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STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

21 CFR Part 314

Applications for FDA Approval to Market a New Drug

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ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
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INDUSTRIES	Pharmaceutical	ONLINE	qesisbest.com/standard-21-cfr-314.html

IN FORCE In force.

What It Covers

The content and handling of new drug applications and abbreviated applications, and — for a manufacturer — the rules for changing an approved product and reporting after approval.

Who It Applies To

Holders of NDAs and ANDAs, and the manufacturers who make products under them.

Key Requirements

- Changes to an approved application reported by category: prior approval supplement, changes-being-effected supplements, or annual report, by potential effect on the product (§314.70).
- Field alert reports within three working days for certain quality problems with distributed batches (§314.81(b)(1)).
- Annual reports and postmarketing safety reporting (§314.80, §314.81).

What an Auditor Asks to See

- Change control records showing the regulatory category decided for each change.
- Field alert evaluations for distribution problems, contamination, or failing batches.

Where Systems Fall Short

- Changes implemented before the filing category was decided.
- Field alert decisions made outside the quality system and never recorded.

How QES helps. Change control that asks the regulatory question before the change is made, not after. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. eCFR — 21 CFR Part 314 — www.ecfr.gov/current/title-21/part-314.

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