United States Senate
WASHINGTON, DC 20510

March 25, 2026

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

Chief Executive Officer[1]
Evita Solutions, LLC
P.O. Box 20055
Roanoke, VA 24018

To Whom It May Concern:

We write with deep concern regarding how Evita Solutions, LLC (Evita) intends to ensure compliance with the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program, as well as with questions surrounding Evita's business practices and transparency prior to the launch of its recently approved generic mifepristone product.

Evita is one of three sponsors approved by the U.S. Food and Drug Administration (FDA) to market the chemical abortion drug, mifepristone, for use in a regimen with misoprostol to terminate a pregnancy through 10 weeks gestation.[2] Evita was approved to sell a generic version of mifepristone in 2025,[3] but it does not appear to have begun marketing and selling the drug as of the date of this letter.[4] Mifepristone appears to be Evita's only product.[5]

Notably, key aspects of Evita's corporate structure and leadership are obscure despite being the sponsor of an FDA-approved drug that will be marketed and sold to Americans. The company has a very minimal online presence and thus far, no principals or spokespeople for the company have been publicly named. While FDA's materials list a P.O. Box address in Roanoke, VA,[6] there is no record of Evita's corporate headquarters. Evita's Articles of Organization list a different address in Glen Allen, VA,[7] but that appears to be the address of its registered agent, CT Corporation System. Publicly available documents do not provide clarity on the company's leadership team or any employees at all. Further, there is no information on Evita's product label about where its

[1] Or equivalent position. No employees of Evita are publicly known.
[2] Mifepristone, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390#tabs-3 (last visited Mar. 25, 2026).
[3] Letter from Ctr. for Drug Evaluation & Rsch. To Evita Solutions, LLC (Sept. 30, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.
[4] EVITA SOLUTIONS, https://www.medicalabortionpill.com/ (last visited Mar. 25, 2026) (Evita's website states that its "new generic mifepristone product is coming soon.").
[5] *Id.*
[6] *See Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG*, U.S. FOOD & DRUG ADMIN. (Sept. 2025), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2025_09_30_REMS_Full.pdf.
[7] *See* Evita Solutions, LLC, *Clerk's Information System*, VA. STATE CORP. COMM'N, https://cis.scc.virginia.gov/EntitySearch/BusinessFilings (last visited Mar. 25, 2026).

mifepristone product is or will be manufactured other than that it is (or will be) made in India.[8] This level of secrecy is unusual given that most pharmaceutical companies are far more transparent, including disclosing where their drugs are manufactured, their leadership teams, and other basic information about their business.

Evita's chemical abortion drug, mifepristone, is subject to a shared system REMS program, along with the brand version Mifeprex and the other generic version, "to mitigate the risk of serious complications associated with mifepristone."[9] The Mifepristone REMS Program has undergone significant changes since it was initially established in 2011, including allowing the drug to be prescribed through 10 weeks gestation (up from seven weeks initially), removing the requirement that prescribers report non-fatal adverse events to the drug manufacturer, and perhaps most concerningly, removing the requirement that the drug be dispensed through an in-person visit with a provider.[10] While we have long urged FDA to reinstate these needed REMS requirements that were recklessly removed by Democrat administrations,[11] we are concerned that Evita will not meet its legal responsibilities to ensure compliance with even the few remaining REMS requirements.

Under the current Mifepristone REMS Program approved in September 2025, the drug may only be dispensed under the supervision of certified prescribers or by certified pharmacies, on prescriptions issued by certified prescribers, and patients must be informed about the risk of serious complications associated with the drug.[12] In order to become a certified prescriber, a health care provider must, among other requirements, be qualified to (1) assess the duration of pregnancy accurately, (2) diagnose ectopic pregnancies, (3) provide surgical intervention in cases of incomplete abortion or severe bleeding, or have plans to provide such care through others, and (4) assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[13] Certified prescribers must also follow the guidelines for use of mifepristone. These guidelines include ensuring (1) the Patient Agreement Form is reviewed with and signed by the patient, (2) the risks of the mifepristone treatment regimen are fully explained to the patient, (3) the patient is provided with a copy of the Patient Agreement Form and Medication Guide, and (4) the signed Patient Agreement Form is placed in the patient's medical record.[14]

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[8] *Label: Mifepristone Tablet*, DAILYMED (Nov. 12, 2025), https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=839d7a7d-de19-42bd-8810-132b3c2a5daf&audience=consumer.

[9] Mifepristone, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390#tabs-3 (last visited Mar. 25, 2026).

[10] *See* New Drug Application (NDA): 020687, *Drugs@FDA: FDA-Approved Drugs*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020687 (last visited Mar. 25, 2026) (providing the documents describing the various REMS changes).

[11] *See, e.g.*, Letter from Sen. Lindsey O. Graham & Sen. Bill Cassidy, M.D. et al., to Robert F. Kennedy, Jr., Sec'y, U.S. Dep't of Health & Hum. Servs. & Martin A. Makary, Comm'r, U.S. Food & Drug Admin. (Oct. 9, 2025), https://www.lgraham.senate.gov/public/_cache/files/db3c8d4f-f16b-4393-9005-13461dcde9c2/letter-from-senator-graham-et-al-to-hhs-and-fda-re-mifepristone.pdf.

[12] *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG*, U.S. FOOD & DRUG ADMIN. 1 (Sept. 2025), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2025_09_30_REMS_Full.pdf.

[13] *Id.*

[14] *Id.* at 1–2.

Evita, for its part, must ensure that all prescribers of mifepristone are specially certified in accordance with these requirements and must de-certify prescribers who do not maintain compliance with certification requirements.[15] Evita must also monitor its distribution data to ensure compliance with the Mifepristone REMS Program, ensure that adequate records are maintained to demonstrate that the REMS requirements have been met, and annually audit new pharmacies and distributors annually.[16] Finally, Evita must report to FDA any deaths associated with mifepristone, whether or not considered drug-related, within 15 days of receiving the information.[17]

We are concerned that Evita will not be able to ensure the REMS requirements are met, especially as it pertains to the online prescribing of mifepristone. Furthermore, because many online clinics allow individuals, including men, to order the drugs anonymously, it is unclear how prescribers can ensure that the Patient Agreement Form is reviewed with the patient, signed by the patient, and placed in the patient's medical record. It is also unclear how an online prescriber could adequately explain the risks of the mifepristone treatment regimen to the patient in accordance with the existing REMS. In terms of patient safety, many online sellers of mifepristone appear to automatically prescribe the drug after an individual merely fills out a cursory intake form, raising questions about whether prescribers could accurately assess gestational age or be able to diagnose an ectopic pregnancy—failures that could lead to serious adverse events for the patient.[18] Additionally, it is unclear how online prescribers can satisfy the REMS requirement to provide surgical intervention themselves, or arrange such care through others, if the individual ordering the drug is anonymous and may be located many states away from the prescriber. Finally, patient anonymity and the lack of an adequate doctor-patient relationship raise concerns about whether patient deaths associated with mifepristone obtained through online prescribers could be reported to Evita, which would again be in violation of the REMS requirements. Notably, many online prescribers advise patients that they do not have to tell a doctor that they took the chemical abortion drugs if they later must seek care for serious adverse events.[19]

There is substantial evidence that women are being harmed not only by serious adverse events associated with chemical abortion drugs,[20] but also by coercion and other risks resulting from inadequate implementation of REMS safeguards intended to protect patients.[21] It is also clear that

[15] *Id.* at 2.
[16] *Id.* at 5.
[17] *Id.*
[18] *See, e.g.*, Video posted by AAPLOG (@aaplog), X (Mar. 11, 2026, at 7:26 PM), (showing how there is little to no actual medical review before prescribing chemical abortion drugs on websites like Aid Access).
[19] *See, e.g.*, *How to use abortion pills*, AID ACCESS, https://aidaccess.org/en/how-to-use-abortion-pills (last visited Mar. 25, 2026).
[20] *See, e.g.*, Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, ETHICS & PUB. POL'Y CTR. (Apr. 28, 2025), https://media.eppc.org/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf (finding that there is a serious adverse event rate of 10.93 percent for women who take chemical abortion drugs).
[21] *See, e.g.*, Anna Callahan, *Abortion Drugs Fuel Abuse: The Women Poisoned Against Their Will*, SUSAN B. ANTHONY PRO-LIFE AMERICA (Feb. 26, 2026), https://sbaprolife.org/latest-news/abortion-drugs-fuel-abuse-the-

the removal of the requirement to report non-fatal adverse events has significantly downplayed the danger mifepristone poses to women. Further, the removal of the in-person dispensing requirement has allowed the drug to be widely prescribed with few guardrails to ensure it is being taken safely, without coercion, and with prompt care available for serious complications. While Evita was just created in 2024[22] and its mifepristone product is not yet being sold, statements on Evita's website create doubts about whether the company will seriously enforce compliance with the Mifepristone REMS Program. For example, Evita's website states that "[m]edical abortion care is rife with medically unnecessary restrictions and social stigma in the United States."[23] It also says that its mission is to "destigmatize abortion care" and "commit to making care accessible."[24] It goes without saying that killing unborn children is not health care, but statements like this show that Evita may not fulfill its legal obligations to ensure that the few remaining REMS safeguards are complied with to protect women from serious harm from chemical abortion drugs.

With chemical abortions provided by online clinics now estimated to account for 27 percent of all abortions in the U.S. (about 160,000 abortions in the first half of 2025),[25] Evita must commit to immediately implementing the Mifepristone REMS Program requirements and de-certifying prescribers who do not comply once it begins to sell mifepristone. If it refuses to do so, Evita will be putting its profits above the health and safety of women and children.

Given these serious concerns regarding Evita's ability to comply with its legal obligations under the Mifepristone REMS Program, we request that you answer the following questions, on a question-by-question basis, **no later than April 8, 2026**. We request that all documents, data, and any other responsive materials be unredacted, produced in electronic form, and Bates stamped.

1. When will Evita begin marketing its generic mifepristone product?
2. Where does Evita currently manufacture mifepristone (or where will it in the future)? Please provide the name and address of each facility where mifepristone is currently manufactured or will be in the future.
3. Please produce records documenting all FDA inspections of your manufacturing facilities, including any pre-approval inspections, and FDA's respective final classifications of such inspections.
4. Where does Evita currently or plan to import the active pharmaceutical ingredient (API) for mifepristone? Please provide the name and address of each facility where the API for mifepristone is currently or planned to be imported from.

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women-poisoned-against-their-will (listing various cases where women were coerced into having a chemical abortion against their will or without their knowledge).

[22] *See* Evita Solutions, LLC, *Clerk's Information System*, VA. STATE CORP. COMM'N, https://cis.scc.virginia.gov/EntitySearch/BusinessFilings (last visited Mar. 25, 2026) (According to Virginia business records, Evita was formed on June 26, 2024).

[23] *Our Values*, EVITA SOLUTIONS, https://www.medicalabortionpill.com/#about-us (last visited Mar. 25, 2026).

[24] *Id.*

[25] *#WeCount report, April 2022 to June 2025*, SOC'Y OF FAM. PLAN., https://societyfp.org/research/wecount/wecount-june-2025-data/ (last visited Mar. 25, 2026).

5. Please produce a list of all current (or future) distributors Evita is contracted with to distribute mifepristone into the U.S. Please also include the dates that each contract began.
6. Has Evita engaged any third-party vendors to administer the Mifepristone REMS Program? If so, please identify any such vendors currently engaged, provide the term of these contracts, and describe the functions each vendor will perform in support of REMS administration.
7. Are any individuals currently certified to prescribe Evita's mifepristone in the Mifepristone REMS Program? Please produce an Excel spreadsheet showing how many prescribers are certified in each state, if any.
8. Are any pharmacies currently certified to dispense Evita's mifepristone in the Mifepristone REMS Program? Please produce an Excel spreadsheet showing how many pharmacies are certified in each state, if any. Please also include the name, address, and date of certification for each pharmacy, if any.
9. Please explain how Evita will ensure that online prescribers of mifepristone review the Patient Agreement Form with patients and fully explain the risks of the mifepristone treatment regimen.
10. Please explain how Evita will ensure that online prescribers of mifepristone consistently require patients to sign the Patient Agreement Form.
11. Please explain how Evita will ensure that online prescribers of mifepristone consistently put the signed Patient Agreement Form into each patient's medical record.
12. Please explain how Evita will ensure that online prescribers of mifepristone have the ability to assess the duration of pregnancy accurately.
13. Please explain how Evita will ensure that online prescribers of mifepristone have the ability to diagnose ectopic pregnancies.
14. Please explain how Evita will ensure that online prescribers of mifepristone have the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or make plans to provide such care through others.
15. Please explain how Evita will ensure that online prescribers of mifepristone assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
16. Please explain how Evita will ensure that all deaths associated with mifepristone are reported to it, especially for mifepristone prescribed by an online prescriber.
17. Please describe whether and how Evita will continually monitor non-fatal adverse events associated with mifepristone and report them to FDA.
18. As you are aware, FDA approved Evita's Abbreviated New Drug Application (ANDA) for mifepristone four years after its filing, well-beyond the 180-day statutory deadline for action on an ANDA. Please produce any written communication between FDA and Evita regarding this delay, including any agreements reached to delay the eventual approval of your product.
19. Virginia state records indicate that Evita was formed as a limited liability company in that state on June 26, 2024. However, in FDA's letter to Evita approving the ANDA for mifepristone, it stated that Evita's application was received on October 1, 2021. Was Evita

previously operating as a different company or under a different name at the time it submitted the ANDA for mifepristone?

a. If yes, please produce business records showing the entity name, entity type, dates that it was active, names of entity leadership, entity addresses, and state of registration that account for the period between October 1, 2021, and June 26, 2024. Please also describe why Evita registered as a new entity in Virginia years after submitting its ANDA for mifepristone. Please also explain whether any former entity or entities are still active.
b. If no, please explain how Evita could have submitted the ANDA for mifepristone over two years before it was a registered company.

Thank you for your attention to this important matter and for your cooperation with our inquiry.

Sincerely,

Bill Cassidy, M.D.
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions

Steve Daines
United States Senator

James Lankford
United States Senator

Cindy Hyde-Smith
United States Senator

Lindsey O. Graham
United States Senator