FDA U.S. FOOD & DRUG ADMINISTRATION

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SEP 26 2019

Re: Docket No. FDA-2019-P-1534

Dear Drs. Harrison and Van Meter:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 31, 2019. Your petition requests that the Agency restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, retain the Mifeprex Risk Evaluation and Mitigation Strategy, and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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