



Secretary Carol Aichele

PENNSYLVANIA STATE BOARD OF PHARMACY



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Compounding of Hydroxyprogesterone Caproate Versus Dispensing the Commercial Product, Makena®

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In a press announcement issued June 15, 2012, the Food and Drug Administration (FDA) announced that "it is applying its normal enforcement policies for compounded drugs to compounded hydroxyprogesterone caproate." This announcement reversed the FDA's March 30, 2011 statement that pharmacies would not face legal challenge for compounding hydroxyprogesterone caproate. The State Board of Pharmacy is including this newsletter article to ensure all pharmacists are aware of the FDA's June announcement so they can comply by dispensing the commercial product Makena® when either Makena® or hydroxyprogesterone caproate injection is ordered or prescribed. An exception exists if hydroxyprogesterone

caproate injection is ordered/prescribed and the patient has a medical condition that necessitates compounding it, such as an allergy to an excipient or another inactive ingredient in Makena®.

Section 460.200 of the FDA's Compliance Policy Guides Manual addresses pharmacy compounding. Specifically this section lists nine acts that the FDA considers when determining whether to initiate an action. The act that is particularly relevant in this circumstance and may initiate action by the FDA is "Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products." Makena is a commercially available FDA-approved drug product.

Pharmacists compounding hydroxyprogesterone caproate after June 15, 2012 should use the prescription or order to document the reason compounding was necessary (unless the prescriber has already included such documentation). If compounded hydroxyprogesterone caproate would not provide a significant difference compared to Makena® and there is no reason that the compounded product is medically necessary for the particular patient, then Makena® should be dispensed. Failure to do so may be a violation of federal and state laws.