

HR 4332

Generic Drug Application Review Fairness Act of 2012

Congress: 112 (2011–2013, Ended)

Chamber: House

Policy Area: Health

Introduced: Mar 29, 2012

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Mar 30, 2012)

Official Text: <https://www.congress.gov/bill/112th-congress/house-bill/4332>

Sponsor

Name: Rep. Pallone, Frank, Jr. [D-NJ-6]

Party: Democratic • **State:** NJ • **Chamber:** House

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Guthrie, Brett [R-KY-2]	R · KY		Mar 29, 2012
Rep. Matheson, Jim [D-UT-2]	D · UT		Apr 18, 2012
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Apr 24, 2012
Rep. Dingell, John D. [D-MI-15]	D · MI		Apr 25, 2012
Rep. DeGette, Diana [D-CO-1]	D · CO		May 9, 2012
Rep. Dold, Robert J. [R-IL-10]	R · IL		May 9, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 30, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 HR 5651	Related bill	Jun 4, 2012: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 420.

Generic Drug Application Review Fairness Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to extend from 30 to 60 months after application the period for a first applicant of a generic drug to obtain tentative approval without forfeiting the 180-day exclusivity period with respect to such drug, unless the failure in meeting the extended period is caused by a change in or review of approval requirements. Limits extension coverage to applications filed within 30 months preceding the enactment of this Act.

Reduces such extended period by six months per year over a five-year period, beginning on October 1, 2013.

Directs the Secretary of Health and Human Services (HHS) to maintain the Office of Generic Drugs as a separate office within the Center for Drug Evaluation and Research of the Food and Drug Administration (FDA).

Actions Timeline

- **Mar 30, 2012:** Referred to the Subcommittee on Health.
- **Mar 29, 2012:** Introduced in House
- **Mar 29, 2012:** Referred to the House Committee on Energy and Commerce.