FDA Office of Media Affairs <FDAOMA@fda.hhs.gov> Fri, Aug 12, 2022 at 3:36 PM
To:
Cc: FDA Office of Media Affairs <FDAOMA@fda.hhs.gov>

Hi, Carole.

I'm writing to provide a response to your inquiry. You can attribute this to "the FDA" or to "an FDA spokesperson."

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The current Mifepristone REMS Program requires certified prescribers to dispense mifepristone directly to the patient in a clinic, medical office, or hospital. However, the Agency has stated its intent to exercise enforcement discretion with respect to the in-person dispensing requirement during the COVID-19 public health emergency (PHE). During the periods when the in-person dispensing requirement has not been enforced, the applicants for Mifeprex and the approved generic version of Mifeprex, Mifepristone Tablets, 200 mg, have used mail order pharmacies to receive and hold mifepristone on behalf of the certified healthcare providers who purchased the product. The PHE is ongoing, and thus FDA's intent to exercise enforcement discretion remains unchanged.

As of December 16, 2021, FDA completed its review of the Mifepristone REMS Program and determined, among other things, that the REMS must be modified to remove the in-person dispensing requirement and add pharmacy certification. In accordance with the typical process for REMS modifications, FDA sent REMS modification notification letters to the applicants for Mifeprex and the approved generic version of Mifeprex, Mifepristone Tablets, 200 mg. Following receipt of these letters, the applicants prepared proposed REMS modifications and submitted them to FDA. FDA will promptly review the REMS modification submissions made by the applicants; once any submissions are approved, the REMS modifications will be effective.

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