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Q1/Q2 Sameness Transparency Provision Expected to Save $800 Million Over 10 Years

On February 3, 2026, Congress enacted legislation that gives generic drug developers clearer, generally binding insight into U.S. Food and Drug Administration (FDA) determinations on formulation sameness, reducing uncertainty at a critical stage of abbreviated new drug application (ANDA) development. FDA requires formulation sameness for certain ANDA products, in particular eye, ear, dermatological products, injectables, and certain complex oral formulations. The change was enacted as part of the 2026 Consolidated Appropriations Act, and includes a targeted amendment to the Federal Food, Drug, and Cosmetic Act through Section 6703, aimed at increasing transparency in FDA's review of ANDAs. According to the Association for Accessible Medicines, this change will save the U.S. health care system more than $800 million over 10 years and bring lower-cost medicines to patients sooner.

Under the new law, a company that has submitted or intends to submit an ANDA may request confirmation from FDA whether its proposed product contains the same inactive ingredients (commonly referred to as "Q1"), in the same concentrations +/- 5% (commonly referred to as "Q2), as the reference listed drug (RLD). This request may be made through controlled correspondence (CC) or a similar FDA process, and FDA may also provide this information on its own initiative during ANDA review. In the past, FDA would permit ANDA applicants to include at most three proposed Q1/Q2 formulations in one CC, where Q1 included the name, grade, salt form, and comparative characterization if a polymer. If an ANDA applicant were not correct in its guess at an RLD's Q1/Q2 formulation, FDA would merely state: "OGD has made a preliminary determination that it would likely refuse to receive an ANDA based on [formulation X]… Your proposed formulation is not Q1/Q2 the same as the RLD with respect to one or more inactive ingredients." Such

ANDA refusals to receive result in market delays and the expenditure of unnecessary resources for applicants.

In addition, if FDA determines that the proposed generic is not Q1/Q2to the RLD, the agency now must identify the specific inactive ingredient(s) that differ and disclose the extent of any quantitative deviation. If FDA determines that a proposed generic is Q1/Q2, that determination generally may not be changed after the ANDA is submitted, except in limited circumstances involving changes to the RLD or the identification of an agency error.

The statute further clarifies that these disclosures are authorized by law and do not otherwise waive trade secret or confidential commercial information protections for reference listed drugs. FDA is also required to issue guidance within one year describing how FDA will assess qualitative and quantitative sameness. While that guidance is forthcoming, the statutory changes apply immediately, and ANDA applicants may begin requesting these determinations now.

For companies developing certain generic products, this new transparency framework may:

- Reduce regulatory uncertainty earlier in formulation development by providing more specific feedback on inactive ingredient differences;
- Lower the risk of late-stage refusals or delays after significant development time and resources have been invested;
- Support more informed formulation, bioequivalence, and regulatory strategy decisions; and
- Improve predictability in ANDA review and development planning.

As FDA begins applying these new Q1/Q2 disclosure provisions in practice, questions around timing, scope, and strategic use of Q1/Q2 sameness determinations, as well as any potential protections from public disclosure, are likely to take on increased importance in ANDA development.

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