1
				CRAMPS	04/12/95	04/12/95	1	1	3	4
				CRAMPS	04/13/95	04/13/95	3	2	3	2
				CRAMPS	04/13/95	04/13/95	2	2	3	4
				CRAMPS	04/14/95	04/15/95	1	2	3	1
				CRAMPS	04/18/95	04/18/95	1	1	7	1
120	04/12/95	04/14/95	04/27/95	NAUSEA	04/12/95	04/12/95	3	1	2	2
				NAUSEA	04/13/95	04/13/95	2	1	2	4
				NAUSEA	04/14/95	04/14/95	3	1	4	1
				CRAMPS	04/14/95	04/14/95	1	1	7	1
				DIARRHEA	04/14/95	04/14/95	2	1	5	1
121	04/12/95	04/14/95	05/02/95	CRAMPS	04/13/95	04/14/95	1	1	3	4
				CRAMPS	04/14/95	04/15/95	3	1	5	2
				DIARRHEA	04/14/95	04/14/95	1	1	5	1
				CRAMPS	04/16/95	04/16/95	1	1	7	1
122	04/12/95	04/14/95	05/19/95	NAUSEA - PRE-STUDY	04/12/95	04/12/95	1	1	1	4
				FATIGUE - PRE-STUDY	04/12/95	04/14/95	1	1	1	1
				NAUSEA	04/13/95	04/13/95	2	1	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
122 (Cont.)				VOMITING	04/13/95	04/13/95	2	1	2	2
				HEADACHE	04/13/95	04/15/95	2	2	1	1
				NAUSEA	04/14/95	04/14/95	1	1	6	1
				VOMITING	04/14/95	04/14/95	1	1	6	1
				CRAMPS	04/14/95	04/15/95	3	2	7	1
				CRAMPS (AFTER MIS)	04/14/95	04/14/95	2	2	5	4
				VAGINAL DISCHARGE	05/11/95	05/15/95	2	1	1	1
123	04/26/95	04/28/95	05/11/95	CRAMPS	04/26/95	04/28/95	3	2	3	3
				NAUSEA (PRE-STUDY X 2-3 WKS)	04/26/95	04/28/95	2	1	2	1
				VOMITING	04/26/95	04/28/95	2	1	2	1
				VAGINAL DISCHARGE	04/26/95	04/26/95	2	1	1	1
				CRAMPS	04/28/95	05/02/95	3	2	7	1
124	04/26/95	04/28/95	05/19/95	CRAMPS	04/26/95	04/28/95	3	2	3	1
				HEADACHE	04/26/95	04/26/95	1	2	2	1
				CRAMPS (AFTER MIS)	04/28/95	04/28/95	3	1	5	2
				CRAMPS (AFTER MIS)	04/28/95	05/02/95	1	1	7	1
				FATIGUE	05/01/95	05/01/95	1	1	1	1
				CRAMPS	05/01/95	05/01/95	1	1	7	1
				HEADACHES	05/02/95	05/19/95	2	2	1	1
				SHARP PAIN IN (L) BREAST	05/17/95	06/23/95	1	1	1	1
				OCC. TWINGE AROUND (L) OVARY	06/14/95	07/05/95	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: 3

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	04/26/95	04/28/95	05/10/95	NAUSEA	04/26/95	04/28/95	3	1	2	2
				NAUSEA	04/28/95	04/30/95	1	1	6	1
				CRAMPS	04/28/95	05/05/95	1	1	7	1
				CRAMPS (AFTER MIS)	04/28/95	04/28/95	3	2	5	2
				VOMITING	04/28/95	04/28/95	3	1	5	1
126	05/03/95	05/05/95	05/17/95	CRAMPS	05/03/95	05/04/95	2	1	3	2
				CRAMPS (PRE-MIS)	05/05/95	05/05/95	1	1	3	4
				CRAMPS (AFTER-MIS)	05/05/95	05/05/95	3	2	7	2
				CRAMPS	05/06/95	05/06/95	1	1	5	4
				CRAMPS	05/07/95	05/08/95	3	1	7	2
				CRAMPS	05/09/95	05/09/95	1	1	7	1
127	05/03/95	05/05/95	05/16/95	CRAMPS	05/03/95	05/04/95	1	1	1	4
				CRAMPS	05/04/95	05/05/95	2	1	2	4
				CRAMPS	05/05/95	05/08/95	2	1	4	4
				CRAMPS	05/05/95	05/05/95	3	1	7	2
				CRAMPS	05/08/95	05/09/95	3	2	6	1
128	05/03/95	05/05/95	06/14/95	CRAMPS	05/04/95	05/05/95	2	1	3	4
				CRAMPS (AFTER-MIS)	05/05/95	05/05/95	3	2	5	2
				CRAMPS (AFTER-MIS)	05/05/95	05/05/95	2	2	5	4
				CRAMPS (AFTER-MIS)	05/05/95	05/09/95	3	2	7	1
				STIFFNESS IN BACK / NECK	05/05/95	05/05/95	2	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: 3

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	05/03/95	05/05/95		NAUSEA	05/03/95	05/03/95	2	1	2	1
				CRAMPS	05/04/95	05/04/95	3	1	3	1
				CRAMPS (AFTER MIS)	05/05/95	Unknown	2	2	5	[5]
130	05/03/95	05/05/95		CRAMPS	05/09/95	08/08/95	2	2	1	1
				DISCHARGE	05/19/95	08/08/95	2	2	1	1
				PELVIC PAIN	06/21/95	06/27/95	1	1	1	4
				ABDOMINAL PRESSURE	06/28/95	08/08/95	1	1	1	1
				PELVIC PAIN	06/28/95	07/05/95	3	2	1	1
				ENDOMETRITIS / SALPINGITIS	06/28/95	08/08/95	2	2	1	1
				PELVIC PAIN	07/21/95	08/08/95	2	2	1	1
				(L) SIDED ADNEXAL PAIN	07/21/95	08/08/95	2	2	1	1
131	05/09/95	05/11/95	05/24/95	FATIGUE	05/10/95	05/10/95	1	1	1	1
				NAUSEA	05/10/95	05/11/95	2	1	2	1
				FAINTING	05/11/95	05/11/95	3	1	5	1
				DRY HEAVING	05/11/95	05/11/95	2	1	2	1
				CRAMPS	05/11/95	05/11/95	1	2	5	4
				CRAMPS	05/11/95	05/14/95	3	2	7	1
				CRAMPS	05/11/95	05/11/95	2	2	5	4
				CRAMPS	05/17/95	05/17/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
132	05/09/95	05/11/95	05/24/95	HEADACHES	05/09/95	05/09/95	3	2	2	2
				NAUSEA	05/09/95	05/09/95	3	1	2	1
				VOMITING	05/09/95	05/09/95	1	1	2	1
				HEADACHES	05/10/95	05/10/95	1	2	2	1
				EXHAUSTION	05/10/95	05/10/95	2	1	1	1
				CRAMPS	05/10/95	05/11/95	1	1	3	4
				CRAMPS (AFTER MIS)	05/11/95	05/11/95	3	2	5	2
				CRAMPS (AFTER MIS)	05/11/95	05/11/95	1	2	5	1
				DIARRHEA	05/11/95	05/12/95	2	1	4	1
				HEADACHES	05/12/95	05/12/95	3	2	2	1
				BACK PAIN	05/13/95	05/14/95	2	2	1	1
				CRAMPS	05/15/95	05/16/95	1	1	6	1
				DIARRHEA	05/16/95	05/16/95	2	1	1	1
				CRAMPS	05/19/95	05/19/95	2	1	1	1
133	05/17/95	05/19/95		CRAMPS (AFTER-MIS)	05/19/95	05/19/95	3	1	5	2
				CRAMPS (AFTER-MIS)	05/19/95	Unknown	2	[5]	5	[5]
134	05/17/95	05/19/95		CRAMPING	05/18/95	05/19/95	1	1	3	4
				CRAMPING (AFTER-MIS)	05/19/95	05/19/95	3	1	5	2
				CRAMPING (AFTER-MIS)	05/19/95	Unknown	2	1	7	1
				"IN & OUT OF CONSCIOUSNESS"	05/21/95	05/21/95	[5]	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
135	05/24/95	05/26/95	06/09/95	FATIGUE	05/24/95	05/26/95	3	1	2	1
				NAUSEA	05/25/95	05/26/95	1	1	2	1
				CRAMPS	05/26/95	05/26/95	2	1	5	2
				CRAMPS	05/27/95	05/27/95	1	1	7	1
136	05/24/95	05/26/95	06/08/95	CRAMPS	05/24/95	05/24/95	1	1	2	4
				CRAMPS (PRE-MIS)	05/25/95	05/26/95	2	1	2	4
				CRAMPS (AFTER-MIS)	05/26/95	05/28/95	2	2	5	2
				CRAMPS (AFTER-MIS)	05/26/95	05/26/95	3	2	5	2
				CONSTIPATED	05/27/95	05/30/95	2	1	1	1
				CRAMPS	05/29/95	05/31/95	1	1	7	1
				CRAMPS	06/05/95	06/06/95	1	1	1	1
137	05/24/95	05/26/95	06/05/95	CRAMPS (PRE-MIS)	05/24/95	05/26/95	2	2	1	4
				NAUSEA	05/24/95	05/24/95	1	1	1	4
				SADNESS	05/25/95	05/25/95	1	1	1	1
				NAUSEA	05/25/95	05/26/95	2	1	2	4
				CRAMPS (POST-MIS)	05/26/95	05/26/95	3	2	5	2
				NAUSEA (AFTER-MIS)	05/26/95	05/26/95	3	1	6	2
				NAUSEA (AFTER-MIS)	05/26/95	05/26/95	1	1	6	1
				CRAMPS	05/27/95	05/27/95	2	1	7	4
				CRAMPS	05/28/95	05/28/95	3	1	7	2
				CRAMPS	05/29/95	05/29/95	2	1	7	2
				CRAMPS	05/30/95	06/01/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
137 (Cont.)				HEADACHE	05/30/95	05/30/95	1	1	1	1
138	05/24/95	05/26/95	06/07/95	FELT WARM (PRE-MIS)	05/26/95	05/26/95	1	1	1	1
				CRAMPS	05/26/95	05/26/95	1	1	5	1
139	05/31/95	06/02/95	06/14/95	NAUSEA	06/01/95	06/01/95	3	1	2	1
				CRAMPS	06/01/95	06/01/95	3	1	3	2
				CRAMPS (PRE-MIS)	06/02/95	06/02/95	1	1	3	4
				CRAMPS (AFTER-MIS)	06/02/95	06/06/95	3	2	5	2
				EXCESSIVE BLEEDING	06/02/95	06/02/95	1	1	5	1
				CRAMPS	06/06/95	06/10/95	1	2	7	1
140	05/31/95	06/02/95	06/14/95	FATIGUE	05/31/95	05/31/95	3	1	2	1
				CRAMPS	05/31/95	05/31/95	1	1	3	4
				NAUSEA	06/01/95	06/01/95	3	1	2	1
				VOMITING	06/01/95	06/01/95	3	1	2	3
				CRAMPS	06/01/95	06/01/95	2	2	3	2
				HEADACHE	06/02/95	06/02/95	1	1	1	1
				NAUSEA (AFTER-MIS)	06/02/95	06/02/95	3	1	4	2
				NAUSEA (AFTER-MIS)	06/02/95	06/02/95	2	1	4	1
				VOMITING (AFTER-MIS)	06/02/95	06/02/95	3	1	4	1
				HEAT FLASHES	06/02/95	06/02/95	2	1	4	1
				COLD SWEATS	06/02/95	06/02/95	2	1	4	1
				CRAMPS (PRE-MIS)	06/02/95	06/02/95	1	1	3	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: 3

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 (Cont.)				CRAMPS (AFTER-MIS)	06/02/95	06/02/95	2	2	5	1
141	05/31/95	06/02/95	06/15/95	FATIGUE		Unknown	2	1	1	[5]
				NAUSEA	05/31/95	05/31/95	1	1	1	4
				FATIGUE	05/31/95	06/01/95	3	1	2	2
				HOT FLASHES	05/31/95	06/13/95	2	1	1	1
				CHILLS	05/31/95	06/13/95	2	1	1	1
				CRAMPS	05/31/95	06/02/95	1	1	2	4
				NAUSEA	06/01/95	06/02/95	2	1	2	2
				FATIGUE	06/01/95	06/01/95	2	1	2	4
				NAUSEA	06/02/95	06/02/95	1	1	2	4
				NAUSEA	06/02/95	06/02/95	2	1	2	1
				FATIGUE	06/02/95	06/03/95	3	1	6	1
				CRAMPS (AFTER-MIS)	06/02/95	06/02/95	2	2	5	4
				CRAMPS (AFTER-MIS)	06/02/95	06/02/95	3	2	5	2
				CRAMPS (AFTER-MIS)	06/03/95	06/03/95	2	2	5	1
				FATIGUE	06/09/95	06/09/95	3	1	1	1
				MOODY	06/09/95	06/09/95	3	1	1	1
				CRAMPS	06/09/95	06/10/95	2	2	7	4
				EXCESSIVE BLDG	06/11/95	06/11/95	2	2	7	1
				CRAMPS	06/11/95	06/11/95	3	2	7	2
				CRAMPS	06/12/95	06/14/95	2	1	7	1
				ENDOMETRITIS	06/13/95	07/14/95	1	2	1	1
				ANEMIA	06/13/95	06/15/95	2	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
141 (Cont.)				ANEMIA	06/15/95	07/14/95	1	2	1	1
				BROWN MUCOUSY DISCHARGE	06/23/95	06/29/95	2	1	1	1
142	06/07/95	06/09/95	06/22/95	NAUSEA	06/07/95	06/09/95	1	1	2	1
				CRAMPS (PRE-MIS)	06/08/95	06/09/95	1	2	3	4
				CRAMPS (AFTER-MIS)	06/09/95	06/12/95	1	2	7	1
143	06/07/95	06/09/95	06/21/95	HEADACHE	06/07/95	06/07/95	3	1	2	1
				CRAMPS (AFTER-MIS)	06/09/95	06/09/95	2	2	5	4
				CRAMPS	06/09/95	06/10/95	3	2	7	2
				CRAMPS	06/10/95	06/10/95	1	1	7	4
				CRAMPS	06/10/95	06/10/95	3	1	7	1
				SKIN REACTION (AFTER STARTING DOXYCYCLINE)	06/21/95	06/26/95	3	1	1	1
				COLD	07/11/95	Unknown	2	1	1	[5]
144	06/07/95	06/09/95	06/22/95	PAIN / CRAMPS	06/07/95	06/09/95	1	2	3	4
				HEADACHE - HAD PRE STUDY	06/07/95	06/08/95	2	2	1	1
				NAUSEA - HAD PRE-STUDY	06/07/95	06/13/95	3	1	1	1
				VOMITING - HAD PRE-STUDY	06/07/95	06/13/95	3	1	1	1
				CRAMPS (AFTER-MIS)	06/09/95	06/09/95	3	2	5	2
				CRAMPS (AFTER-MIS)	06/09/95	06/09/95	2	1	7	1
				CRAMPS	06/12/95	06/12/95	1	1	7	1
				CRAMPS	06/14/95	06/15/95	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
144 (Cont.)				CRAMPS (ON & OFF)	06/22/95	07/07/95	1	1	1	1
				OCCASIONAL SHARP PAIN (L) SIDE	06/22/95	07/07/95	2	1	1	1
				SPORADIC D/C: STRINGY, LIGHT BROWN	06/22/95	07/07/95	1	1	1	1
				BLOOD IN STOOL (POSSIBLY)	07/07/95	Unknown	2	1	1	1
145	06/07/95	06/09/95	06/22/95	LEG CRAMPS	06/08/95	06/08/95	2	2	2	1
				MUSCLE ACHES	06/08/95	06/08/95	2	2	2	1
				STOMACH CRAMPS (PRE-MIS)	06/08/95	06/08/95	1	2	1	3
				STOMACH CRAMPS (PRE-MIS)	06/08/95	06/09/95	1	2	3	4
				CRAMPS (AFTER-MIS)	06/09/95	06/09/95	1	1	5	1
				STOMACH CRAMPS (PRE-MIS)	06/10/95	06/11/95	3	2	7	2
				NAUSEA	06/10/95	06/10/95	3	1	6	1
				VOMITING	06/10/95	06/10/95	3	1	6	1
				STOMACH CRAMPS	06/12/95	06/13/95	1	2	7	4
				STOMACH CRAMPS	06/14/95	06/14/95	3	2	7	2
				STOMACH CRAMPS	06/15/95	06/15/95	2	2	7	2
				CRAMPS	06/16/95	06/16/95	1	1	1	1
				CRAMPS	06/19/95	06/19/95	3	2	1	2
				CRAMPS	06/20/95	06/20/95	2	2	1	4
146	06/14/95	06/16/95	06/28/95	CRAMP	06/14/95	06/14/95	2	1	3	1
				WATERY DISCHARGE	06/15/95	06/15/95	2	1	1	1
				FATIGUE	06/16/95	06/16/95	1	1	1	1
				CONTRACTIONS	06/16/95	06/16/95	3	1	5	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
146 (Cont.)				CRAMPS (AFTER-MIS)	06/16/95	06/16/95	2	1	5	1
				NAUSEA	06/16/95	06/16/95	1	1	5	1
				CONTRACTIONS / CRAMPS	06/18/95	06/18/95	3	1	7	2
				CRAMPS	06/19/95	06/20/95	1	1	7	4
				ACHES IN LEG MUSCLES	06/19/95	Unknown	3	1	1	[5]
				SIATIC NERVE PAIN	06/19/95	Unknown	3	1	1	[5]
				SORE (IN UTERINE AREA AND VAGINALLY)	06/19/95	06/28/95	1	1	7	1
				CRAMPS	06/20/95	06/28/95	2	1	7	1
				(EARLY) ENDOMETRITIS	06/28/95	Unknown	1	2	7	[5]
147	06/21/95	06/23/95		DIZZINESS	06/21/95	06/21/95	2	1	2	1
				FREQUENT URINATION	06/21/95	06/21/95	2	1	1	1
				HEADACHE	06/21/95	06/22/95	[5]	2	2	1
				CRAMPS	06/22/95	06/22/95	1	2	3	4
				CRAMPS (AFTER-MIS)	06/23/95	06/23/95	3	2	5	2
				CRAMPS (AFTER-MIS)	06/23/95	Unknown	1	2	5	[5]
148	06/21/95	06/23/95	07/07/95	UPSET STOMACH	06/22/95	06/22/95	1	1	2	1
				CRAMPS (AFTER-MIS)	06/23/95	06/23/95	3	2	5	2
				CRAMPS	06/23/95	06/23/95	2	2	7	2
				DIZZINESS (AFTER-MIS)	06/23/95	06/23/95	1	1	4	1
				BACKACHES (HAS W/MENSES)	06/23/95	07/04/95	3	1	1	1
				FATIGUE	06/23/95	06/23/95	2	1	4	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
148 (Cont.)				CRAMPS	06/24/95	06/25/95	1	2	7	4
				CRAMPS	06/30/95	07/01/95	2	1	7	1
149	06/21/95	06/23/95	07/07/95	CRAMPING	06/22/95	07/07/95	1	1	3	1
				HEADACHE	06/23/95	06/23/95	2	2	1	1
				HEADACHE	06/29/95	06/29/95	3	2	1	1
				(L) SIDE PAIN	07/07/95	Unknown	2	1	1	[5]
				FISHY ODOR	07/07/95	Unknown	2	1	1	[5]
				MILKY, GRAYISH DISCHARGE	07/07/95	Unknown	2	1	1	[5]
				BACTERIAL VAGINOSIS	07/21/95	Unknown	2	1	1	[5]
150	06/21/95	06/23/95	07/14/95	NAUSEA	06/21/95	06/22/95	3	1	2	1
				VOMITING	06/21/95	06/22/95	3	1	2	1
				CRAMPING	06/22/95	06/22/95	1	1	3	4
				CRAMPING (AFTER-MIS)	06/23/95	06/23/95	3	1	5	1
				HEADACHE	06/26/95	06/26/95	1	2	1	1
				CRAMPING	07/02/95	07/04/95	1	1	1	1
				BREAST CHANGES	07/07/95	Unknown	1	1	1	[5]
151	06/21/95	06/23/95	07/05/95	SINUS CONGESTION	06/22/95	06/22/95	2	1	1	1
				ODOR (VAGINAL)	06/23/95	06/23/95	2	1	1	1
				CRAMPS	06/23/95	06/25/95	2	2	7	1
				ASYMPTOMATIC (L) OVARIAN CYST 3.1 X 2.7 CM	06/23/95	Unknown	1	1	1	[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: 3

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.)				ABD. PAIN (STOMACH)	06/26/95	06/28/95	1	2	1	1
				NECK PAIN	06/28/95	Unknown	2	2	1	[5]
				HEADACHE	06/28/95	Unknown	2	2	1	[5]
				NECK TENSION	06/28/95	Unknown	2	2	1	[5]
152	06/28/95	06/30/95	07/12/95	CRAMPING (PRE-MIS)	06/29/95	06/30/95	1	1	3	4
				DIARRHEA	06/29/95	06/29/95	1	1	2	1
				STOMACH CRAMPS	06/29/95	07/09/95	2	1	1	1
				CRAMPS (AFTER-MIS)	06/30/95	06/30/95	3	2	5	2
				DIAPHORESIS	06/30/95	06/30/95	1	1	4	1
				CRAMPS	07/01/95	07/03/95	1	2	7	4
				NAUSEA	07/02/95	07/02/95	2	1	6	1
				CRAMPS	07/04/95	07/05/95	2	1	7	1
				GENITAL WART	07/12/95	Unknown	1	2	1	[5]
153	06/28/95	06/30/95	07/12/95	FATIGUE	06/28/95	06/29/95	3	1	1	1
				CRAMPS	06/29/95	06/30/95	1	2	3	4
				CRAMPS (AFTER-MIS)	06/30/95	07/01/95	3	2	5	2
				CRAMPS	07/01/95	07/01/95	2	2	7	2
				CRAMPS	07/02/95	07/04/95	1	2	7	1
154	06/28/95	06/30/95	07/13/95	VOMITING	06/28/95	06/28/95	2	1	2	1
				NAUSEA (PRE-MIS)	06/28/95	06/30/95	1	1	2	3
				NAUSEA (AFTER-MIS)	06/30/95	06/30/95	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: 3

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 (AFTER-MIS)	06/30/95	07/01/95	1	1	5	1
155	07/12/95	07/14/95	07/27/95	CRAMPS	07/12/95	07/13/95	1	1	3	1
				NAUSEA	07/12/95	07/13/95	2	1	3	2
				VOMITING	07/12/95	07/13/95	2	1	2	2
				NAUSEA (PRE-MIS)	07/14/95	07/14/95	1	1	2	1
				VOMITING (PRE-MIS)	07/14/95	07/14/95	1	1	2	1
				CRAMPS (AFTER-MIS)	07/14/95	07/14/95	1	1	5	1
156	07/12/95	07/14/95	08/02/95	CRAMPS (PRE-MIS)	07/13/95	07/14/95	1	2	3	4
				CRAMPS (AFTER-MIS)	07/14/95	07/14/95	3	2	5	2
				CRAMPS (AFTER-MIS)	07/14/95	07/15/95	1	2	5	1
				NAUSEA	07/14/95	07/14/95	2	1	2	1
				VOMITING	07/14/95	07/14/95	2	1	2	1
				CRAMPS	07/18/95	07/18/95	1	1	7	1
				CRAMPS	07/21/95	07/21/95	1	1	7	1
157	07/19/95	07/21/95	08/04/95	HEADACHE	07/19/95	07/20/95	2	2	2	1
				NAUSEA	07/19/95	07/19/95	2	1	2	1
				VOMITING	07/19/95	07/19/95	2	1	2	1
				CRAMPS (AFTER-MIS)	07/21/95	07/21/95	2	2	5	2
				CRAMPS	07/22/95	07/22/95	1	2	7	4
				CRAMPS	07/23/95	07/23/95	2	2	7	2
				CRAMPS	07/24/95	07/24/95	1	2	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
157 (Cont.)				CRAMPS	07/25/95	07/25/95	2	2	7	2
				CRAMPS	07/26/95	07/27/95	1	2	7	4
				CRAMPS	07/28/95	07/29/95	2	2	7	1
				CRAMPS	08/14/95	08/14/95	1	1	1	1
				EXCESSIVE BLDG	08/14/95	08/15/95	2	1	1	1
				BACTERIAL VAGINOSIS	08/30/95	Unknown	1	2	1	1
				LIGHT-HEADEDNESS (WITH STANDING)	08/30/95	Ongoing	1	1	1	[5]
				ANEMIA	08/30/95	Unknown	1	2	1	[5]
				WHITE DISCHARGE	08/30/95	09/07/95	1	1	1	1
158	07/19/95	07/21/95	08/15/95	CRAMPS	07/19/95	07/19/95	1	1	2	1
				NAUSEA	07/19/95	07/20/95	2	1	2	4
				VOMITING	07/19/95	07/20/95	2	1	2	4
				VOMITING	07/20/95	07/20/95	3	1	2	1
				NAUSEA	07/20/95	07/21/95	3	2	2	1
				CRAMPS	07/21/95	07/25/95	3	1	7	1
				CHILLS / SHAKING	07/21/95	07/21/95	3	1	1	1
				HOT	07/23/95	07/23/95	1	1	1	1
159	07/19/95	07/21/95	08/04/95	NAUSEA	07/20/95	07/20/95	1	1	2	1
				DIARRHEA	07/20/95	07/21/95	1	1	2	1
				CRAMPS (PRE-MIS)	07/20/95	07/21/95	1	1	3	3
				CRAMPS (AFTER-MIS)	07/21/95	07/27/95	1	1	5	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
160	07/19/95	07/21/95	08/08/95	LOWER BACKACHE	07/19/95	07/21/95	1	1	2	1
				CRAMPS	07/19/95	07/21/95	1	1	3	4
				CRAMPS (AFTER-MIS)	07/21/95	07/23/95	3	2	5	2
				CRAMPS	07/24/95	07/25/95	2	2	7	2
				CRAMPS	07/26/95	07/28/95	1	1	7	1
				CRAMPS	08/02/95	08/02/95	1	2	7	1
161	07/26/95	07/28/95	08/10/95	CRAMPS (PRE-MIS)	07/27/95	07/27/95	1	1	3	4
				NAUSEA	07/28/95	07/28/95	3	1	2	1
				CRAMPS (AFTER-MIS)	07/28/95	07/28/95	3	1	5	2
				CRAMPS (AFTER-MIS)	07/28/95	07/28/95	2	1	5	2
				CRAMPS	07/29/95	07/29/95	1	1	7	4
				CRAMPS	07/30/95	07/31/95	3	2	7	2
				CRAMPS	08/01/95	08/01/95	2	1	7	2
				CRAMPS	08/02/95	08/02/95	1	1	7	1
162	08/02/95	08/04/95		HOT FLASH	08/04/95	08/04/95	2	1	1	1
163	08/02/95	08/04/95	08/16/95	NAUSEA	08/02/95	08/04/95	2	1	2	1
				CRAMPS	08/02/95	08/03/95	2	2	3	2
				CRAMPS (AFTER-MIS)	08/04/95	08/04/95	3	2	5	2
				CRAMPS (AFTER-MIS)	08/04/95	08/04/95	2	2	5	1
				VOMITING	08/04/95	08/04/95	3	1	1	1
				CRAMPS (PRE-MIS)	08/04/95	08/04/95	1	2	3	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: 3

Patient Number	Visit 1 Date	Visit 2 Date	Visit 3 Date	Description	Start Date	Stop Date	Severity [1]	Action [2]	Related [3]	Outcome [4]
163 (Cont.)				CRAMPS	08/06/95	08/06/95	3	2	7	2
				HEADACHES	08/06/95	08/07/95	2	2	1	1
				CRAMPS	08/07/95	08/07/95	2	2	7	1
164	08/09/95	08/11/95	08/25/95	HEADACHE	08/10/95	08/10/95	2	2	2	1
				CRAMPS (PRE-MIS)	08/11/95	08/11/95	2	1	3	3
				CRAMPS (AFTER-MIS)	08/11/95	08/11/95	2	2	5	4
				CRAMPS	08/11/95	08/14/95	3	2	7	1
				LIGHTHEADED / DIZZY	08/11/95	08/11/95	2	1	1	1
				BACTERIAL VAGINOSIS (BORDERLINE)	08/25/95	Unknown	1	2	1	[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.

Dr. Suzanne T. Poppema (Center #3)

Case Record Forms for the Following Patient Nos.:

008
041
051
060
069
075
084
091
096
105
118
124
130

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
425-486-8788

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
a.m. 9:00
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.

Suzanne T. Poppema, M.D.
Aurora Medical Services, Inc.
Seattle, WA CFN 3032921
EI: November 1-5, 1999

SUMMARY OF FINDINGS

Inspection of Clinical Investigator Suzanne T. Poppema, M.D., was conducted in response to a CDER User Fee New Drug Application (NDA) Inspection assignment, for NDA20687, to audit a study conducted with Mifepristone and Misoprostol. This was the initial inspection of this Principal Investigator.

The study was conducted under Protocol Number 166A, "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of Up To 63 Days". Statement of Investigator Forms FDA 1572 were signed for the study performed at this site.

The study sponsor, The Population Council, Inc., contracted with ——— to monitor this study for the NDA submission to the FDA.

This audit by Seattle District Consumer Safety Officer ——— was conducted in accordance with Compliance Program 7348.811.

Comparison of the source documents, the Case Report Forms, and documentation provided with this assignment revealed no deviations or inaccuracies associated with efficacy assessments, adverse events, and concomitant medications. Inaccuracies were revealed associated with drug accountability, and record keeping.

Closeout discussions were held with Dr. Poppema and ——— , on November 5, 1999. FDA's ——— reiterated the discussion items that were observed during the course of this audit. No Inspectional Observations Form FDA 483 was issued. Dr. Poppema and ——— acknowledged and agreed with the discussion items.

INSPECTION REPORT

Persons Interviewed:

I issued a Notice of Inspection FDA Form 482 and showed my credentials to Suzanne T. Poppema, M.D., Clinical Investigator, on November 1, 1999. Also present at the initial meeting was ——— Aurora Medical Services, Inc. ——— provided the majority of relevant information during this audit. Dr. Poppema was available during each day of the audit and provided information as requested.

Study Organization:

A total of 164 subjects were enrolled at this site. They were divided into three subsets, based on the assessed duration of present amenorrhea, and are summarized in the table below:

GROUP 1	AMENORRHEA OF ≤ 49 DAYS
GROUP 2	AMENORRHEA OF 50 THROUGH 56 DAYS
GROUP 3	AMENORRHEA OF 57 THROUGH 63 DAYS

The sixty-five subjects enrolled into Group 1 were audited at this site.

Authority and Administration:

Dr. Suzanne T. Poppema, Principal Investigator had primary responsibility for the conduct of the study. Statement of Investigator Forms FDA 1572 (FDA 1572) were signed for the study performed at this site. The FDA 1572s are attached as **exhibit 1**, and the changes in the FDA 1572s are summarized in the following table:

DATE SIGNED	CHANGES	EXHIBIT NUMBER 1, PAGES
08/16/94		1-2
11/08/94	Block 4: Added [redacted]	3-4
03/06/95	Block 6: Added the following Sub-Investigators: [redacted]	5-6

Dr. Poppema stated that she retained control and knowledge of the study through her review of each of the study files, and the completion of the Investigator's Questionnaire portion of the CRF.

[redacted] were Sub-Investigators who participated in this study at Dr. Poppema's site.

[redacted] was the primary Study Coordinator.

A Study Personnel Signature Registry is attached as **exhibit 2**.

Curricula vitae (CV) are on file for the Sub-Investigator's listed above. Dr. Poppema's CV is

attached as **exhibit 3**.

A listing of Dr. Poppema's clinical research projects is attached as **exhibit 4**. Documents related to her participation in IND [redacted] ' are attached as **exhibit 5**.

Dr. Poppema was recruited to participate in this study through telephone conversations with the study sponsor based on previous professional associations. An intensive study orientation meeting was held for the Clinical Investigators on 10/03-04/94.

Laboratory testing for βHcg was performed under the direction of [redacted] had an agreement with [redacted] Therefore some βHcg samples were tested at that site, and the results were recorded on that laboratory's letterhead. Dr. Poppema served as Laboratory Director for the in-house laboratory, which performed hematocrit, urine pregnancy, and Rh antibody determinations. I verified the adequacy of the clinic's laboratory facilities. Accreditation certificates for the laboratories and supporting documentation are attached as **exhibit 6**

Sponsor/Monitor:

The sponsor of this study was The Population Council, Inc., 1230 York Avenue, New York, NY, 10021. They contracted with [redacted] to monitor this study. In addition, the monitor provided Institutional Review Board (IRB) services for this study. [redacted] communicated directly with The Population Council to provide study progress information.

Source documents revealed ongoing communication between the sponsor, the monitor and Dr. Poppema. The Investigator Documentation file was well organized. The entire monitor communications file is attached as **exhibit 7**. Dr. Poppema stated that all aspects of this study were adequately explained, and that all questions were dealt with in full by the monitor and sponsor. Further, [redacted] personnel also attended the start-up meeting, and were trained in the requirements to conduct this study. [redacted] stated that the sponsor and monitor were extremely thorough, and provided an enormous amount of support to this study site.

All adverse events (AE) were reported to the sponsor. Notification of the AEs to the IRB, and their response, were also on record. The sponsor AE correspondence file is attached as **exhibit 8**. It appears that the monitor and sponsor were adequately informed of the study's progress.

[redacted] stated that the monitor compared most, if not all, of the Case Report Forms (CRF) to original records during the on-site monitoring visits. Site sign-in logs are attached as **exhibit 9**, and are summarized in the table below.

DATE(S)	PURPOSE OF VISIT
08/16/94	SITE VISIT
11/08/94	INITIATION
11/30/94	MONITORING
01/05/95	MONITORING
02/06-09/95	MONITORING
03/14-16/95	MONITORING
03/21/95	SITE VISIT
04/26-27/95	MONITORING
05/23-25/95	MONITORING
07/12-13/95	MONITORING
09/25-28/95	MONITORING
11/15/95	MONITORING
03/18-20/96	AUDIT

A Site Visit Report (Patient Roster), prepared as a result of the site visit on 11/15/95, is attached as **exhibit 10.**

Protocol Review:

The protocol provided with the assignment, dated 05/05/95, was on file with the Investigator. In addition, a protocol dated 10/13/94 was on file **(exhibit 11)**. Dr. Poppema stated that this was the protocol that was followed for this subject subset of the study. All of the Group 1 subjects were enrolled prior to the effective date of the 05/05/95 protocol.

Dr. Poppema's signature sheets are attached as **exhibit 12**. These sheets indicated that the original protocol was dated 07/15/94. This protocol was not on file at the study site. A summary sheet of modifications to the protocol following the 10/3-4/94 Investigator's meeting is attached as **exhibit 13**. The signature sheets are summarized in the following table:

APPEARS THIS WAY
ON ORIGINAL

DOCUMENT DATE	SIGNATURE DATE
07/15/94	08/16/94
10/13/94	04/12/95
10/13/94	10/17/95
05/05/95	10/17/95

I questioned Dr. Poppema regarding the length of time that elapsed in signing the agreements, as well as why two signature sheets were on file for the 10/13/94 protocol. She stated that she does not recall why the signature sheet for the protocol in use was not signed until approximately 6 months into the study. A memo on file, generated after a site visit on 11/08/94, noted that the signature sheet was outstanding **(page 68 of exhibit 7)**. With regards to having two signature sheets on file, she stated that the monitor could not locate the sheet during another audit, and requested that a second one be signed. A memo from the sponsor to Dr. Poppema, dated 10/05/95 supports this observation **(page 15 of exhibit 7)**. This observation is also discussed in the **Discussion With Management** section of this EIR.

Institutional Review Board (IRB)/Ethics Committee:

The Chairman of the IRB was [redacted] and the IRB office was located at [redacted] This IRB operated under the auspices of [redacted] The IRB correspondence file is attached as **exhibit 14**. This file primarily consists of IRB approvals and correspondence regarding the receipt of Medwatch adverse event forms.

The IRB granted initial approval of the study on 10/12/94 **(page 9 of exhibit 14)**. An expedited review approval, dated 10/27/94, was on file for the protocol used for the Group 1 subjects **(page 8 of exhibit 14)**. The IRB approved consent forms are attached as exhibits in the **Informed Consent** section of this EIR.

No promotional materials were utilized in the enrollment of study subjects. Subjects were referred from local organizations (i.e. Planned Parenthood), or were informed through local media coverage of this study.

This IRB required semi-annual review of its research projects. Progress reports to the IRB are attached as **exhibit 15**.

Informed Consent:

The IRB approved Informed Consent Form (ICF) utilized for the Group 1 subjects is attached as **exhibit 16**. I also collected the IRB approved ICF associated with the 05/05/95 revision of the protocol (**exhibit 17**). This ICF was not IRB approved until 05/24/95, and therefore was not used for any of the subjects enrolled into Group 1.

Original ICFs were confirmed for all 65 subjects enrolled into Group 1. An example of an ICF signed by a subject is attached as pages 12-16 of **exhibit 18**.

It was noted that Subject 069 did not have an original ICF in the study file. stated that she did not know why an original was not on file. This record keeping deficiency is also discussed in the **Discussion With Management** section of this EIR.

Subject Records:

164 subjects were enrolled into the study. A Patient Roster (Site Visit Report) is attached as **exhibit 10**. In this audit, portions of the CRFs and the medical record files were reviewed for all 65 subjects enrolled into Group 1.

The following information was audited for all Group 1 subjects:

- Inclusion/exclusion criteria
- Group assignment
- Dosing and time of study drug administration
- Progress reports
- Investigator's Questionnaire
- Pregnancy testing source documents
- Vaginal ultrasound source documents
- Informed consent
- Outcome of pregnancy
- Completeness of Case Report Forms (CRF)

The following information was audited in full for at least half of the subjects and spot checked for the remaining subjects:

- Adverse events, with comparison to data provided with the assignment
- Concomitant medications

In addition, I compared the CRFs provided with the assignment with those on file at the clinic.

There is adequate documentation to assure that subjects did exist and were alive and available for their stated participation in the study.

All files were organized, legible, and readily retrieved. The files for all 164 subjects were made available to me. Source records supported clinical laboratory testing. Each record contained verification of the subject's condition at the time of entry into the study, exposure to the test article, observations during participation in the study, and identity of persons involved in the collection of the data.

The staff utilized raw data worksheets. Examples are attached as exhibits under Subjects 004 and 091 Although there were several examples of improper corrections of raw data (i.e. overwriting), the practice was not prevalent. There were few monitor generated data correction requests. My limited review did not reveal any transcription errors from the source documents to the CRFs. However, the review revealed that for 9 of the 65 subjects, the Day 1, in-house, urine pregnancy test results were not dated. and Dr. Poppema acknowledged the observation. Examples are attached as exhibits under the individual subject headings. This observation is also discussed in the **Discussion With Management** section of this EIR.

As stated previously, the subject pool was drawn from referrals to the clinic from other organizations (i.e. Planned Parenthood), and from local media coverage of the study.

Non-Remarkable Subjects:

The following subjects had no remarkable observations:

003
006
007
008
010
019
041
044
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047
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057

APPEARS THIS WAY
ON ORIGINAL

Suzanne T. Poppema, M.D.
Aurora Medical Services, Inc.
Seattle, WA CFN 3032921
EI: November 1-5, 1999

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APPEARS THIS WAY
ON ORIGINAL

Remarkable Study Subjects:

Subject 002

This subject, dosed with Mifepristone on 11/08/94, was the first subject enrolled into Group 1 of this study.

Subject 004

This subject's source document file, attached as **exhibit 18**, is provided as an example of the forms in use at this clinic.

Subject 021

This file did not contain the subject's diary. However, the CRF documented the subject's AEs and concomitant medications. Review of the source documents revealed that the subject threw away the diary **(exhibit 19)**. ——— stated that the subject's data was obtained through interviews with the subject.

Subject 022

This subject underwent a surgical abortion on ———

Subject 046

The Day 1, in-house, urine pregnancy test result was not dated **(exhibit 20)**.

Subject 051

The Day 1, in-house, urine pregnancy test result was not dated **(exhibit 21)**.

Subject 052

The Day 1, in-house, urine pregnancy test result was not dated **(exhibit 22)**.

Subject 069

The original Informed Consent form was not present in this subject's file. A photocopy was on file. ——— stated that she did not know why the original was not on file.

This subject underwent a uterine —— vacuum aspiration (surgical rescue) on ——— to stop uterine bleeding.

Subject 071

The Day 1, in-house, urine pregnancy test result was not dated **(exhibit 23)**.

Subject 072

This subject was lost to follow-up after visit 2. The subject did not complete the visit 3 scheduled for 03/02/95. However, the CRF for visit 3 was completed with information gathered on a visit on 04/26/95.

Subject 075

The Day 1, in-house, urine pregnancy test result was not dated **(exhibit 24)**.

Subject 078

This subject received two doses of Mifepristone. The subject vomited after the first dosing.

Subject 081

This file did not contain the subject's diary. Review of the source documents revealed that the subject stated that she would mail the diary to the clinic after the third visit, but did not comply. The subject completed visit 3 on 03/15/95, one week after the scheduled date of 03/08/95.

Subject 084

This file did not contain the subject's diary, and this subject was lost to follow-up.

Subject 091

This subject's source document file, attached as **exhibit 25**, is provided as an example of the forms in use at this clinic.

The Day 1, in-house, urine pregnancy test result was not dated **(page 12 of exhibit 25)**.

Subject 094

This subject underwent a surgical abortion on

Subject 095

This file did not contain the subject's diary, and this subject was lost to follow-up.

Subject 105 ——

The Day 1, in-house, urine pregnancy test result was not dated (exhibit 26).

Subject 106 ——

The Day 1, in-house, urine pregnancy test result was not dated (exhibit 27).

Subject 113 ——

This file did not contain the subject's diary, and this subject was lost to follow-up.

Subject 118 ——

This subject was lost to follow-up.

Subject 129 ——

This subject was lost to follow-up.

The Day 1, in-house, urine pregnancy test result was not dated (exhibit 28).

Subject 130 ——

This was the final subject enrolled into Group 1 of this study.

This subject underwent a surgical abortion on ——

Drug Storage and Accountability:

Test article accountability records are complete. However, there is insufficient information to reconcile the amount of test article received, dispensed, and returned.

—— supplied the study drug to Dr. Poppema. The test drug was stored under appropriate conditions. Medication/Device Inventory sheets are attached as exhibit 29. I noted that on two of the forms, the lot number and drug identity were not recorded (pages 1-2 of exhibit 29). —— stated that the —— representative completed the forms. This observation is also discussed in the **Discussion With Management** section of this EIR.

An —— memo to Dr. Poppema, dated 02/26/96, regarding final drug accountability is attached as **exhibit 30**. Review of this memo, in conjunction with the inventory sheets, revealed a discrepancy in drug accountability. The following Table summarizes the drug inventory sheets:

DATE SIGNED BY DR. POPPEMA	NUMBER OF TABLETS RECEIVED	CUMMULATIVE TOTAL
11/08/94	—	—
01/19/95	—	—
03/21/95	—	—
05/03/95	—	—
09/29/95	—	—

The ——memo indicated that — tablets had been provided to the study site. I noted that the final delivery of 15 tablets was dated after all 164 subjects had completed the study. Further, all previous shipments of the study drug had been provided in full bottles of 51 tablets. Also, the Medication/Inventory Mifepristone/Misoprostol Study inventory sheets **(page 10 of exhibit 31)**, indicated that the remaining drug was scheduled to be returned to —— on 09/29/95. The handwritten note read:

"On 9/27/95 – 15 tablets left of Mifepristone in one bottle
2 empty bottles of Mifepristone
4 bottles of 51 Mifepristone tablets.
All should be put in Fed ex box and shipped to ——on 9/29/95."

This statement correlates with the following calculation:

164 subjects x 3 tablets/subject = 492 tablets
492 + 3 tablets for the one subject that required 2 doses = 495 tablets dosed
714 tablets received – 495 tablets dosed = 219 tablets not used
From the note above: 4 bottles of 51 tablets + 1 bottle of 15 tablets = 219 tablets.

Finally, a memo from —— to Dr. Poppema dated 10/05/95 **(page 15 of exhibit 7)** stated "Please be advised that there is no remaining study drug at your facility. I performed a complete drug accountability on all the remaining study medication. All study drug was 100% accounted for and your documentation reflected the calculation. I signed and dated the drug inventory log and recorded the drug accountability, as well as returning all remaining study drug to ——

——————nd Dr. Poppema did not know why the final inventory sheet of 15 tablets was generated **(page 5 of exhibit 29)**. They stated that logically, no drug would have been given to the study site after the closure of the trial.

During the course of this audit, the Population Council faxed a memo dated 11/04/99 regarding the reconfirmation of the site's drug accountability records. Accompanying the memo was a Medication Inventory sheet regarding the amount of drug returned to the sponsor by ——— and an —— record documenting the amount of drug shipped to Dr. Poppema. These documents support that a total of 714 Mifepristone tablets were supplied to Dr. Poppema, and are attached as **exhibit 32**.

The inability to reconcile the amount of drug received, used, and returned to the study sponsor was discussed again at the close-out meetings and is also discussed in the **Discussion With Management** section of this EIR.

The drug accountability record for all 164 subjects is attached as **exhibit 31**. This record was reconcilable with the source documents. This form accurately recorded the second dosing of Subject 078 —— The distribution of the test article was limited to the individuals delegated by the Investigator.

Records Retention:

Dr. Poppema stated that source documents are archived at the clinic for a period of 10 years. The files for any subjects that were lost to follow-up will be retained for 30 years. Dr. Poppema stated that all of the records will be retained for at least two years following the date on which the study drug is approved by the FDA for marketing for the purposes which were the subject of the clinical investigation.

Computer/Electronic Data Systems:

No electronic data systems were located at this audit site.

Discussion With Management:

This audit revealed the following discussion items:

1. Lack of sufficient information to reconcile the amount of test article received, dispensed, and returned. Sponsor and monitor records indicate that a total of 714 tablets of Mifepristone were supplied to the study site. The individual drug accountability records that Dr. Poppema signed indicate that 729 tablets of Mifepristone were received at the study site.

2. Failure to maintain complete and/or accurate records.
   a. The Day 1, in-house, urine pregnancy test results were not dated for 9 of the 65 subjects enrolled into Group 1 of this study.
   b. Two of five Medication Inventory receipts do not indicate the identity and lot number of medication received at the study site.
   c. The original Informed Consent form was not on file for Subject 069 ——
   d. The signature sheet for the protocol dated 10/13/94 was not signed by Dr. Poppema until 04/12/95, approximately 6 months after initiating the study.

Closeout discussions were held with Dr. Poppema and ———— on November 5, 1999. I reiterated the discussion items outlined above. No Inspectional Observations Form FDA 483 was issued. Dr. Poppema and ———— acknowledged and agreed with the discussion items.

ATTACHMENT AND EXHIBITS

Attachment:

1. Assignment dated October 1, 1999 from ———— HFD-46

Exhibits:

Administrative Documents

1. FDA 1572s
2. Study Personnel Signature Registry

Clinical Investigator

3. CV Dr. Poppema
4. Listing of clinical research projects
5. Documents related to IND ——

Laboratory Documentation

6. Laboratory certifications

Monitor/Sponsor

7. Monitor/Sponsor correspondence file
8. Monitor/Sponsor AE file
9. Monitor site visit record
10. Site visit report dated 11/15/95

Protocol/Procedure Manual

11. Protocol 166A, dated 10/13/94
12. Protocol signature sheets
13. Modifications to protocol following 10/3-4/94 Investigator's meeting

Institutional Review Board (IRB) Correspondence

14. IRB correspondence file
15. Study progress reports

Informed Consent

16. IRB approved Informed Consent Form dated 10/13/94
17. IRB approved Informed Consent Form dated 05/05/95

Subject Records

18. Subject 004 ——
19. Subject 021 ——
20. Subject 046 ——
21. Subject 051 ——
22. Subject 052 ——
23. Subject 071 ——
24. Subject 075 ——
25. Subject 091 ——
26. Subject 105 ——
27. Subject 106 ——
28. Subject 129 ——

Drug Accountability

29. Medication/Device Inventory sheets
30. Memo from —— to Dr. Poppema, dated 02/26/96, regarding final drug accountability
31. Medication/Inventory Mifepristone/Misoprostol Study sheets
32. Memo and documentation supplied by the sponsor regarding drug accountability

Suzanne T. Poppema, M.D.
Aurora Medical Services, Inc.
Seattle, WA CFN 3032921
EI: November 1-5, 1999

/S/

Consumer Safety Officer
Seattle District

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) Part 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014.
Expiration Date: November 30, 1995.
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

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

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED:

☒ CURRICULUM VITAE ☐ OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

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

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

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

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).

Institutional Review Board
Under the auspices of [redacted]

6. NAMES OF THE SUBINVESTIGATORS *(e.g., research fellows, residents, associates)* WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

[redacted]

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

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.

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

MIF 002499

. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION:

☐ PHASE 1 INVESTIGATIONS, A GENERAL OUTLINE OF THE PLANNED INVESTIGATION INCLUDING THE ESTIMATED DURATION OF E STUDY AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED.

☐ FOR PHASE 2 OR 3 INVESTIGATIONS, AN OUTLINE OF THE STUDY PROTOCOL INCLUDING AN APPROXIMATION OF THE NUMBER OF SUBJECTS TO BE TREATED WITH THE DRUG AND THE NUMBER TO BE EMPLOYED AS CONTROLS, IF ANY; THE CLINICAL USES TO BE INVESTIGATED; CHARACTERISTICS OF SUBJECTS BY AGE, SEX, AND CONDITION; THE KIND OF CLINICAL OBSERVATIONS AND LABORATORY TESTS TO BE CONDUCTED; THE ESTIMATED DURATION OF THE STUDY; AND COPIES OR A DESCRIPTION OF CASE REPORT FORMS TO BE USED.

9. COMMITMENTS:

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, ·ept where necessary to eliminate apparent immediate hazards to human subjects.

,ree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR:

Suzanne T. Poppema, M.D.
Seattle, WA CFN 3032921
EI: 11/01/99-11/05/99
Exhibit 1 Page 2 of 6

1. Complete all sections. Attach a separate page if additional space is needed.
2. Attach curriculum vitae or other statement of qualifications as described in Section 2.
3. Attach protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. SIGNATURE OF INVESTIGATOR	11. DATE
[signature] MD	8-16-94

Public reporting burden for this collection of information is estimated to average 84 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any ·aspect of this collection of information, including suggestions for reducing this burden to:

. .orts Clearance Officer, PHS
Hubert H. Humphrey Building, Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
Attn: PRA

and to:

Office of Management and Budget
Paperwork Reduction Project (0910-0014)
Washington, DC 20503

Please DO NOT RETURN this application to either of these addresses.