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Comments Sought by December 19th on the FDA's Proposed Criteria for "First Generic" Applications

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This morning, the Food and Drug Administration (FDA) opened a public docket and requested comments on its proposed criteria for expedited review of "first generic" Abbreviated New Drug Applications (ANDAs). The comment period ends on December 19, 2014. If you would like assistance submitting a comment, please contact any of the attorneys listed in this advisory.

This public docket follows up on the Office of Generic Drug's public hearing held on September 17, 2014. Opening this docket is a step in implementing the Generic Drug User Fee Amendments of 2012 (GDUFA), specifically the FDA's commitments to: (1) expedite review of potential first-to-file ANDAs; (2) try to act within 30 months of submission to avoid forfeiture of 180-day exclusivity for failure to timely obtain tentative approval; and (3) expedite review of "first generic" ANDAs for which there are no blocking patents or exclusivities.

The FDA proposes defining a "first generic" application as a received ANDA: (1) that is eligible for 180-day exclusivity, or for which there are no blocking patents or exclusivities; and (2) for which there is no previously approved ANDA for the drug product. Review of these ANDAs would be prioritized by the FDA, although an ANDA could potentially lose its priority treatment due to "changes in the patent or exclusivity landscape," which could include a finding of infringement in Hatch-Waxman patent litigation.

The FDA seeks comments regarding these criteria for "first generics," including whether the FDA should change the review prioritization for an ANDA that no longer meets these criteria at some point during its review. The FDA also seeks comments on mechanisms by which ANDA applicants could timely submit information relevant to an ANDA's ongoing eligibility for expedited treatment as a first generic (e.g., developments in related patent litigation).

The FDA's online notice posted today is available here.

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