PROVIDER Bulletin

KERN HEALTH SYSTEMS

April 11, 2023

FDA Removes Approval of Makena (hydroxyprogesterone)

Dear Provider,

The following was shared by the State Board of Pharmacy:

Today, the U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

"It is tragic that the scientific research and medical communities have not yet found a treatment shown to be effective in preventing preterm birth and improving neonatal outcomes—particularly in light of the fact that this serious condition has a disparate impact on communities of color, especially Black women," said FDA Commissioner Robert M. Califf, M.D. "Fundamentally, however, the touchstone of FDA drug approval is a favorable benefit-risk assessment; without that favorable assessment, the drug should not have the status of being FDA-approved."

The FDA approved Makena under the accelerated approval pathway in 2011 based on a determination that the sponsor had demonstrated a drug effect on an intermediate clinical endpoint that was reasonably likely to predict clinical benefit. The agency's approval included a requirement that the sponsor conduct a post marketing confirmatory study. The ensuing confirmatory study did not verify clinical benefit and the FDA's Center for Drug Evaluation and Research (CDER) proposed withdrawing the drug's approval in 2020. The sponsor requested a hearing, which was held in October 2022.

Following the hearing, the FDA Commissioner and Chief Scientist reviewed the record for this matter, including the submissions by CDER and sponsor Covis Pharma, public comments to the docket, the transcript of the hearing and the Presiding Officer's report. Based on that review, they have decided to withdraw approval of Makena and generic versions of Makena.

The decision issued today by the FDA Commissioner and Chief Scientist outlines their rationale and also recognizes the crucial need to develop treatments to reduce the serious risks associated with preterm birth.

"We acknowledge at the outset the serious problems of preterm birth with respect to both maternal and neonatal health and the contribution of institutional forces that have led to health disparities, including preterm birth, among Black women," said FDA Chief Scientist Namandjé Bumpus, Ph.D. "Nothing in this opinion today is intended to minimize these concerns – to the contrary, our hope is that this decision will help galvanize further research."

While the approvals of Makena and its generics have been withdrawn, the agency recognizes that there is a supply of product that has already been distributed. Patients who have questions should talk to their healthcare provider. Approvals of these drugs have been withdrawn because the drugs are no longer shown

to be effective and the benefits do not outweigh the risks for the indication for which they were approved. For additional information, see Makena Information on FDA.gov.

KHS posts all bulletins on the KHS website, www.kernfamilyhealthcare.com, choose Provider, then Bulletins.

For any questions, please contact your Provider Relations Representative at 1-800-391-2000.

Sincerely,

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Kern Health Systems