Contains Nonbinding Recommendations

Draft Guidance on Podofilox

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Podofilox

Form/Route: Solution/Topical

I. Waiver option:

a. To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of Podofilox Topical Solution, 0.5% must contain the same active drug ingredient in the same concentration and dosage form as the Reference Listed Drug (RLD) and must not have an inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability.

b. For a topical drug product with inactive ingredients that differ from the RLD or are present in significantly different amounts [as permitted by the chemistry, manufacturing and controls regulations for abbreviated new drug applications, 21 CFR 314.94(a)(9)(v)], the regulation specifies that the applicant must identify and characterize the formulation differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

c. In addition, adequate information must be provided to ensure that the composition of the applicators provided with the solution will not affect the performance of the product.

II. In Vivo option:

Recommended studies: 1 study

Type of study: Bioequivalence (BE) Study with Clinical Endpoint
Design: Randomized, double blind, parallel, placebo-controlled in vivo
Strength: 0.5%
Subjects: Healthy males and females with external genital warts (Condyloma acuminatum).
Additional comments: FDA recommends submitting a protocol for review and comment prior to conducting the study.

Analytes to measure (in appropriate biological fluid): Not Applicable

Bioequivalence based on (90% CI): Clinical endpoint (in vivo option)

Dissolution test method and sampling times: Not Applicable