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REPLY TO DC

October 10, 2025

The Honorable Martin A. Makary
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

CC: **The Honorable Robert F. Kennedy Jr.**
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Lee Zeldin
Administrator, U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Commissioner Makary,

Along with numerous others, we are gravely concerned by the FDA's recent approval of Evita Solutions LLC's Abbreviated New Drug Application (ANDA) for generic mifepristone tablets.[1]

Though we believe it vital to underscore mifepristone's known safety concerns, particularly as the most recent, reliable evidence shows a complication rate based on real-world events that is *22 times higher* than the rate reported on the FDA-approved drug label, we more narrowly wish to draw your attention to the known and potential environmental harms associated with the abortion drug regimen. Related, while we understand the rationale that federal law (presumably the Federal Food, Drug, and Cosmetic Act[2]) may have required the FDA to approve the Evita Solutions ANDA, we respectfully propose that other portions of federal law provide the FDA with the requisite

authority to pause and revoke approval for all generic and brand-name versions of the abortion drug mifepristone.

As the following excerpts from our recent Special Report on *Abortion In Our Water* summarize, while "[ANDAs] may rely on previous findings 'that the **reference listed drug (RLD)** is safe and effective,'"[3] the RLD in question (Mifeprex[4]) is *neither safe nor effective.*[5] Indeed, in addition to increasing instances of coerced or forced abortions,[6] serious adverse events, ranging from hemorrhage to sepsis and more,[7] affect 1 in 10 women.[8] Furthermore, in both the New Drug Application (NDA) and subsequent 2019 ANDA for the abortion drug regimen,[9] "the FDA failed to adequately adhere to the Clean Water Act (CWA) and National Environmental Policy Act (NEPA),"[10] both of which make clear that where a federal agency's activity or actions (e.g., approving a drug) may pollute the environment, a detailed environmental document is required:

- The CWA states that "each officer, agent, or employee [of a department, agency, or instrumentality of the executive, legislative, and judicial branches of the Federal Government] in the **performance of his official duties [e.g., approving drug applications, including ANDAs],** shall be subject to, and comply with, all Federal, State, interstate, and local requirements, administrative authority, and process and sanctions respecting the control and abatement of water pollution."[11] According to the CWA, mifepristone and its active metabolites would qualify as pollutants ("chemical wastes") that are discharged into wastewater systems and likely to enter our water supply, given conventional wastewater treatment plants do not fully remove these types of contaminants.[12] Under the CWA, fetal remains generated from chemical abortions also qualify as "pollutants" that may be discharged into our water systems, threatening environmental safety as said remains lead to clogs, and subsequently, contribute to sewer system overflows.[13]
- The NEPA similarly outlines that **even major federal actions [e.g., an ANDA approval] with no "reasonably foreseeable significant effect on the quality of the human environment," or whose significance is unknown, shall at the least include an environmental assessment,** unless an exclusion applies – and none should.[14] According to the Code of Federal Regulations, "significantly" as used in NEPA includes consideration of "The degree to which the effects on the quality of the human environment are likely to be highly controversial."[15] Fetal remains being flushed into the sewer system is, in the eyes of many, highly controversial.

None of the above was adequately considered in the original environmental assessment for mifepristone. Subsequently, the abortion industry continues to instruct women to sit on the toilet[16] during chemical abortions, with the full knowledge that fetal remains of 10+ weeks gestation, which can range upwards of one inch in size,[17] will be flushed into our sewers. This not only traumatizes women, who can see a fully formed baby floating in their toilet,[18] but (as outlined above) can adversely impact our environment by contributing to sewer system overflows, among other things. Wastewater treatment systems are not meant to process such medical waste and

human remains — morgues and medical waste facilities exist for this purpose. Indeed, consider if another industry established a standard practice of instructing its clientele to flush something that was large enough to cause a sewer system overflow. There would undoubtedly be calls to prohibit such a practice. Yet the abortion industry, with the assistance of "deep state" actors at the FDA, seems impervious to such scrutiny.

A final point: The Evita Solutions ANDA was submitted in 2021.[19] In other words, it has been in process for four years. It seems not only illogical but irresponsible that the FDA would suddenly provide final approval for it, predicated on an RLD that should not have been approved in the first place, particularly in light of Health and Human Services Secretary Robert F. Kennedy's promised safety review of mifepristone and acknowledgement that "recent studies already point to serious risks when mifepristone is used without proper medical oversight."[20] Indeed, reasonable FDA reviewers should have concluded the original NDA was insufficient, lacked a legally compliant environmental assessment, and therefore not only denied approval of the Evita Solutions ANDA, but, as recommended by 22 Attorneys General, considered "withdrawing mifepristone from the market until [FDA] completes its review and can decide on a course of action based on objective safety and efficacy criteria."[21]

Rather than perpetuate the dangerous, unsupervised use of mifepristone by allowing a generic version of the drug to flood the market (which — according to the principles of a free market — will likely drive down costs and increase access to said drug), we respectfully propose the FDA both consider the advice of the aforementioned Attorneys General, and at the least, revoke approval for the Evita Solutions ANDA pending a thorough, legally compliant environmental assessment.

We would sincerely appreciate the opportunity to discuss these matters further at a time and place convenient to you.

Sincerely,

Mathew D. Staver, Esq.
Founder and Chairman, Liberty Counsel Action

John Stemberger
President, Liberty Counsel Action

Jonathan Alexandre
Vice President of Governmental Affairs and Senior Counsel, Liberty Counsel Action

Endnotes

[1] Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.
[2] Office of the Law Revision Counsel, 21 U.S.C. §355(j), accessed October 7, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[3] Liberty Counsel Action, "Abortion in Our Water: A Special Report," 2025, https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf. See also: "Determining Whether to Submit an ANDA or a 505(b)(2) Application Guidance for Industry," U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), May 2019, https://www.fda.gov/media/124848/download.
[4] Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf. Specifically, the letter states "We have determined your Mifepristone Tablets, 200 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Mifeprex (mifepristone) tablets, 200 mg, of Danco Laboratories, LLC NDA – 020687."
[5] Jamie Bryan Hall and Ryan T. Anderson, "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event," Ethics and Public Policy Center, April 28, 2025, https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/.
[6] Carole Novielli, "Woman sues baby's father and abortion pill business for wrongful death of preborn child," Live Action, August 11, 2025, https://www.liveaction.org/news/woman-sues-father-abortion-pill-wrongful-death; Melanie Israel, "Abortion Pills, Coercion, and Abuse," The Heritage Foundation, September 23, 2025, https://www.heritage.org/life/commentary/abortion-pills-coercion-and-abuse.
[7] Jamie Bryan Hall and Ryan T. Anderson, "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event," Ethics and Public Policy Center, April 28, 2025, https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/.
[8] Ibid.
[9] Letter to the Population Council, from the Food and Drug Administration, "NDA 20-687," September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf; Letter to GenBioPro, Inc., from the Food and Drug Administration, "ANDA APPROVAL," April 11, 2019; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf; Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=216616.
[10] Liberty Counsel Action, "Abortion in Our Water: A Special Report," 2025, https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf.
[11] Office of the Law Revision Counsel, 33 U.S.C. §1323, accessed October 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim. For more detail on the CWA and NEPA, see https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf.
[12] For further information on this point, see Liberty Counsel Action's White Paper, "Stemming the Tide of Chemical Abortions Contaminating Our Water," 2025, https://lcaction.org/LCA-PDFs/StemmingtheTideofChemicalAbortionsContaminatingOurWater.pdf.
[13] According to the EPA, combined sewer system overflows (CSOs) "are a major water pollution and public health concern for approximately 700 communities in the United States. CSOs can contain bacteria, debris, and other hazardous substances that can be harmful to people, pets, and wildlife. CSOs can also cause beach closures, shellfish bed closures, algae growth, reduced oxygen levels in waterways, and aesthetic impacts from floating debris or oil slicks." See: "Combined Sewer Overflow Basics," U.S. Environmental Protection Agency, updated August 28, 2025, https://www.epa.gov/npdes/combined-sewer-overflow-basics. The EPA also states, "[p]reventable toilet and sewer backups can pose a threat to human health and present an extra challenge to our water utilities and their workforce. Flushing anything other than toilet paper [wipes, tampons, etc.] . . . can damage internal plumbing, local sewer systems and septic systems." See: "EPA Encourages Americans to Only Flush Toilet Paper," United States Environmental Protection Agency, March 30, 2020, https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper.
[14] Office of the Law Revision Counsel, 42 U.S.C. §4336, accessed October 7, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim. Specifically this section states "An agency shall prepare an environmental assessment with respect to a proposed agency action that does

not have a reasonably foreseeable significant effect on the quality of the human environment, or if the significance of such effect is unknown, unless the agency finds that the proposed agency action is excluded pursuant to one of the agency's categorical exclusions, another agency's categorical exclusions consistent with section 4336c of this title, or another provision of law. Such environmental assessment shall be a concise public document prepared by a Federal agency to set forth the basis of such agency's finding of no significant impact or determination that an environmental impact statement is necessary." The 1998 CFR, which remained in similar form in the 2014 CFR, outlines that even in cases where an exclusion applies, the "FDA will require at least an EA for any specific action [e.g. approving a drug] that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment." See: Code of Federal Regulations, Title 21, Chapter I, §25.21, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1.pdf; Code of Federal Regulations, Title 21, Chapter 1, §25.21, 2014, https://www.govinfo.gov/content/pkg/CFR-2014-title21-vol1/pdf/CFR-2014-title21-vol1.pdf and Food and Drug Administration | Department of Health and Human Services, "Final Rule" | National Environmental Policy Act; Revision of Policies and Procedures, July 29, 1997, https://www.govinfo.gov/content/pkg/FR-1997-07-29/pdf/97-19566.pdf. A 1998 FDA guidance adds more clarity, outlining "extraordinary circumstances … can be based on the production, use, or disposal from use of the FDA-regulated article."

Given that:

1. A "disposal from use" of the FDA-regulated articles (abortion drugs) would be necessary, as after the drug(s) is(are) used to end a pregnancy, human remains and medical waste must be disposed of, and
2. Failure to dispose of said remains properly could significantly affect (per the definition of significant) the quality of the human environment,

the "extraordinary circumstance" of medical waste generation should have been considered in subsequent approvals of the two-drug abortion pill protocol. (NB: the guidance document goes into yet greater detail, reiterating that, "The Food and Drug Administration (FDA) is required under the NEPA to consider the environmental impacts of approving drug and biologics applications as an integral part of its regulatory process.") See: Environmental Assessment of Human Drug and Biologics Applications | Guidance for Industry," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research Center for Biologics Evaluation and Research, July 1998, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/environmental-assessment-human-drug-and-biologics-applications.

[15] Code of Federal Regulations, Title 40, Chapter 5, §1508.27, 2020, https://www.govinfo.gov/content/pkg/CFR-2020-title40-vol37/pdf/CFR-2020-title40-vol37.pdf. (NB: In 2021, this portion of the CFR became "Reserved." It is unclear if changes were made. The Evita Solutions, LLC ANDA was submitted in 2021.)

[16] Kendall @ Planned Parenthood, "What do I need to do before I take abortion pills?", Planned Parenthood, October 4, 2022, https://www.plannedparenthood.org/blog/what-do-i-need-to-do-before-i-take-abortion-pills; "Aftercare Instructions: Medication Abortion," Comprehensive Women's Health Center, accessed April 7, 2025, https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html.

[17] While estimates vary, multiple sources suggest a 10-week fetus is at least one inch; for examples, see: Karen Miles, "How fast is your baby growing? See how fetal weight and height change by week during pregnancy," Baby Center, May 30, 2025, https://www.babycenter.com/pregnancy/your-body/growth-chart-fetallength-and-weight-week-by-week_1290794; "Better Health | Start For Life, Week 10," National Health Service, accessed October 7, 2025, https://www.nhs.uk/start-for-life/pregnancy/week-by-week-guide-to-pregnancy/1st-trimester/week-10/.

[18] Lisa Bast, "Helpline founder sees spike in women 'seeing their fully formed babies' after abortion pill," Live Action, February 20, 2024, https://www.liveaction.org/news/national-helpline-calls-chemical-abortions. See also: "Live Action's new 'I Saw My Baby' website shines a light on abortion pill trauma," Live Action, August 5, 2023, https://www.liveaction.org/news/live-action-saw-baby-abortion-pill-trauma.

[19] Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.

[20] @SecKennedy, X Post, October 2, 2025, https://x.com/SecKennedy/status/1973866621245567344.

[21] "Over 20 Attorneys General Cite EPPC Abortion Pill Study in Call for the FDA to Reinstate Safeguards," Ethics and Public Policy Center, August 13, 2025, https://eppc.org/news/over-20-attorneys-general-cite-eppc-abortion-pill-study-in-call-for-the-fda-to-reinstate-safeguards/.