HR 1051

To amend the Federal Food, Drug, and Cosmetic Act to allow for the approval of an abbreviated new drug application submitted by a subsequent applicant in the case of a failure by a first applicant to commence commercial marketing within a certain period, and for other purposes.

Congress: 119 (2025–2027, Current)
Chamber: House
Policy Area: Health
Introduced: Feb 6, 2025
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (Feb 6, 2025)
Official Text: https://www.congress.gov/bill/119th-congress/house-bill/1051

Sponsor

Name: Rep. Budzinski, Nikki [D-IL-13]
Party: Democratic • **State:** IL • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Feb 6, 2025

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 6, 2025)

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.

Actions Timeline

- **Feb 6, 2025:** Introduced in House
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