S 131

FAIR Generics Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jan 8, 2015
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. (Jan 8, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/131

Sponsor

Name: Sen. Vitter, David [R-LA]
Party: Republican • **State:** LA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Franken, Al [D-MN]	D · MN		Jan 8, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jan 8, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jan 8, 2015)

Fair And Immediate Release of Generic Drugs Act or the FAIR Generics Act

This bill amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to disqualify from being a “first applicant” an applicant submitting an abbreviated new drug application (for a generic drug) to the Food and Drug Administration that has entered into a specified agreement. Currently, any generic drug applicant submitting an application on the first day an application is submitted for that drug is a “first applicant” and is granted a 180-day marketing exclusivity period.

An agreement that disqualifies a generic drug applicant from being a first applicant is an agreement between the applicant and the holder of the application or a patent for the brand name drug whereby the applicant agrees not to seek approval or begin marketing the generic drug until the expiration of the exclusivity period awarded to another applicant.

“First applicant” is expanded to include applicants that did not submit an application on the first day an application was submitted. These first applicants must not have a patent infringement action pending against them and must not have been found to have infringed a patent. If an applicant that submitted an application on the first day an application was submitted has begun marketing the drug, a first applicant that submitted after the first day cannot begin marketing until 30 days after the first day applicant began marketing.

A first applicant that has entered into an agreement not to seek approval of an application or begin marketing at the earliest possible date cannot seek approval or begin marketing until the earlier of: (1) the latest date set forth in the agreement, or (2) 180 days after a first day applicant begins marketing.
An action for infringement of a drug patent must be brought within the 45-day period described in FFDCA.

Actions Timeline

- **Jan 8, 2015:** Introduced in Senate
- **Jan 8, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.