

HR 5750

Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2014

Congress: 113 (2013–2015, Ended)

Chamber: House

Policy Area: Health

Introduced: Nov 20, 2014

Current Status: Sponsor introductory remarks on measure. (CR H8938)

Latest Action: Sponsor introductory remarks on measure. (CR H8938) (Dec 10, 2014)

Official Text: <https://www.congress.gov/bill/113th-congress/house-bill/5750>

Sponsor

Name: Rep. Bilirakis, Gus M. [R-FL-12]

Party: Republican • **State:** FL • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Nov 20, 2014
Rep. Hastings, Alcee L. [D-FL-20]	D · FL		Nov 20, 2014
Rep. McCaul, Michael T. [R-TX-10]	R · TX		Nov 20, 2014
Rep. Quigley, Mike [D-IL-5]	D · IL		Dec 10, 2014

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Nov 21, 2014

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2014 - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services (HHS) to extend by six months the exclusivity period for a drug or biological product approved by the Food and Drug Administration (FDA) when the product is additionally approved to prevent, diagnose, or treat a new indication that is a rare disease or condition (also known as an “orphan disease”).

Allows the Secretary to revoke an extension if the application submitted to the FDA for the new indication contained an untrue material statement.

Requires the sponsor of a product receiving an extension to notify HHS one year prior to discontinuing production for commercial reasons.

Requires the Secretary to notify the public of products that receive this extension.

Limits a product to one extension under this Act. Sets forth that extensions under this Act are in addition to other extensions.

Applies only to products approved after enactment of this Act for a new indication that is a rare disease or condition.

Actions Timeline

- **Dec 10, 2014:** Sponsor introductory remarks on measure. (CR H8938)
- **Nov 21, 2014:** Referred to the Subcommittee on Health.
- **Nov 20, 2014:** Introduced in House
- **Nov 20, 2014:** Referred to the House Committee on Energy and Commerce.