Contains Nonbinding Recommendations

Draft Guidance on Hydroxyprogesterone Caproate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient:	Hydroxyprogesterone caproate
Dosage Form; Route:	Solution; subcutaneous
Strength:	275 mg/1.1 mL (250 mg/mL)
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements

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Waiver:

To qualify for a waiver of in vivo bioequivalence (BE) studies on the basis that BE is self-evident under 21 CFR 320.22(b), a generic hydroxyprogesterone caproate 275 mg/1.1 mL (250 mg/mL) product must be qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the Reference Listed Drug (RLD).

An applicant may seek approval of a drug product intended for parenteral use that differs from the RLD in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.[3]

Device:

The RLD product is a drug-device combination product[4] in which the drug constituent part consists of a parenteral solution and the device constituent part consists of an autoinjector. It is recommended that a threshold analyses of the proposed generic delivery device be conducted to identify and assess any differences compared to the RLD in the design of the user interface including associated controls and displays, as well as product labeling and packaging. Please refer to the Guidance for Industry: *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.

In addition, in vitro studies should be conducted to support the functionality, accuracy, and robustness of the proposed generic product. Please refer to the Guidance for Industry: *Technical*

[1] Q1 (qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference listed drug.
[2] Q2 (quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ± 5% of those used in the reference listed drug.
[3] 21 CFR 314.94(a)(9)(iii).
[4] See 21 CFR 3.2(e)(1).

Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products for general considerations and recommendations on injector performance testing.