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FDA Announces Draft Guidance on Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial Is Underway

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On January 6, the FDA announced the availability of draft guidance on accelerated approval for drugs and biological products, and consideration for determining whether a confirmatory trial is underway. Under the Consolidated Appropriations Act, 2023, Congress gave the FDA the authority to require that a confirmatory trial be underway prior to the granting of accelerated approval or within a specific time period after the date of accelerated approval. This latest guidance comes on the heels of the accelerated approval guidance issued by the agency just last month (see prior analysis here), in which the agency stated its intent to address the 2023 authority in a separate guidance.

The guidance lays out the agency's policy for requiring a confirmatory trial be underway prior to the granting of approval. The guidance notes that, in some cases, the FDA may require enrollment to be complete at the time of approval. The agency also acknowledges that there may be limited circumstances for which the agency may not require the confirmatory trial to be underway prior to accelerated approval, specifically noting the unique challenges that sponsors seeking approval for drugs intended to treat some rare disease may encounter in initiating post-approval confirmatory trials prior to approval as one such example. The announcement also includes a 60-day comment period (March 10, 2025).

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