

S 504

FAIR Generics Act

Congress: 113 (2013–2015, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Mar 7, 2013

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 7, 2013)

Official Text: <https://www.congress.gov/bill/113th-congress/senate-bill/504>

Sponsor

Name: Sen. Franken, Al [D-MN]

Party: Democratic • **State:** MN • **Chamber:** Senate

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Durbin, Richard J. [D-IL]	D · IL		Mar 7, 2013
Sen. Sanders, Bernard [I-VT]	I · VT		Mar 7, 2013
Sen. Shaheen, Jeanne [D-NH]	D · NH		Mar 7, 2013
Sen. Vitter, David [R-LA]	R · LA		Mar 7, 2013
Sen. Klobuchar, Amy [D-MN]	D · MN		Mar 11, 2013
Sen. Udall, Tom [D-NM]	D · NM		Mar 20, 2013

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 7, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Fair And Immediate Release of Generic Drugs Act or FAIR Generics Act - Amends the Federal Food, Drug, and Cosmetic Act (FDCA) 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 patent holder 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applicant is not the first generic applicant; (2) either no action for patent infringement was brought, such action was withdrawn or dismissed by a court without a decision that the patent was valid and infringed, or the court decided that the patent was invalid or not infringed; and (3)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 FDCA within the 45-day period prescribed.

Actions Timeline

- **Mar 7, 2013:** Introduced in Senate
- **Mar 7, 2013:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.