S. 3014, Ensuring Timely Access to Generics Act of 2025 Section by Section

Section 1. Short Title.

This section provides that the short title is "Ensuring Timely Access to Generics Act of 2025."

Section 2. Ensuring Timely Access to Generics.

This section expands the authority of the Food and Drug Administration (FDA) to deny citizen petitions submitted under section 505(q) of the Federal, Food, Drug, and Cosmetic Act by allowing the agency to deny a petition if it determines the petition was submitted with the primary purpose of delaying the approval of a follow-on generic or biosimilar application, or if the petition does not raise valid scientific or regulatory issues. The section provides a list of factors FDA may consider when determining whether a petition was submitted with the primary purpose of delaying the application. The section requires a petition to be submitted within 60 days after the petitioner knew, or reasonably should have known, the information that formed the basis of the petition. The section eliminates the 150-day deadline under current law for FDA to respond to 505(q) petitions, and requires that parties file a 505(q) petition before filing suit against FDA to challenge the agency's approval of a new drug through the 505 (b)(2) pathway, a generic drug, or a biosimilar product.