HR 5272

Prescription Drug Fair Competition Act of 2002

Congress: 107 (2001–2003, Ended)
Chamber: House
Policy Area: Health
Introduced: Jul 26, 2002
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jul 29, 2002)
Official Text: https://www.congress.gov/bill/107th-congress/house-bill/5272

Sponsor

Name: Rep. Brown, Sherrod [D-OH-13]
Party: Democratic • **State:** OH • **Chamber:** Senate

Cosponsors (20 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Waxman, Henry A. [D-CA-29]	D · CA		Jul 26, 2002
Rep. Lowey, Nita M. [D-NY-18]	D · NY		Sep 10, 2002
Rep. McDermott, Jim [D-WA-7]	D · WA		Sep 10, 2002
Rep. Rivers, Lynn N. [D-MI-13]	D · MI		Sep 11, 2002
Rep. Olver, John W. [D-MA-1]	D · MA		Sep 17, 2002
Rep. Ross, Mike [D-AR-4]	D · AR		Sep 17, 2002
Rep. Wexler, Robert [D-FL-19]	D · FL		Sep 17, 2002
Rep. Baird, Brian [D-WA-3]	D · WA		Sep 24, 2002
Rep. Barcia, James A. [D-MI-5]	D · MI		Sep 24, 2002
Rep. Barrett, Thomas M. [D-WI-5]	D · WI		Sep 24, 2002
Rep. Frank, Barney [D-MA-4]	D · MA		Sep 24, 2002
Rep. Kildee, Dale E. [D-MI-9]	D · MI		Sep 24, 2002
Rep. Maloney, Carolyn B. [D-NY-14]	D · NY		Sep 24, 2002
Rep. McCollum, Betty [D-MN-4]	D · MN		Sep 24, 2002
Rep. Schiff, Adam B. [D-CA-27]	D · CA		Sep 24, 2002
Rep. Thurman, Karen L. [D-FL-5]	D · FL		Sep 24, 2002
Rep. Filner, Bob [D-CA-50]	D · CA		Sep 26, 2002
Rep. McCarthy, Karen [D-MO-5]	D · MO		Sep 26, 2002
Rep. Payne, Donald M. [D-NJ-10]	D · NJ		Sep 26, 2002
Rep. Abercrombie, Neil [D-HI-1]	D · HI		Oct 1, 2002

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 29, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jul 26, 2002)

Prescription Drug Fair Competition Act of 2002 - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning the timing of generic drug availability.
Requires applicants (pharmaceutical companies) to register their patents with the Food and Drug Administration (FDA) within 30 days of approval (or issuance for subsequently issued patents).

Makes failure to timely register a bar to civil actions for patent infringement.

Requires applications for new drugs (NDA) or abbreviated new drug applications (ANDA) which rely upon investigations not conducted by or for the applicant and which concern a patent that claims both the drug and a method of use or more than one method of use to include a certification on a claim-by-claim basis that the patent is invalid or will not be infringed (known as a Paragraph IV filing/certification) by the new drug's (generic) manufacture and a statement regarding the method(s) of use claim.

Prohibits (for subsequently issued patents) an extension of the 30 month stay of FDA approval for any new drug where an ANDA or NDA contains a Paragraph IV filing/certification and the patent holder indicates an intention to bring a patent infringement suit against the new (generic) drug's manufacturer.

Makes failure to timely file a civil action for infringement a bar to later action.

Requires the first generic applicant with a Paragraph IV filing to forfeit the 180 day marketing exclusivity period to a subsequent generic applicant if the first generic applicant engages in certain behaviors which delay or prevent the marketing of the generic drug.

Revises notice requirements for Paragraph IV filings to include and protect certain proposed formulation, composition, or method of use information.

Excludes an applicants's ability to pay damages from a court's consideration of whether or not to provide injunctive relief before the expiration of the 30 month stay of approval period.

Actions Timeline

- **Jul 29, 2002:** Referred to the Subcommittee on Health.
- **Jul 26, 2002:** Introduced in House
- **Jul 26, 2002:** Referred to the House Committee on Energy and Commerce.

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