HR 6022

Lower PRICED Drugs Act

Congress: 109 (2005–2007, Ended)
Chamber: House
Policy Area: Health
Introduced: Jul 28, 2006
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Aug 1, 2006)
Official Text: https://www.congress.gov/bill/109th-congress/house-bill/6022

Sponsor

Name: Rep. Waxman, Henry A. [D-CA-30]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeLauro, Rosa L. [D-CT-3]	D · CT		Jul 28, 2006
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Jul 28, 2006
Rep. Paul, Ron [R-TX-14]	R · TX		Nov 9, 2006

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Aug 1, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 S 2300	Related bill	**Feb 27, 2006:** Star Print ordered on the bill.

Summary (as of Jul 28, 2006)

Lower Prices Reduced with Increased Competition and Efficient Development of Drugs Act or the Lower PRICED Drugs Act - Amends the Federal Food, Drug, and Cosmetic Act to require an abbreviated application for a new drug containing certain antibiotics, the approved labeling for which includes a method of use that is claimed by a patent, to include a statement: (1) that identifies the relevant patent and the approved use covered by the patent; and (2) that the applicant is not seeking approval of such use.

Requires the court to consider the totality of circumstances and the public interest in deciding whether to shorten the 30-month period that delays the approval of an abbreviated drug application when a patent infringement case is filed against the applicant.

Limits market exclusivity provided for conducting pediatric studies of new or already approved drugs to only those drugs for which the Secretary of Health and Human Services approves labeling that provides specific, therapeutically meaningful information about the use of the drug in pediatric patients.

Sets forth provisions governing petitions seeking any action relating to the approval of certain new drug or abbreviated new drug applications, including the delay of such approval. Allows the Secretary to approve a petition to delay approval only when necessary to protect the public health. Requires the Secretary to take final agency action on a petition within 180 days of receipt, with no extensions allowed.

Extends the 30-month period that the Secretary has to approve or disapprove an abbreviated application for a new drug by the amount of time that lapses from the date the Secretary receives a petition and the date of the final agency action on the petition, without regard to whether the Secretary grants or denies the petition.

Actions Timeline

- **Aug 1, 2006:** Referred to the Subcommittee on Health.
- **Jul 28, 2006:** Introduced in House
- **Jul 28, 2006:** Introduced in House
- **Jul 28, 2006:** Referred to the House Committee on Energy and Commerce.