



October 6, 2022

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*Sent via email to:* [rtetlow@acog.org](mailto:rtetlow@acog.org)

Dear Petitioner:

Your submission requesting that the Commissioner to ask Danco to submit an sNDA to add miscarriage management as an indication to the mifepristone label and to modify the REMS so that it does not unduly burden its use for miscarriage management was received and processed under CFR 10.30 by this office on 10/06/2022.

It was assigned docket number FDA-2022-P-2425. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin  
Acting Director  
Dockets Management Staff  
FDA/Office of Operations (OO)