



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

April 1, 2019

Donna J. Harrison M.D.
Executive Director
American Association of Pro-Life Obstetricians and Gynecologists
PO Box 395
Eau Claire, MI 49111-0395

Quentin L. Van Meter, M.D., FCP
President
American College of Pediatricians
PO Box 357190
Gainesville, FL 32635-7190

Sent via email to : donna@aaplog.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug Administration restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, retain the Mifeprex Risk Evaluation and Mitigation Strategy (REMS), and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber was received by this office on 03/31/2019.

It was assigned docket number FDA-2019-P-1534. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)