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FAIR Generics Act

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Nov 16, 2011
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S7616-7617) (Nov 16, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/1882

Sponsor

Name: Sen. Bingaman, Jeff [D-NM]
Party: Democratic • **State:** NM • **Chamber:** Senate

Cosponsors (12 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Brown, Sherrod [D-OH]	D · OH		Nov 16, 2011
Sen. Merkley, Jeff [D-OR]	D · OR		Nov 16, 2011
Sen. Vitter, David [R-LA]	R · LA		Nov 16, 2011
Sen. Sanders, Bernard [I-VT]	I · VT		Nov 17, 2011
Sen. Franken, Al [D-MN]	D · MN		Dec 7, 2011
Sen. Klobuchar, Amy [D-MN]	D · MN		Jan 30, 2012
Sen. Kohl, Herb [D-WI]	D · WI		Feb 6, 2012
Sen. Udall, Tom [D-NM]	D · NM		May 9, 2012
Sen. Johnson, Tim [D-SD]	D · SD		May 14, 2012
Sen. Shaheen, Jeanne [D-NH]	D · NH		May 14, 2012
Sen. Durbin, Richard J. [D-IL]	D · IL		Jun 21, 2012
Sen. Webb, Jim [D-VA]	D · VA		Sep 10, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Nov 16, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Nov 16, 2011)

Fair And Immediate Release of Generic Drugs Act or the FAIR Generics Act - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise the definition of “first applicant” for purposes of the 180-day exclusivity period given to first applicants to file an abbreviated new drug application (generic drug). Makes applicants for a generic drug eligible for the exclusivity period only if they have not entered into a disqualifying agreement (an agreement between a generic drug applicant and the holder of the application for the listed drug [brand name drug] or the patentholder for the brand name drug whereby the generic drug applicant agrees not to seek approval of its generic drug or not to begin the commercial marketing of its generic drug until the expiration of the exclusivity period awarded to another generic applicant).

Expands the definition of “first applicant” to include an applicant that meets the following criteria: (1) the applicant is not the first generic applicant; (2) either no action for patent infringement was brought, such action was withdrawn or dismissed by a court without a decision that the patent was valid and infringed, or the court decided that the patent was invalid or not infringed; and (3) the applicant does not begin commercial marketing of such drug until 30 days after the first applicant began such commercial marketing.

Prohibits a party that enters an agreement to delay seeking approval of its generic drug application or to delay the commercial marketing of a generic drug from seeking approval of its application or beginning commercial marketing before the earlier of: (1) the latest date set forth in the agreement to seek approval or market the drug without regard to any earlier date under the agreement when commercial marketing could begin, or (2) 180 days after another first applicant begins commercial marketing of such drug.

Requires notice to the Secretary of the Health and Human Services (HHS) of the details of any agreement under this Act not later than ten business days after execution of the agreement.

Declares that the exclusive remedy for an infringement of a patent included within a new drug application shall be an action brought under the FFDCA within the 45-day period prescribed.

Actions Timeline

- **Nov 16, 2011:** Introduced in Senate
- **Nov 16, 2011:** Sponsor introductory remarks on measure. (CR S7616)
- **Nov 16, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S7616-7617)