April 13, 2023

Product Information Bulletin

On April 6, 2023 the U.S. Food and Drug Administration announced its final decision to withdraw approval of Makena® (hydroxyprogesterone caproate injection, 250 mg/ml) and the generic versions. The decision was issued jointly by the FDA Commissioner and Chief Scientist. As a result, Makena and its generics are no longer FDA approved.

Upon receipt of FDA's decision, American Regent immediately stopped distribution of its hydroxyprogesterone caproate injection. There may be limited supply of American Regent product that had already been distributed, including to physicians' offices and pharmacies. FDA acknowledged in its communication that "some health care providers might continue to prescribe or administer that limited remaining supply to their patients … and should consider FDA's conclusion that these drug products are not shown to be effective for the indication for which they were approved and do not have benefits that outweigh their risks to patients." Patients that were being treated with hydroxyprogesterone caproate injection, 250 mg/ml, should consult with their physician about their future treatment options.

Although American Regent manufactures and distributes certain unapproved drug products, it is under limited circumstances in accordance with an FDA Compliance Policy Guide entitled, 'Marketed New Drugs without Approved NDAs or ANDAs, and in discussions with the FDA regarding the continued manufacture and sale of these products (sometimes in response to FDA requests to continue production in order to avoid shortages of critical drugs). We do not currently expect to be conducting any further manufacture or distribution of hydroxyprogesterone caproate injection.

Healthcare Professionals with requests for Medical Information regarding American Regent's hydroxyprogesterone caproate injection can be found here.

Additional information regarding American Regent's Sales and Returns policies can be found here.

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