LIVE ACTION [redacted]

Media Request: Changes to Mifeprex REMS

FDA Office of Media Affairs <FDAOMA@fda.hhs.gov> Fri, Jan 21, 2022 at 1:21 PM
To: [redacted]

Hi [redacted]

The responses to your questions are as follows:

1. **Would the FDA please send details of the FDA's recent changes to the REMS on the drug Mifeprex (Mifepristone), including copies of correspondence sent to the members of the media as well as those involved in litigation on this topic?**

Please visit the Mifeprex Q&A page for information on the REMS update.

2. **Could the FDA explain the certification process for pharmacies and whether this pertains only to online pharmacies or if walk in pharmacies can 1). stock Mifeprex and 2). sell Mifeprex over the counter?**

On Dec. 16, 2021, the Agency determined that the Mifepristone REMS Program must be modified. As modified, the REMS will allow for the drug to be dispensed by mail order or specialty pharmacies. We based our conclusions on a comprehensive review of the published literature, other relevant safety and adverse event data, information provided by advocacy groups, individuals and the applicants, and information submitted by plaintiffs in the ongoing Chelius v. Becerra litigation. At this time, we don't have data to determine whether mifepristone for medical termination of early pregnancy can be dispensed safely through retail pharmacies in accordance with the REMS.

Consistent 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, which were sent on Dec. 16, 2021, the applicants will prepare proposed REMS modifications and submit them to FDA within 120 days. The specific qualifications necessary for pharmacies to be certified in the program will be further clarified through FDA's review and approval of the proposed REMS modifications submitted by the applicants. Any pharmacy that meets those qualifications will be able to be certified. The pharmacy certification requirement will ensure that pharmacies are aware of and agree to follow applicable REMS requirements and ensure that mifepristone is only dispensed with a written prescription from certified prescribers.

3. **Can the FDA also send a citation listing any studies or literature FDA reviewed for drawing their recent conclusions published on December 16, 2021, for changes to Mifeprex (REMS).**

The 2021 REMS review involved detailed analysis of a significant amount of data. On Dec. 16, 2021, FDA also issued a response to a Citizen Petition that requested certain modifications to the Mifepristone REMS Program. The agency's response to the petitioner includes an analysis of the REMS elements and discusses the Agency's review of multiple different sources of information, including published literature. The agency's response is available on Regulations.gov.

4. **In addition, please send a list of all FDA experts who reviewed the studies/literature and FDA experts involved in the process of making the decision to change the REMS on Mifeprex on December 16, 2021.**

FDA career staff with the appropriate training and expertise undertook a comprehensive review of the published literature, other relevant safety data (including adverse event data), information provided by advocacy groups, individuals and the applicants, and information submitted by plaintiffs in the ongoing litigation, and concluded that the Mifepristone REMS Program must be modified. The agency does not release the names of individual staff employees who work on issues related to the regulation of the products that are subject to this REMS.

Thank you,

FDA Office of Media Affairs