HR 2415

To amend the Federal Food, Drug, and Cosmetic Act to provide for establishment of a streamlined data review program.

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: May 19, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 22, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/2415

Sponsor

Name: Rep. Burgess, Michael C. [R-TX-26]
Party: Republican • **State:** TX • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Engel, Eliot L. [D-NY-16]	D · NY		May 19, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 22, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 6	Related bill	**Jul 13, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 19, 2015)

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to establish a streamlined data review program under which the holder of an approved application for a drug or biological product may submit a summary of clinical data to support approval of the drug for the treatment of cancer or another indication subject to the program.

For a drug to be eligible for the streamlined data review program there must be a database regarding the safety of the drug and the full data sets used to develop the data summaries must be submitted, unless the FDA determines that the full data sets are not required.

The FDA must annually publish: (1) the number of applications reviewed under the streamlined data review program, (2) the average time for completion of review under the streamlined data review program compared to review of other applications for new indications, and (3) the number of applications reviewed under the streamlined data review program for which the FDA made use of full data sets.

Actions Timeline

- **May 22, 2015:** Referred to the Subcommittee on Health.
- **May 19, 2015:** Introduced in House
- **May 19, 2015:** Referred to the House Committee on Energy and Commerce.