

HR 1506

FAIR Generics Act

Congress: 116 (2019–2021, Ended)

Chamber: House

Policy Area: Health

Introduced: Mar 5, 2019

Current Status: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.

Latest Action: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet. (Apr 8, 2019)

Official Text: <https://www.congress.gov/bill/116th-congress/house-bill/1506>

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	Mar 6, 2019
Judiciary Committee	House	Referred to	Apr 8, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 S 1801	Related bill	Jun 12, 2019: Read twice and referred to the Committee on Finance.

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

This bill disqualifies from being a *first applicant* an applicant submitting a generic drug application to the Food and Drug Administration if the applicant has entered into a specified disqualifying 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.

A disqualifying agreement 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.

The bill expands the definition of *first applicant* to include applicants that did not submit an application on the first day an application was submitted. To be included, 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 may not begin marketing until 30 days after the first-day applicant began marketing.

A first applicant that has entered into an agreement to not seek approval of an application or begin marketing at the earliest possible date may not 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.

Actions Timeline

- **Apr 8, 2019:** Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
- **Mar 6, 2019:** Referred to the Subcommittee on Health.
- **Mar 5, 2019:** Introduced in House
- **Mar 5, 2019:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.