



Kristan Hawkins, President
Students for Life of America
1000 Winchester Street, Suite 301
Fredericksburg, VA 22401

Kristi Hamrick, Chief Media & Policy Strategist
Students for Life of America
1000 Winchester Street, Suite 301
Fredericksburg, VA 22401

Re: Docket No. FDA-2022-P-2872

May 12, 2023

Dear Ms. Hawkins and Ms. Hamrick:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on November 15, 2022. Your petition requests that the Agency “modify the Risk Evaluation and Mitigation Strategy (REMS) regarding mifepristone (Mifeprex[®] or RU-486) ... to require prescribers to include a Medical Waste bag and Catch-Kit with all Mifepristone prescriptions.”

FDA has been unable to reach a decision on your petition because it raises complex issues. We note that FDA received another citizen petition from Students for Life of America on April 19, 2023 (Docket No. FDA-2023-P-1528) that raises similar issues, and we are in the process of reviewing both citizen petitions. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Patrizia A.

Cavazzoni -S

Digitally signed by Patrizia
A. Cavazzoni -S
Date: 2023.05.12 11:34:29
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Patrizia Cavazzoni, M.D.

Director

Center for Drug Evaluation and Research