ACCELERATE COMPLEX GENERIC DRUG APPROVALS BY INCREASING Q1/Q2 TRANSPARENCY
The Increasing Transparency in Generic Drug Applications Act of 2022

Q1/Q2 FDA Disclosure Background

Q1/Q2 is a term referring to active and inactive ingredient assessments in Abbreviated New Drug Applications (ANDAs). FDA requires certain types of generic products, either by regulation or through product specific bioequivalence guidance to demonstrate Q1/Q2 sameness, meaning the generic drug submitted for **approval must contain the same active and inactive ingredients (qualitatively the same, or Q1) in the same concentration (quantitatively the same, or Q2) as the reference listed drug (RLD).** Consequently, complex generic drug applicants often must demonstrate that their proposed generic drugs are qualitatively and quantitively (Q1/Q2) the same as the brand name drug that they are referencing.

In the past, when FDA determined that a proposed generic drug formulation was not Q1/Q2 the same as the RLD, FDA's practice was to fully disclose the deficiency to the ANDA applicant. Specifically, FDA would identify the ingredient or ingredients at issue and provide general direction of the deviation (*e.g.*, "the amount of Ingredient A is too high"). **This practice allowed ANDA applicants to quickly address the deviation, thereby facilitating timely submission and approval of generic drugs.**

The Problem: FDA Changed its ANDA Disclosure Practices and Assessment of Q1/Q2 Sameness Without Notice Resulting in Delayed Approval of Complex Generic Drugs

In 2015, **FDA changed its disclosure policies regarding Q1/Q2 deficiencies.** FDA will now inform ANDA applicants that a proposed generic drug is not Q1/Q2 the same as the RLD, but FDA will no longer disclose either the ingredient at issue or the general direction of the deviation**. FDA implemented this new policy without warning or notice to the generic drug industry.**

FDA also recently changed the way it determines whether a proposed generic product is Q1/Q2 the same as the RLD without explaining the change or providing notice to the generic drug industry. As a result, in some instances, years after FDA informed a generic drug applicant that its proposed formulation was Q1/Q2 the same as the RLD, FDA is now informing the applicant, without explanation, that the formulation is not Q1/Q2 the same as the RLD even though no changes have been made to the RLD formulation. In other instances, FDA has done the reverse – informing a potential applicant that a previously proposed formulation that FDA stated was not Q1/Q2 the same is in fact Q1/Q2 the same as the RLD**. A company's inability to rely on FDA's Q1/Q2 assessment can cost a potential applicant years in unnecessary development work and delay patient access to lower-cost generic drugs.**

The recently released HHS "Comprehensive Plan for Addressing High Drug Prices" identified this issue as a barrier to patient access to affordable drugs and expressed support for a proposal to "clarify that it is not an improper disclosure by the FDA to provide a potential generic drug sponsor with the names and amounts of inactive ingredients used in the formulation of a reference listed drug when a generic drug is required to have the same formulation to obtain approval.

The Solution: Increasing Transparency in Generic Drug Applications Act of 2022

The Increasing Transparency in Generic Drug Applications Act of 2022, seeks to increase transparency around Q1/Q2 assessments to facilitate timely approval of complex generic drugs. The bill would re-establish FDA's prior policies by requiring the Agency to:

- Disclose to ANDA applicants critical information about the deficiencies identified, including the identity of the ingredient or ingredients that cause the proposed generic product not to be Q1/Q2 the same as the RLD and the direction of any identified deviation.
- Require FDA to issue guidance on the criteria it uses to assess Q1/Q2 sameness and provide an opportunity for notice and comment prior to implementing any future policy changes.