U.S. FOOD & DRUG ADMINISTRATION

July 18, 2018

In Response Refer to File: ***2018-3575***

William F. Marshall
Judicial Watch, Inc.
425 Third Street, SW
Suite 800
Washington, DC 20024

Dear Requestor,

This is in response to your Freedom of Information Act submission, in which you requested records reflecting summary data relating to adverse effects (AE) reported to the FDA by consumers, health professionals, FDA-regulated companies (including but not limited to Danco Laboratories and/or its affiliates) and foreign drug suppliers regarding any and all adverse reactions to drugs administered for chemically induced abortions, including but not limited to mifepristone, misoprostol, and methotrexate. In an email dated June 20, 2018, to Darshini Satchi of this office, you agreed to accept the AE summary reports from 2005 through 2018 for Mifeprex (mifepristone) for medical abortion in full satisfaction of the request. Your request was received in the Center for Drug Evaluation and Research on June 20, 2018.

The releasable document is enclosed

The following charges may be included in a monthly invoice:

Computer Search: $0.00 Review: $0.00 Other: $1.00 TOTAL: $1.00

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me at 301-796-3498.

Sincerely,

Diderot Nicolas
Regulatory Counsel
Division of Information Disclosure Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research

If you are not satisfied with any aspect of the processing and handling of this request please contact:

FDA FOIA Liaison
Office of the Executive Secretariat
5630 Fishers Lane Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Enclosure: Combined AE summaries; date range: 2005-2017. (1 CD).

PID # D050121
Mifepristone US Postmarketing Adverse Events Summary 02/15/2005

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US at this time is over 300,000 women.

Post-Marketing Adverse Events in US Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	02/15/2005
Cases with any adverse event	752
Died [1]	3
Hospitalized, excluding deaths	160
*Ectopic pregnancies [2]	20
*Experienced blood loss requiring transfusions [3]	78
*Infections [4]	38

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with a ruptured ectopic pregnancy in one case and with septic shock in the other two. There were three additional deaths in foreign women (one in a foreign clinical trial associated with septic shock, and two in post marketing experience associated with a ruptured gastric ulcer in one and with uterine hemorrhage in the other) who used mifepristone for termination of pregnancy.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, and women with toxic shock syndrome not associated with a pelvic infection.

PID D050309
Mifepristone US Postmarketing Adverse Events Summary 05/09/2005

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of April 2005 is over 436,500 women.

Post-Marketing Adverse Events in US Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	05/09/2005
Cases with any adverse event	805
Died [1]	4
Hospitalized, excluding deaths	177
*Ectopic pregnancies [2]	18
*Experienced blood loss requiring transfusions [3]	88
*Infections [4]	49

* The majority of these women are included in the hospitalized category.
[1] Deaths were associated with a ruptured ectopic pregnancy in one case and with septic shock in the other two. The preliminary cause of death in the fourth case was cardiopulmonary arrest, possibly in the setting of sepsis. There were three additional deaths in foreign women (one in a foreign clinical trial associated with septic shock, and two in post marketing experience associated with a ruptured gastric ulcer in one and with uterine hemorrhage in the other) who used mifepristone for termination of pregnancy.
[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).
[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.
[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, and women with toxic shock syndrome not associated with a pelvic infection.

PID D050461
Mifepristone US Postmarketing Adverse Events Summary 08/05/2005

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of June 2005 is over 460,000 women.

Post-Marketing Adverse Events in US Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	08/03/2005
Cases with any adverse event	866
Died [1]	5
Hospitalized, excluding deaths	200
*Ectopic pregnancies [2]	23
*Experienced blood loss requiring transfusions [3]	100
*Infections [4]	63

* The majority of these women are included in the hospitalized category.
[1] Deaths were associated with a ruptured ectopic pregnancy in one case and with septic shock in the other two. The preliminary cause of death in the fourth case was cardiopulmonary arrest, possibly in the setting of sepsis. The fifth case was also possibly related to sepsis. There were three additional deaths in foreign women (one in a foreign clinical trial associated with septic shock, and two in post marketing experience associated with a ruptured gastric ulcer in one and with uterine hemorrhage in the other) who used mifepristone for termination of pregnancy.
[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).
[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.
[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, and women with toxic shock syndrome not associated with a pelvic infection.

PID D050652
Mifepristone US Postmarketing Adverse Events Summary 11/05/2005

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of October 2005 is approximately 508,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	11/05/2005
Cases with any adverse event	905
Died [1]	6
Hospitalized, excluding deaths	220
*Ectopic pregnancies [2]	25
*Experienced blood loss requiring transfusions [3]	105
*Infections [4] (Severe infections[5])	80 (16)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in four cases (all cases tested positive for *Clostridium sordellii)*, the fifth death was associated with a ruptured ectopic pregnancy and the sixth death was associated with delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were three additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other two foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer in one and with uterine hemorrhage in the other.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on a medical review of the case details. Severe infections generally involve hospitalization for at least 3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

PID D060125
Mifepristone US Postmarketing Adverse Events Summary Through 01/31/2006

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of October 2005 is approximately 508,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	01/31/2006
Cases with any adverse event	944
Died [1]	6
Hospitalized, excluding deaths	234
*Ectopic pregnancies [2]	26
*Experienced blood loss requiring transfusions [3]	114
*Infections [4] (Severe infections[5])	85 (17)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in four cases (all cases tested positive for *Clostridium sordellii)*, the fifth death was associated with a ruptured ectopic pregnancy and the sixth death was associated with delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were three additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other two foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer in one and with uterine hemorrhage in the other.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on a medical review of the case details. Severe infections generally involve hospitalization for at least 3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

PID D060452
Mifepristone US Postmarketing Adverse Events Summary Through 04/30/2006

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of March 2006 is approximately 575,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	04/30/2006
Cases with any adverse event	1,027
Died [1]	9
Hospitalized, excluding deaths	250
*Ectopic pregnancies [2]	28
*Experienced blood loss requiring transfusions [3]	129
*Infections [4] (Severe infections[5])	103 (18)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in five cases (4 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were three additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other two foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer in one and with uterine hemorrhage in the other.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve hospitalization for at least 3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

PID D060590
Mifepristone US Postmarketing Adverse Events Summary Through 07/24/2006

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of June 2006 is approximately 612,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	07/24/2006
Cases with any adverse event	1,077
Died [1]	9
Hospitalized, excluding deaths	261
*Ectopic pregnancies [2]	28
*Experienced blood loss requiring transfusions [3]	135
*Infections [4] (Severe infections[5])	120 (21)

* The majority of these women are included in the hospitalized category.
[1] Deaths were associated with sepsis in five cases (4 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were four additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other three foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, and "multivisceral failure".
[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).
[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.
[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.
[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

PID 2006-265
Mifepristone US Postmarketing Adverse Events Summary Through 09/15/2006

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of June 2006 is approximately 612,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	09/15/2006
Cases with any adverse event	1,079
Died [1]	9
Hospitalized, excluding deaths	263
*Ectopic pregnancies [2]	28
*Experienced blood loss requiring transfusions [3]	135
*Infections [4] (Severe infections[5])	122 (22)

* The majority of these women are included in the hospitalized category.
[1] Deaths were associated with sepsis in five cases (4 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were four additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other three foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, and "multivisceral failure".
[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).
[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.
[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.
[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

PID 2006-795
Mifepristone US Postmarketing Adverse Events Summary Through 10/31/2006

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of June 2006 is approximately 612,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/2006
Cases with any adverse event	1,119
Died [1]	9
Hospitalized, excluding deaths	273
*Ectopic pregnancies [2]	29
*Experienced blood loss requiring transfusions [3]	140
*Infections [4] (Severe infections[5])	130 (22)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in five cases (4 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were four additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other three foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, and "multivisceral failure".

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
Mifepristone US Postmarketing Adverse Events Summary Through 1/31/2007

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of June 2006 is approximately 612,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/07	1/31/2007
Cases with any adverse event	1,119	1,154
Died [1]	9	9
Hospitalized, excluding deaths	273	292
*Ectopic pregnancies [2]	29	31
*Experienced blood loss requiring transfusions [3]	140	150
*Infections [4] (Severe infections[5])	130 (22)	134 (24)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in five cases (4 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were four additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other three foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, and "multivisceral failure".

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
Mifepristone US Postmarketing Adverse Events Summary Through 1/31/2007

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of May 2007 is approximately 750,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	1/31/2007	4/30/2007
Cases with any adverse event	1,154	1,199
Died [1]	9	9
Hospitalized, excluding deaths	292	311
*Ectopic pregnancies [2]	31	33
*Experienced blood loss requiring transfusions [3]	150	160
*Infections [4] (Severe infections[5])	134 (24)	138 (26)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in five cases (4 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
Mifepristone US Postmarketing Adverse Events Summary Through 07/31/2007

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of May 2007 is approximately 750,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	4/30/2007	7/31/07
Cases with any adverse event	1,199	1,243
Died [1]	9	10
Hospitalized, excluding deaths	311	320
*Ectopic pregnancies [2]	33	36
*Experienced blood loss requiring transfusions [3]	160	166
*Infections [4] (Severe infections[5])	138 (26)	148 (27)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in six cases (5 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
Mifepristone U.S. Postmarketing Adverse Events Summary Through 10/31/2007

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of May 2007 is approximately 750,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	7/31/07	10/31/07
Cases with any adverse event	1,243	1,283
Died [1]	10	10
Hospitalized, excluding deaths	320	331
*Ectopic pregnancies [2]	36	37
*Experienced blood loss requiring transfusions [3]	166	172
*Infections [4] (Severe infections[5])	148 (27)	154 (28)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in six cases (5 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
Mifepristone U.S. Postmarketing Adverse Events Summary Through 1/31/2008

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of January 2008 is approximately 855,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/07	1/31/08
Cases with any adverse event	1,283	1,310
Died [1]	10	10
Hospitalized, excluding deaths	331	336
*Ectopic pregnancies [2]	37	37
*Experienced blood loss requiring transfusions [3]	172	172
*Infections [4] (Severe infections[5])	154 (28)	157 (29)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in six cases (5 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
Mifepristone U.S. Postmarketing Adverse Events Summary through 7/31/2008

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of September 2008 is approximately 979,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	4/30/08	7/31/08
Cases with any adverse event	1350	1398
Died [1]	10	10
Hospitalized, excluding deaths	348	360
*Ectopic pregnancies [2]	37	37
*Experienced blood loss requiring transfusions [3]	179	190
*Infections [4] (Severe infections[5])	164 (29)	**168** **(30)**

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in six cases (5 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 10/31/2008

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of September 2008 is approximately 979,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	7/31/08	10/31/08
Cases with any adverse event	1398	1436
Died [1]	10	10
Hospitalized, excluding deaths	359†	368
*Ectopic pregnancies [2]	37	37
*Experienced blood loss requiring transfusions [3]	190	198
*Infections [4] (Severe infections[5])	**168** **(30)**	**170** **(30)**

* The majority of these women are included in the hospitalized category.
[1] Deaths were associated with sepsis in six cases (5 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.
[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).
[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.
[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.
[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.
†Correction: The number of hospitalizations was incorrectly reported as 360 on the pervious update

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 01/31/2009

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of September 2008 is approximately 979,000 women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/08	01/31/09
Cases with any adverse event	1436	1483
Died [1]	10	10
Hospitalized, excluding deaths	368	385
*Ectopic pregnancies [2]	37	39
*Experienced blood loss requiring transfusions [3]	198	208
*Infections [4] (Severe infections[5])	**170** **(30)**	**174** **(32)**

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in six cases (5 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 07/31/2009

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of May 2009 is approximately 1.1 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	4/30/09	07/31/09
Cases with any adverse event	1517	1576
Died [1]	10	11
Hospitalized, excluding deaths	397	415
*Ectopic pregnancies [2]	40	43
*Experienced blood loss requiring transfusions [3]	208	216
*Infections [4] (Severe infections[5])	**180** **(33)**	**186** **(35)**

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in seven cases (6 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 010/31/2009

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of December 2009 is approximately 1.23 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	07/31/09	10/31/09
Cases with any adverse event	1576	1663
Died [1]	11	12
Hospitalized, excluding deaths	415	437
*Ectopic pregnancies [2]	43	46
*Experienced blood loss requiring transfusions [3]	216	227
*Infections [4] (Severe infections[5])	**186** **(35)**	**202** **(36)**

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The four remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 01/31/2010

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of December 2009 is approximately 1.23 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/09	01/31/10
Cases with any adverse event	1663	1764
Died [1]	12	13
Hospitalized, excluding deaths	437	468
*Ectopic pregnancies [2]	46	50
*Experienced blood loss requiring transfusions [3]	227	252
*Infections [4] (Severe infections[5])	**202** **(36)**	**214** **(37)**

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The five remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2010

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of December 2009 is approximately 1.23 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	01/31/10	04/30/10
Cases with any adverse event	1764	1852
Died [1]	13	13
Hospitalized, excluding deaths	468	494
*Ectopic pregnancies [2]	50	51
*Experienced blood loss requiring transfusions [3]	252	267
*Infections [4] (Severe infections[5])	**214** **(37)**	**221** **(39)**

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The five remaining U.S. deaths involved unique events; there was one case each of ruptured ectopic pregnancy, substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 07/31/2010

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of July 2010 is approximately 1.35 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	04/30/10	07/31/10
Cases with any adverse event	1852	1947
Died [1]	13	14
Hospitalized, excluding deaths	494	524
*Ectopic pregnancies [2]	51	53
*Experienced blood loss requiring transfusions [3]	267	287
*Infections [4] (Severe infections[5])	221 (39)	233 (39)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved unique events; there was one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*) and two cases of ruptured ectopic pregnancy. There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 10/31/2010

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of July 2010 is approximately 1.35 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	07/31/10	10/31/10
Cases with any adverse event	1947	2036
Died [1]	14	14
Hospitalized, excluding deaths	524	555
*Ectopic pregnancies [2]	53	55
*Experienced blood loss requiring transfusions [3]	287	301
*Infections [4] (Severe infections[5])	233 (39)	241 (40)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved unique events; there was one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*) and two cases of ruptured ectopic pregnancy. There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 01/31/2011

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of January 2011 is approximately 1.46 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/10	01/31/11
Cases with any adverse event	2036	2116
Died [1]	14	14
Hospitalized, excluding deaths	555	580
*Ectopic pregnancies [2]	55	55
*Experienced blood loss requiring transfusions [3]	301	315
*Infections [4] (Severe infections[5])	241 (40)	248 (43)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens)*. All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved unique events; there was one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*) and two cases of ruptured ectopic pregnancy. There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports that we have identified, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of April 2011 is approximately 1.52 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	01/31/11	04/30/11
Cases with any adverse event	2116	2207
Died [1]	14	14
Hospitalized, excluding deaths	580	612
*Ectopic pregnancies [2]	55	58
*Experienced blood loss requiring transfusions [3]	315	339
*Infections [4] (Severe infections[5])	248 (43)	256 (48)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight cases (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens)*. All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved unique events; there was one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*) and two cases of ruptured ectopic pregnancy. There were five additional deaths in foreign women who used mifepristone for termination of pregnancy. One death in a foreign clinical trial was associated with septic shock (*Clostridium sordellii* was identified in tissue samples). The other four foreign deaths were from the post marketing experience and were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the mifepristone labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 07/31/2011

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of August 2011 is approximately 1.6 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	04/30/11	07/31/11
Cases with any adverse event	2207	2292
Died [1]	14	14
Hospitalized, excluding deaths	612	641
*Ectopic pregnancies [2]	58	58
*Experienced blood loss requiring transfusions [3]	339	349
*Infections [4] (Severe infections[5])	256 (48)	270 (52)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight of the 14 reported fatalities (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens)*. All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were six additional deaths in women from foreign countries (non-US) who used mifepristone for termination of pregnancy. These included one death associated with septic shock (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, and five deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, “multivisceral failure”, a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, and toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures), respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 10/31/2011

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of August 2011 is approximately 1.6 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	07/31/11	10/31/11
Cases with any adverse event	2292	2385
Died [1]	14	14
Hospitalized, excluding deaths	641	678
*Ectopic pregnancies [2]	58	59
*Experienced blood loss requiring transfusions [3]	349	366
*Infections [4] (Severe infections[5])	270 (52)	279 (53)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight of the 14 reported fatalities (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens)*. All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were six additional deaths in women from foreign countries (non-US) who used mifepristone for termination of pregnancy. These included one death associated with septic shock (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, and five deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, “multivisceral failure”, a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, and toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures), respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 1/31/2012

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of December 2011 is approximately 1.68 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	10/31/11	01/31/12
Cases with any adverse event	2385	2475
Died [1]	14	14
Hospitalized, excluding deaths	678	705
*Ectopic pregnancies [2]	59	62
*Experienced blood loss requiring transfusions [3]	366	380
*Infections [4] (Severe infections[5])	279 (53)	289 (56)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight of the 14 reported fatalities (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens)*. All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were six additional deaths in women from foreign countries (non-US) who used mifepristone for termination of pregnancy. These included one death associated with septic shock (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, and five deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, “multivisceral failure”, a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, and toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures), respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2012

Mifepristone is FDA approved for the medical termination of intrauterine pregnancy through 49 days' pregnancy (Mifeprex, 2000) and to control high blood sugar levels (hyperglycemia) in adults with endogenous Cushing's syndrome (Korlym, 2012). The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used Mifeprex in the US through the end of December 2011 is approximately 1.68 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	01/31/12	04/30/12
Cases with any adverse event	2475	2570
Died [1]	14	14
Hospitalized, excluding deaths	705	730
*Ectopic pregnancies [2]	62	62
*Experienced blood loss requiring transfusions [3]	380	392
*Infections [4] (Severe infections[5])	289 (56)	293 (56)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight of the 14 reported fatalities (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were seven additional deaths in women from foreign countries (non-US) who used mifepristone for termination of pregnancy. These included one death associated with septic shock (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, and one death associated with sepsis reported to a foreign regulatory agency (not confirmed), and five deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure", a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, and toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures) respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 10/31/2012

Mifepristone is FDA approved for the medical termination of intrauterine pregnancy through 49 days' pregnancy (2000) and to control high blood sugar levels (hyperglycemia) in adults with endogenous Cushing's syndrome (2012). The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US for termination of pregnancy through the end of October 2012 is approximately 1.88 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy		
Cut off date of cumulative reports since approval date in US (September 2000)	04/30/12	10/31/12
Cases with any adverse event	2570	2740
Died [1]	14	14
Hospitalized, excluding deaths	730	768
*Ectopic pregnancies [2]	62	66
*Experienced blood loss requiring transfusions [3]	392	416
*Infections [4] (Severe infections[5])	293 (56)	308 (57)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight of the 14 reported fatalities (7 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*). There were seven additional deaths in women from foreign countries (non-US) who used mifepristone for termination of pregnancy. These included one death associated with septic shock (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, and one death associated with sepsis reported to a foreign regulatory agency (not confirmed), and five deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure", a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, and toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures) respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

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Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2014

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the US for the medical termination of pregnancy through the end of April 2014 is approximately 2.26 million women, an increase of approximately 380,000 since October 2012.

Table 1. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†]- 04/30/14
Died [1]	15
*Ectopic pregnancies [2]	77

* The majority of these women are included in the hospitalized category in Table 2.
[†] U.S. approval date

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†]- 10/31/12	11/1/12 - 04/30/14[‡]
Cases with any adverse event	2740	504
Hospitalized, excluding deaths	768	110
*Experienced blood loss requiring transfusions [3]	416	66
Infections [4] (*Severe infections [5])	308 (57)	37 (5)

* The majority of these women are included in the hospitalized category in Table 2.
[†] U.S. approval date

‡ FDA implemented FAERS on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

[1] Deaths were associated with sepsis in eight of the 15 reported fatalities (7 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The seven remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*), and one case in which cause of death based on autopsy findings could not be established and tissue samples were negative for *C. sordellii*. There were 10 additional deaths in women in foreign countries who used mifepristone for termination of pregnancy. These included one death associated with sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, one death associated with sepsis reported to a foreign regulatory agency (not confirmed), and eight deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure", a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures), asthma attack with cardiac arrest, Group A *Streptococcus pyogenes* (positive on vaginal swab and blood culture), and *Clostidium sordellii* sepsis in a published literature report, respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

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Mifepristone U.S. Postmarketing Adverse Events Summary through 10/31/2014

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the US for the medical termination of pregnancy through the end of October 2014 is approximately 2.4 million women, an increase of approximately 140,000 since April 2014.

Table 1. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†]- 04/30/14	05/01/14 – 10/31/14
Died [1]	15	0
*Ectopic pregnancies [2]	77	2

* The majority of these women are included in the hospitalized category in Table 2.
[†] U.S. approval date

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†]-10/31/12	11/1/12 - 04/30/14[‡]	05/1/14 - 10/31/14
Cases with any adverse event	2740	504	222
Hospitalized, excluding deaths	768	110	48
*Experienced blood loss requiring transfusions [3]	416	66	37
Infections [4] (*Severe infections [5])	308 (57)	37 (5)	14 (2)

* The majority of these women are included in the hospitalized category in Table 2.
[†] U.S. approval date

‡ FDA implemented FAERS on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

[1] Deaths were associated with sepsis in eight of the 15 reported fatalities (7 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The seven remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*), and one case in which cause of death based on autopsy findings could not be established and tissue samples were negative for *C. sordellii*. There were 10 additional deaths in women in foreign countries who used mifepristone for termination of pregnancy. These included one death associated with sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, one death associated with sepsis reported to a foreign regulatory agency (not confirmed), and eight deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure", a thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures), asthma attack with cardiac arrest, Group A *Streptococcus pyogenes* (positive on vaginal swab and blood culture), and *Clostidium sordellii* sepsis in a published literature report, respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

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Mifepristone U.S. Post-marketing Adverse Events Summary through 04/30/2015

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of April 2015 is approximately 2.5 million women, an increase of approximately 100,000 since October 2014.

Table 1. Cumulative Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†]- 10/31/14	11/01/14 - 04/30/15
Died [‡]	15	1[§]
*Ectopic pregnancies [||]	79	10

[†] U.S. approval date

[‡] Deaths were associated with sepsis in eight of the 16 reported fatalities (7 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Seven of the eight remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; and a case of delayed onset toxic shock-like syndrome. In the eighth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for *C. sordellii*. There were 11 additional deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium sordellii* sepsis (from a published literature report).

[§] An additional U.S. death was reported in July 2015. This case is pending further evaluation.

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†]-10/31/12	11/01/12 - 10/31/14[‡]	11/01/14 - 04/30/15
Cases with any adverse event	2740	726	258
Hospitalized, excluding deaths	768	158	39
*Experienced blood loss requiring transfusions [§]	416	103	31
Infections [||] (*Severe infections [¶])	308 (57)	51 (7)	23 (2)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

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Mifepristone U.S. Post-marketing Adverse Events Summary through 10/31/2015

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of October 2015 is approximately 2.68 million women, an increase of approximately 180,000 since April 2015.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in this summary.

Table 1. Cumulative Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†] - 4/30/15	5/01/15 - 10/31/15
Died [‡]	16	1
*Ectopic pregnancies [||]	89	4

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 17 reported fatalities (7 cases tested positive for Clostridium sordellii, and one case tested positive for Clostridium perfringens). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Seven of the nine remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; and a case of delayed onset toxic shock-like syndrome. In the eighth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for C. sordellii. The ninth case was reported in July 2015 and the cause of death was natural death due to severe pulmonary emphysema. There were 11 additional deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum*sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00 -10/31/12	11/01/12 - 4/30/15[‡]	5/01/15 - 10/31/15
Cases with any adverse event	2740	984	232
Hospitalized, excluding deaths	768	197	44
*Experienced blood loss requiring transfusions [§]	416	134	26
Infections [‖] (*Severe infections [¶])	308 (57)	74 (9)	13 (2)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[‖] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

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Mifepristone U.S. Post-marketing Adverse Events Summary through 12/31/2015

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of December 2015 is approximately 2.7 million women, an increase of approximately 20,000 since October 2015.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in this summary.

Table 1. Cumulative Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†]- 10/31/15	11/01/15 - 12/31/15
Died [‡]	17	0
*Ectopic pregnancies [||]	93	0

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 17 reported fatalities (7 cases tested positive for Clostridium sordellii, and one case tested positive for Clostridium perfringens). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Eight of the nine remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; delayed onset toxic shock-like syndrome; and a case of natural death due to severe pulmonary emphysema. In the ninth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for C. sordellii. There were 11 additional deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 10/31/15[‡]	11/01/15 - 12/31/15
Cases with any adverse event	2740	1216	6
Hospitalized, excluding deaths	768	241	4
*Experienced blood loss requiring transfusions [§]	416	160	1
Infections [||] (*Severe infections [¶])	308 (57)	87 (11)	1 (0)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

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Mifepristone U.S. Post-marketing Adverse Events Summary through 06/30/2016

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of June 2016 is approximately 2.87 million women, an increase of approximately 152,000 since December 2015.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in this summary.

Table 1. Cumulative Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†] - 12/31/15	01/01/16 - 06/30/16
Died [‡]	17	0
*Ectopic pregnancies [||]	93	2

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 17 reported fatalities (7 cases tested positive for Clostridium sordellii, and one case tested positive for Clostridium perfringens). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Eight of the nine remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; delayed onset toxic shock-like syndrome; and a case of natural death due to severe pulmonary emphysema. In the ninth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for C. sordellii. There were 11 additional deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 12/31/15[‡]	01/01/16 - 06/30/16
Cases with any adverse event	2740	1222	177
Hospitalized, excluding deaths	768	245	20
*Experienced blood loss requiring transfusions [§]	416	161	9
Infections [||] (*Severe infections [¶])	308 (57)	88 (11)	15 (1)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

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NDA 20-687

Mifepristone U.S. Post-marketing Adverse Events Summary through 12/31/2016

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of December 2016 is approximately 3.01 million women, an increase of approximately 141,000 since June 2016.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in this summary.

Table 1. Cumulative Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†] - 06/30/16	07/01/16 - 12/31/16
Died [‡]	17	0
*Ectopic pregnancies [||]	95	2

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 17 reported fatalities (7 cases tested positive for Clostridium sordellii, and one case tested positive for Clostridium perfringens). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Eight of the nine remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; delayed onset toxic shock-like syndrome; and a case of natural death due to severe pulmonary emphysema. In the ninth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for C. sordellii. There were 11 additional deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 06/30/16[‡]	07/01/16 - 12/31/16
Cases with any adverse event	2740	1399	27
Hospitalized, excluding deaths	768	265	4
*Experienced blood loss requiring transfusions [§]	416	170	10
Infections [||] (*Severe infections [¶])	308 (57)	103 (12)	0 (0)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

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Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2017

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of June 2017 is approximately 3.2 million women, an increase of approximately 168,000 since December 2016.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in a footnote in Table 1.

Table 1. Cumulative Post-Marketing Fatal and Ectopic Pregnancy Reports in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†] - 12/31/16	01/01/17 - 06/30/17
Died [‡]	17	3
*Ectopic pregnancies [||]	97	0

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 20 reported fatalities (7 cases tested positive for *Clostridium sordellii*, and one case tested positive for *Clostridium perfringens*). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Eleven of the twelve remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; drug intoxication; suspected homicide; suicide; delayed onset toxic shock-like syndrome; hemorrhage; unintentional overdose resulting in liver failure; and a case of natural death due to severe pulmonary emphysema. In the twelfth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for *C. sordellii*. There were 11 additional reported deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy			
Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 12/31/16[‡]	01/01/17 - 06/30/17
Cases with any adverse event	2740	1426	13
Hospitalized, excluding deaths	768	269	4
*Experienced blood loss requiring transfusions [§]	416	180	2
Infections [||] (*Severe infections [¶])	308 (57)	103 (12)	0 (0)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

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Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2017

The following information is from United States post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for the medical termination of pregnancy through the end of December 2017 is approximately 3.4 million women, an increase of approximately 163,000 since June 2017.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in a footnote in Table 1.

Table 1. Cumulative Post-Marketing Fatal and Ectopic Pregnancy Reports in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†] - 12/31/17
Died [‡]	22
*Ectopic pregnancies [||]	97

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 22 reported fatalities (7 cases tested positive for *Clostridium sordellii*, and one case tested positive for *Clostridium perfringens*). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Thirteen of the fourteen remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; drug intoxication; suspected homicide; suicide; delayed onset toxic shock-like syndrome; hemorrhage; unintentional overdose resulting in liver failure; drug overdose of undetermined intent and cardiac arrest; combined drug intoxication/overdose; and a case of natural death due to severe pulmonary emphysema. In the fourteenth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for *C. sordellii*. There were 11 additional reported deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 12/31/17[‡]
Cases with any adverse event	2740	1445
Hospitalized, excluding deaths	768	273
*Experienced blood loss requiring transfusions [§]	416	182
Infections [||] (*Severe infections [¶])	308 (57)	103 (12)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.