HR 3205

FDA Renewing Efficiency From Outside Reviewer Management Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 14, 2011
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 18, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/3205

Sponsor

Name: Rep. Paulsen, Erik [R-MN-3]
Party: Republican • **State:** MN • **Chamber:** House

Cosponsors (16 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Altmire, Jason [D-PA-4]	D · PA		Oct 14, 2011
Rep. Bachmann, Michele [R-MN-6]	R · MN		Oct 14, 2011
Rep. Bilbray, Brian P. [R-CA-50]	R · CA		Oct 14, 2011
Rep. Blackburn, Marsha [R-TN-7]	R · TN		Oct 14, 2011
Rep. Bono Mack, Mary [R-CA-45]	R · CA		Oct 14, 2011
Rep. Cassidy, Bill [R-LA-6]	R · LA		Oct 14, 2011
Rep. Cravaack, Chip [R-MN-8]	R · MN		Oct 14, 2011
Rep. Guthrie, Brett [R-KY-2]	R · KY		Oct 14, 2011
Rep. Kinzinger, Adam [R-IL-11]	R · IL		Oct 14, 2011
Rep. Kline, John [R-MN-2]	R · MN		Oct 14, 2011
Rep. Latta, Robert E. [R-OH-5]	R · OH		Oct 14, 2011
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Oct 14, 2011
Rep. Shimkus, John [R-IL-19]	R · IL		Oct 14, 2011
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Oct 25, 2011
Rep. Culberson, John Abney [R-TX-7]	R · TX		Dec 2, 2011
Rep. Rokita, Todd [R-IN-4]	R · IN		Jan 23, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 18, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 14, 2011)

FDA Renewing Efficiency From Outside Reviewer Management Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act to revise and extend through October 1, 2017, provisions authorizing accredited persons to provide classification reports for a medical device and to inspect class II device or class III device facilities.

Deems a recommendation of an accredited person as to the classification of a medical device to be accepted by the Secretary of Health and Human Services (HHS) if the Secretary fails to make a determination with respect to the recommendation within 30 days.

Requires the Secretary to regularly publish: (1) detailed decision summaries for each clearance of a device, classification of a device, approval of an application of a device, or grant of exemption for a device occurring after the enactment of this Act; and (2) total product life cycles information for devices.

Expands the devices for which an accredited person may perform a review to include: (1) a class II device for which clinical data is required in the report, and (2) a class II device which is intended to be permanently implantable or life sustaining or supporting only if notification is provided to the Secretary before such a review. Deems the review permissible if the Secretary does not object within 60 days.

Requires the Secretary to provide for the initial training and periodic updating of training of accredited persons.

Makes accreditation valid for three years. Sets forth provisions regarding reaccreditation.

Prohibits an accredited person from being a sole practitioner. Provides that the prohibitions against an accredited person being owned or controlled by a manufacturer, supplier, or vendor of devices or engaging in the design, manufacture, promotion, or sale of devices shall apply only if the devices are of the same type for which the person is accredited.

Actions Timeline

- **Oct 18, 2011:** Referred to the Subcommittee on Health.
- **Oct 14, 2011:** Introduced in House
- **Oct 14, 2011:** Referred to the House Committee on Energy and Commerce.

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