*Contains Nonbinding Recommendations*

**Draft Guidance on Latanoprost**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Latanoprost

**Form/Route:** Solution/Drops; Ophthalmic

**Recommended study:** Request for Waiver of *In vivo* Bioequivalence Study Requirements

To qualify for a waiver of the *in vivo* bioequivalence (BE) study requirements under 21 CFR 320.22(b)(1), a generic latanoprost ophthalmic solution product must have the same active and inactive ingredients in the same concentration as the reference listed drug product (RLD).

For an ophthalmic drug product that differs from the RLD in preservative, buffer, substance to adjust tonicity, or thickening agent [(as permitted by the chemistry, manufacturing and controls (CMC) regulations for abbreviated new drug applications (ANDAs), 21 CFR 314.94(a)(9)(iv)], the regulation specifies that the applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

Changes in any of the inactive ingredients can change the safety and efficacy of an ophthalmic drug product. Therefore, an *in vivo* clinical endpoint bioequivalence study is requested for any latanoprost ophthalmic solution that has a different inactive ingredient or a difference of more than 5% in the amount of any inactive ingredient compared to that of the RLD. Please submit a protocol to the Clinical Review Team in the Office of Generic Drugs for review and concurrence prior to conducting the *in vivo* clinical endpoint BE study for such a product.