S 1767

Combination Product Regulatory Fairness Act of 2016

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jul 15, 2015
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 414.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 414. (Apr 5, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/1767

Sponsor

Name: Sen. Isakson, Johnny [R-GA]
Party: Republican • **State:** GA • **Chamber:** Senate

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		Jul 15, 2015
Sen. Roberts, Pat [R-KS]	R · KS		Jul 15, 2015
Sen. Toomey, Patrick [R-PA]	R · PA		Aug 3, 2015
Sen. Kirk, Mark Steven [R-IL]	R · IL		Sep 25, 2015
Sen. Donnelly, Joe [D-IN]	D · IN		Oct 20, 2015
Sen. Cassidy, Bill [R-LA]	R · LA		Dec 14, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 5, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 34	Related bill	**Dec 13, 2016:** Became Public Law No: 114-255.

Summary (as of Apr 5, 2016)

Combination Product Regulatory Fairness Act of 2016

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to revise provisions regarding products that are a combination of a drug, medical device, or biological product.

The primary mode of action of a combination product must be the mode of action that makes the greatest contribution to the product's therapeutic effect. (Combination products are regulated based on their primary mode of action.) The FDA is prohibited from determining that a combination product is a drug or biological product solely because the product has a chemical action. If the sponsor of a combination product disagrees with the FDA's determination of the primary mode of action of the product, the FDA must provide the rationale for its determination and the sponsor and the FDA may agree to studies to inform a reevaluation of the product.

After the primary mode of action of a product is determined, the sponsor and the FDA may agree to a combination product review plan that may address the standards and requirements applicable to the product's review, postmarket modification, or manufacturing. The plan must remain in effect unless the sponsor and the FDA agree otherwise or an issue essential to determining the safety or effectiveness of the product is identified.

The FDA may require the sponsor of a combination product that contains an approved constituent part to submit to the FDA only information that is necessary to assess the safety and effectiveness of the combination product, taking into account prior findings regarding the approved constituent part. If the approved constituent part is a drug, the application for the combination product must comply with specified requirements for drug applications.

The FDA Office of Combination Products must coordinate reviews of combination products and oversee feedback regarding such reviews. The office must review FDA agreements, guidance, and practices regarding combination products.
The FDA must: (1) issue guidance that describes the process and best practices for review of combination products, and (2) propose that certain types of combination products may adopt good manufacturing practices that vary from requirements in regulations.

Actions Timeline

- **Apr 5, 2016:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 414.
- **Mar 9, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jul 15, 2015:** Introduced in Senate
- **Jul 15, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.