HR 2831

Prompt Approval of Safe Generic Drugs Act

Congress: 117 (2021–2023, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 26, 2021
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 27, 2021)
Official Text: https://www.congress.gov/bill/117th-congress/house-bill/2831

Sponsor

Name: Rep. Barragan, Nanette Diaz [D-CA-44]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 27, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HR 8588	Related bill	**Nov 1, 2022:** Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.

Summary (as of Apr 26, 2021)

Prompt Approval of Safe Generic Drugs Act

This bill authorizes the Food and Drug Administration (FDA) to approve certain applications to market a drug even if the drug's labeling lacks certain safety information.

Specifically, an abbreviated application for approval of a generic drug shall not be ineligible for approval solely because the drug's labeling omits safety information that is protected under another drug's exclusivity protections. Similarly, a drug that is approved under this bill shall not be considered mislabeled for lacking such safety information.

Generally, an abbreviated application, for the purposes of this bill, is one that (1) uses required information from studies not conducted by the applicant; or (2) seeks approval of a drug that is, for drug approval purposes, a duplicate of an already-approved drug.

For any drug approved under this bill, the FDA shall require the drug's labeling to include any safety information that is necessary to assure safe use.

Actions Timeline

- **Apr 27, 2021:** Referred to the Subcommittee on Health.
- **Apr 26, 2021:** Introduced in House
- **Apr 26, 2021:** Referred to the House Committee on Energy and Commerce.

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