

FDA May Take Action Against Pharmacies and Outsourcing Facilities that Compound Hydroxyprogesterone Caproate

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The Food and Drug Administration (FDA) posted a page on its website in July reminding pharmacists and outsourcing facilities not to regularly compound hydroxyprogesterone caproate or any drug products that are essentially a copy of an FDA-approved drug, such as Makena®. The link for this page is <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm402614.htm>. The page reinforces the same stance the FDA took previously in its June 15, 2012 statement on pharmacist compounding of hydroxyprogesterone caproate. The 2012 statement preceded the Drug Quality and Security Act (DQSA), which added new sections to the Food, Drug and Cosmetic Act. Because the DQSA addresses outsourcing facilities and pharmacist compounding, it seems reasonable that the FDA reissued the information in the 2012 statement and enhanced it by referencing the new requirements of Section 503A and 503B of the Food, Drug and Cosmetic Act. The July statement reminds pharmacists that they must fill prescriptions for hydroxyprogesterone caproate with Makena® unless the prescribing practitioner determines that the patient requires a compounded product that is clinically different from the FDA-approved product; for example, a prescriber might prescribe a compounded version for a patient who is allergic to the castor oil in Makena®. In such instances, a notation of the clinical need is required on the prescription. The other instance in which hydroxyprogesterone caproate could be compounded would be if its status was listed as “Currently in Shortage” in the Drug Shortage Database Search at <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Summary:

If a prescriber determines that product clinically different than Makena® is necessary for a patient or Makena® appears on the shortage list, then the pharmacist may compound hydroxyprogesterone caproate. Otherwise, the following statements are applicable.

1. Pharmacies may not compound hydroxyprogesterone caproate. The FDA's stance on pharmacist compounding of hydroxyprogesterone caproate as stated in 2012 has not been changed by the new law known as the Drug Quality and Security Act.
2. Outsourcing facilities may not compound hydroxyprogesterone caproate.
3. The FDA may take action against pharmacies or outsourcing facilities that compound drug products that are essentially identical to FDA-approved drug products, such as Makena®.