S 1114

Expanding Access to Low-Cost Generics Act of 2023

Congress: 118 (2023–2025, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 30, 2023
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 108.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 108. (Jun 22, 2023)
Official Text: https://www.congress.gov/bill/118th-congress/senate-bill/1114

Sponsor

Name: Sen. Smith, Tina [D-MN]
Party: Democratic • **State:** MN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Mar 30, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jun 22, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 3839	Related bill	**Jun 9, 2023:** Referred to the Subcommittee on Health.
118 S 775	Related bill	**Mar 14, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 22, 2023)

Expanding Access to Low-Cost Generics Act of 2023

This bill modifies provisions related to market exclusivity for a generic drug.

Currently, the Food and Drug Administration (FDA) awards 180 days of exclusivity on the market to a first applicant to file a qualifying application for market approval of a generic drug. Generally, this exclusivity period begins upon a first applicant's commercial marketing of the drug.

The bill authorizes the FDA to approve a subsequent generic drug application prior to a first applicant's first date of commercial marketing if (1) the subsequent application is ready for full approval, (2) the applicant certifies that there are no conditions that would prevent commercial marketing of the drug within 75 days of approval and that the applicant intends to do so, (3) a first applicant's application has been pending for at least 33 months, (4) the approval of a first applicant's application is not precluded by patent infringement claims asserted against that first applicant, and (5) no first applicant's application has been effectively approved on the date that all such conditions are met.

If an applicant fails to begin commercially marketing their drug within 75 days of approval via the aforementioned process, the applicant's approval is deemed tentative and the applicant is no longer eligible for subsequent approvals, unless the applicant certifies that the failure was due to unforeseen issues that have since been resolved.

Additionally, the FDA must inform generic drug applicants, upon request or during review, whether the drug is qualitatively and quantitatively the same as the listed brand-name drug (and if not, the reasons why).

Actions Timeline

- **Jun 22, 2023:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Sanders with an amendment in the nature of a substitute. Without written report.
- **Jun 22, 2023:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 108.
- **May 11, 2023:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 30, 2023:** Introduced in Senate
- **Mar 30, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.