FDA STATEMENT
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FDA Statement on Makena

On February 3, 2011, the U.S. Food and Drug Administration approved the drug Makena (hydroxyprogesterone caproate) for the reduction of the risk of certain preterm births in women who have had at least one prior preterm birth. KV Pharmaceuticals, the drug's owner, received considerable assistance from the federal government in connection with the development of Makena by relying on research funded by the National Institutes of Health to demonstrate the drug's effectiveness. It also obtained seven years of exclusivity under the Orphan Drug Act, obtained approval under FDA's accelerated approval program, and received expedited review.

For many years, a version of the active ingredient of Makena, which is a synthetic progestin, has been available to patients whose physicians requested the drug from a pharmacist who compounded the drug. Generally, FDA has exercised enforcement discretion with respect to most products made through traditional pharmacy compounding. This has included products made from the active ingredient in Makena, hydroxyprogesterone caproate.

Because Makena is a sterile injectable, where there is a risk of contamination, greater assurance of safety is provided by an approved product. However, under certain conditions, a licensed pharmacist may compound a drug product using ingredients that are components of FDA approved drugs if the compounding is for an identified individual patient based on a valid prescription for a compounded product that is necessary for that patient. FDA prioritizes enforcement actions related to compounded drugs using a risk-based approach, giving the highest enforcement priority to pharmacies that compound products that are causing harm or that amount to health fraud.

FDA understands that the manufacturer of Makena, KV Pharmaceuticals, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is not correct.

In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. As always, FDA may at any time revisit a decision to exercise enforcement discretion.