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Q&A: FDA Seeks to Clarify '3-Year Exclusivity' with New Guidance

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In March 2026, the Food and Drug Administration (FDA) **issued** draft guidance for the industry, *New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers*, providing additional clarity on eligibility for and requests for 3-year exclusivity under the Federal Food, Drug and Cosmetic Act for qualifying drug products.

Three-year exclusivity, established by the Hatch-Waxman Amendments, may apply to certain new drug applications (NDAs) and NDA supplements that rely on new clinical investigations essential to approval and conducted or sponsored by the applicant. During the exclusivity period, FDA may not approve certain 505(b)(2) applications or abbreviated new drug applications (ANDAs) for the exclusivity-protected conditions of approval.

The draft guidance, presented in a question-and-answer format, outlines recurring questions from industry regarding the statutory and regulatory criteria for obtaining this 3-year exclusivity. Among other things, the guidance includes questions and answers on what constitutes a "clinical investigation" for exclusivity purposes, when a study is considered "essential to approval," and what it means for an investigation to be "conducted or sponsored."

The draft guidance also outlines procedural expectations for submitting exclusivity requests, describes FDA's process for making exclusivity determinations and assigning exclusivity codes in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the *Orange Book*).

FDA notes that the guidance is intended to enhance transparency around its application of the statutory exclusivity framework and help facilitate the development, approval, and timely marketing of both innovator and follow-on drug products.

FDA is accepting comments on the draft guidance until May 4, 2026.

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