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FDA Announces Draft Guidance for Industry Regarding Accelerated Approval for Drugs and Biologics

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By: Anna K. Abram, Nathan A. Brown, Caroline D. Kessler

On December 5, 2024, FDA unveiled the draft guidance for industry regarding accelerated approval for drugs and biologics. This guidance provides additional information regarding the development of drugs and biologics to treat serious conditions for which there is an unmet need, and for which the sponsor is seeking accelerated approval. In particular, the guidance details the conditions for confirmatory study or studies that sponsors are required to conduct under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Consolidated Appropriations Act, 2023. This guidance also elaborates on the process for the expedited withdrawal of an accelerated approval. In announcing the availability of the draft guidance, the agency has requested comments be submitted by February 4, 2025.

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