S 2187

FDA Regulatory Efficiency Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Oct 21, 2015
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Oct 21, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/2187

Sponsor

Name: Sen. Donnelly, Joe [D-IN]
Party: Democratic • **State:** IN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Gardner, Cory [R-CO]	R · CO		Oct 21, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 21, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 5983	Related bill	**Dec 20, 2016:** Placed on the Union Calendar, Calendar No. 693.
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.
114 HR 2422	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.

Summary (as of Oct 21, 2015)

FDA Regulatory Efficiency Act

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to establish a third-party quality system assessment program to accredit persons to assess whether a medical device manufacturer's quality system can ensure the safety and effectiveness or substantial equivalence of an approved medical device after certain changes, including changes in manufacturing or changes to enhance device safety.

Device manufacturers with quality systems that have been certified by an accredited person are allowed to make changes to a device without submitting to the FDA the premarket notification, 30-day notice, or premarket approval supplement that would otherwise be required.

An accredited person who assesses a device manufacturer's quality system must submit a summary of their assessment and, as appropriate, a certification of the quality system to the FDA within 30 days of the assessment. An assessment summary and certification is deemed accepted by the FDA 30 days after submission unless the FDA determines that additional information is needed to support certification, the assessment or certification is unwarranted, or an action other than acceptance of the certification is otherwise justified.

Device manufacturers who make changes to devices without submitting a premarket notification must describe the changes in an annual summary submitted to the FDA. Changes made without submitting a 30-day notice or a premarket approval supplement must be described in a periodic report.

Certifications accepted by the FDA remain in effect for two years.
The FDA must report on this quality system assessment program no later than January 31, 2022. The program is terminated at the end of FY2022.

Actions Timeline

- **Oct 21, 2015:** Introduced in Senate
- **Oct 21, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.