Questions and Answers on Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate (the active ingredient in Makena)

What is pharmacy compounding?

The FDA regards pharmacy compounding as the combining or altering of the ingredients of a drug by a licensed pharmacist to produce a drug tailored to an individual patient's particular medical needs, based on a valid prescription from a licensed medical practitioner. For example, compounding may occur if a patient needs a medication to be produced without a dye or preservative due to an allergy, or needs a medication in a liquid or suppository form because the patient cannot swallow a pill.

Should health care professionals prescribe and patients take the FDA-approved drug product rather than the compounded product?

If there is an FDA-approved drug that is medically appropriate for a patient, the FDA-approved product should be prescribed and used. Makena was approved based on an affirmative showing of safety and efficacy. The company also demonstrated the ability to manufacture a quality product. The pre-market review process included a review of the company's manufacturing information, such as the source of the API used in the manufacturing of the drug, proposed manufacturing processes, and the firm's adherence to current good manufacturing practice.

Compounded drugs do not undergo the same premarket review and thus lack an FDA finding of safety and efficacy and lack an FDA finding of manufacturing quality. Therefore, when an FDA-approved drug is commercially available, the FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.

How will a patient know if she is receiving Makena or a compounded product?

A patient can ask her health care provider what product is being administered. A label will also be visible on the vial or syringe with information such as the patient name, prescription number, and name of the product. Typically, if the pharmacy dispenses the FDA-approved product, it will have the brand name "Makena" on the label.

Will the agency take any enforcement action against pharmacies compounding versions of hydroxyprogesterone caproate products?

The FDA may take enforcement action against compounding pharmacies if warranted. The FDA makes its enforcement decisions about compounded products on a case-by-case basis after considering the particular facts at issue. As we explained in the June 15, 2012, statement[1], the compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding.

Are pharmacies free to compound large volumes of hydroxyprogesterone caproate as long as none of their drugs are tested and found to be unsafe?

No. The FDA does not consider compounding large volumes of copies, or what are essentially copies, of any approved commercially-available drug to fall within the scope of traditional pharmacy practice. One factor that the agency considers in determining whether a drug may be compounded is whether the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.

The FDA may take enforcement action against pharmacies that compound large volumes of drugs that are essentially copies of commercially available products and for which there does not appear to be a medical need for individual patients to whom the drug is dispensed.

The FDA stated it is using a risk-based approach to enforcement action against compounding pharmacies. The FDA also stated that its investigation did not identify a major safety issue, so does that mean that the FDA does not intend to take enforcement action against the compounders of hydroxyprogesterone caproate?

No. A risk-based approach to enforcement relates to how the FDA generally prioritizes its enforcement efforts. The FDA's June 15, 2012 statement should not be interpreted to mean that the FDA will take enforcement action only if the agency identifies a

particular safety problem. We reiterate that the compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding.

Links on this page:

1. /NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. /NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm