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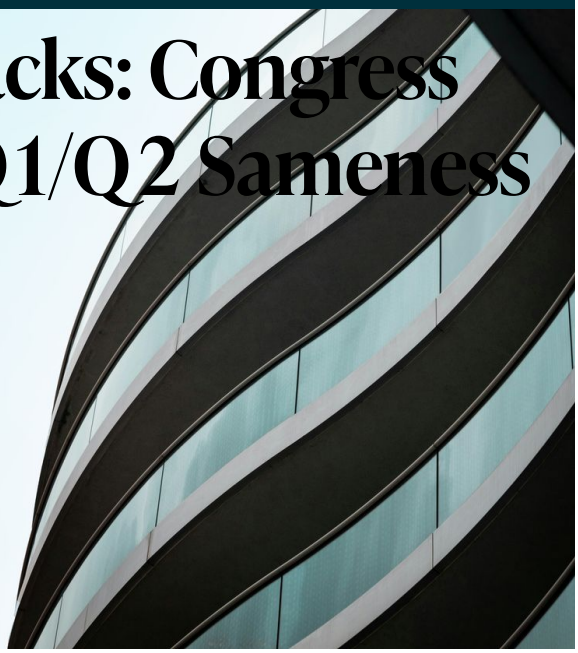
No More Needles in Haystacks: Congress Requires FDA to Explain Q1/Q2 Sameness



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By: Ross E. Blau, Jody Karol, Emalee A. Peterson

Last week, on February 3, 2026, Congress passed the Consolidated Appropriations Act ("the Act"), providing generic drug manufacturers much-needed clarity as to when inactive ingredients in an ANDA are qualitatively and quantitatively ("Q1/Q2") the same as those in the reference listed drug ("RLD"). Per regulation, parenteral, ophthalmic, and otic drugs must have Q1/Q2 sameness. FDA also often recommends Q1/Q2 sameness for demonstrating bioequivalence in product-specific guidance.

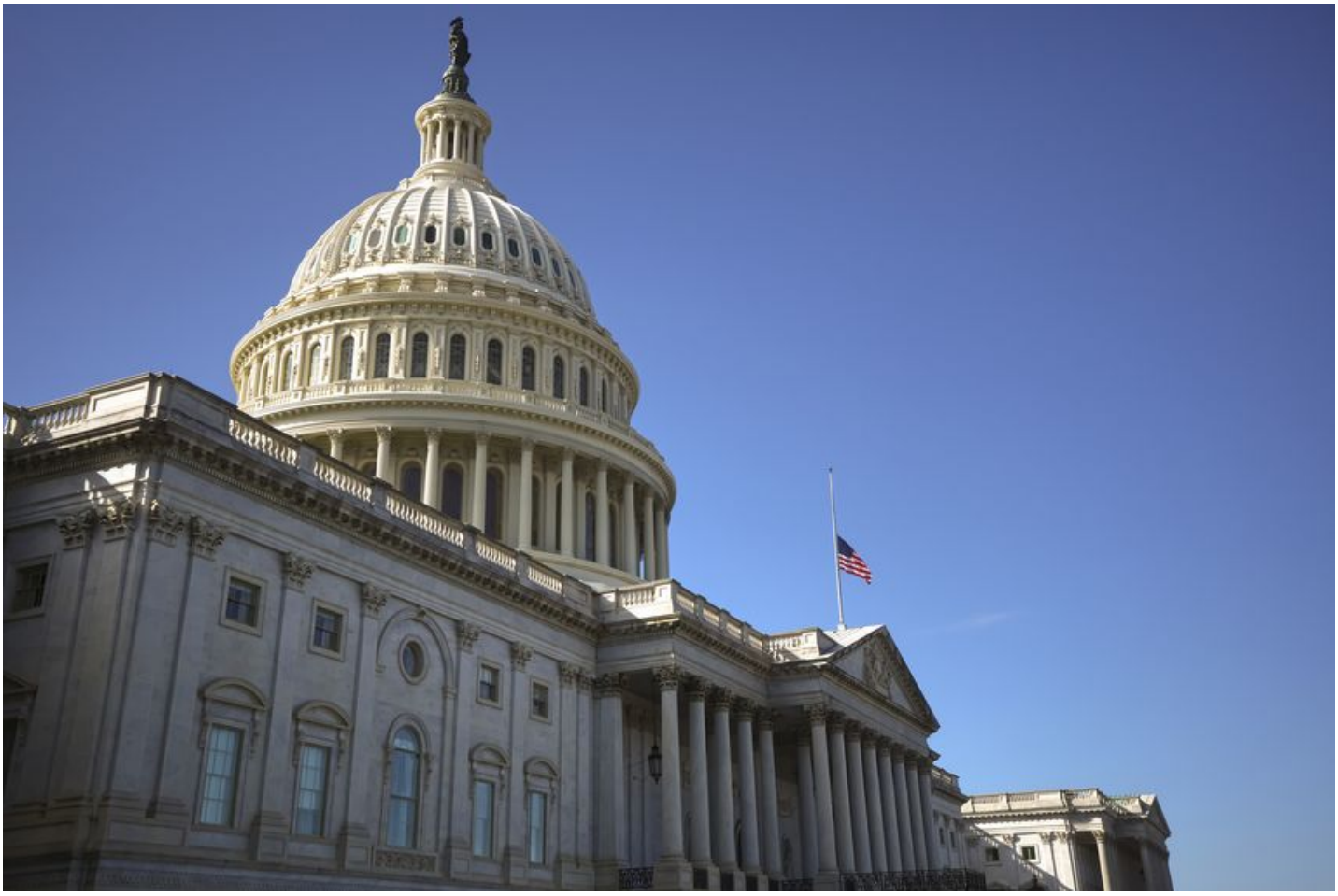
Prior to the Act, ANDA filers were left in the dark as to why their application was denied; FDA would simply respond to controlled correspondence to inform an ANDA filer if its drug product passed or failed Q1/Q2 sameness without any explanation. This led to ANDA filers speculating as to which inactive ingredient was dissimilar and attempting to develop their own "precedent" from prior ANDAs. This old system would often lead to a back-and-forth, where the ANDA filer attempted numerous alternatives and awaited FDA's final determination if Q1/Q2 sameness was met, or the ANDA filer gave up its pursuit.

Now, under Section 6703 of the Act, amending 21 U.S.C. § 355(j)(3), FDA must disclose the specific ingredient(s) that are not quantitatively or qualitatively the same as the RLD. If there is a quantitative deviation, FDA must disclose the amount of the deviation.

Further, FDA cannot rescind a determination that a generic is Q1/Q2 the same as the RLD unless there has been a change to the RLD's formulation and the prior formulation was deemed withdrawn for reasons of safety or effectiveness. But, if FDA determines that an error was made, FDA can rescind such a determination once it provides notice and a copy of the written determination to the ANDA filer.

Within one year of the Act's enactment, FDA must publish draft guidance describing how it will determine whether a drug is the same as the RLD. Notably, pH adjusters, for which final guidance on waiver requests was released last November, are expressly mentioned in Section 6703. ANDA filers should be on the lookout for such guidance this year.

The increased transparency that comes with this Act will finally give ANDA filers the clarity that they have been requesting for Q1/Q2 sameness. This may facilitate a smoother and less costly ANDA process, as well as quicker entry of generic drugs onto the market.



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Ross E. Blau

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