S 934

FDA Reauthorization Act of 2017

Congress: 115 (2017–2019, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 25, 2017
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 76.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 76. (May 11, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/senate-bill/934

Sponsor

Name: Sen. Alexander, Lamar [R-TN]
Party: Republican • **State:** TN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Murray, Patty [D-WA]	D · WA		Apr 25, 2017

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	May 11, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 HR 2430	Related bill	**Aug 18, 2017:** Became Public Law No: 115-52.
115 HR 2562	Related bill	**May 26, 2017:** Referred to the Subcommittee on Health.
115 S 1115	Related bill	**May 11, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1093	Related bill	**May 10, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1069	Related bill	**May 8, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1070	Related bill	**May 8, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 HR 2376	Related bill	**May 5, 2017:** Referred to the Subcommittee on Health.
115 S 1048	Related bill	**May 4, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1049	Related bill	**May 4, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1062	Related bill	**May 4, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 HR 1652	Related bill	**Mar 24, 2017:** Referred to the Subcommittee on Health.
115 S 670	Related bill	**Mar 21, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 11, 2017)

FDA Reauthorization Act of 2017

TITLE I--FEES RELATING TO DRUGS

Prescription Drug User Fee Amendments of 2017

(Sec. 102) This bill amends the Federal Food, Drug, and Cosmetic Act to extend through FY2022 and revise Food and Drug Administration (FDA) user fees for new drug applications. User fees are eliminated for supplements to new drug applications and drug manufacturing facilities.

TITLE II--FEES RELATING TO DEVICES

Medical Device User Fee Amendments of 2017

(Sec. 203) The bill extends through FY2022 and revises FDA user fees for medical devices. A user fee is established for requests to classify devices that are not substantially equivalent to marketed devices. The FDA is no longer granted the discretion to waive or reduce fees in the interest of public health.

(Sec. 205) The FDA must establish a pilot program to accredit testing laboratories to determine whether medical devices conform to performance standards.

(Sec. 206) The bill revises the types of medical devices that the FDA may accredit third parties to review.

TITLE III--FEES RELATING TO GENERIC DRUGS

Generic Drug User Fee Amendments of 2017

(Sec. 303) The bill extends through FY2022 and revises FDA user fees for generic drugs. User fees are eliminated for supplements to generic drug applications. An annual fee is assessed on holders of approved generic drug applications.

TITLE IV--FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Biosimilar User Fee Amendments of 2017

(Sec. 403) The bill extends through FY2022 and revises FDA user fees for biosimilars. (Biosimilars are biological products approved by the FDA based on their similarity to an already-approved biological product.) User fees are eliminated for supplements to biosimilar applications and biosimilar manufacturing facilities. An annual fee is assessed on holders of approved applications for biosimilars. The bill sets the annual amount of revenue that must be generated by fees.

TITLE V--PEDIATRIC DRUGS AND DEVICES

(Sec. 501) The bill revises requirements for the FDA to report on pediatric use of medical devices.

The bill extends and revises the authorization for certain medical devices for pediatric patients to be sold above cost under the humanitarian device exemption.

TITLE VI--REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

(Sec. 601) The bill extends through FY2022 programs and policies including Critical Path Public-Private Partnerships and support for development of medical products for rare conditions.

(Sec. 604) Except in cases of a drug shortage or certain importation of drugs from Canada, prescription drugs manufactured outside the United States may only be imported if authorized by the manufacturer and appropriately labeled.

TITLE VII--DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

(Sec. 701) The bill revises provisions regarding FDA inspections of establishments that manufacture or process medical devices.

(Sec. 703) The bill extends through FY2022 accreditation by the FDA of third parties to conduct inspections of medical device establishments.

(Sec. 704) The bill revises provisions regarding FDA certification of medical devices for export.

(Sec. 711) The FDA must categorize certain hearing aids as over-the-counter hearing aids and issue regulations regarding those hearing aids.

TITLE VIII--ADDITIONAL PROVISIONS

(Sec. 803) User fee performance reports must include an analysis of: (1) the number of product applications filed and approved, (2) whether the relevant FDA review office has met performance enhancement goals, and (3) circumstances affecting the ability of the FDA to meet review time and performance enhancement goals.

TITLE IX--GENERIC DRUG ACCESS

Subtitle A--Removing Regulatory Barriers to Competition

(Sec. 901) The FDA must prioritize the review of generic drug applications and supplements for drugs for which there are not more than three approved drugs or that are in a shortage.

Subtitle B--Incentivizing Competition

(Sec. 911) The FDA, upon request, must expedite the development and review of generic drug applications for drugs with three or fewer approved generic drug applications or that are in a shortage.

(Sec. 912) The holder of an approved drug application must notify the FDA within 180 days of withdrawing the drug from sale, withdrawing the application, or transferring the application.

The FDA must maintain a list of generic drugs with three or fewer holders of approved applications.

Actions Timeline

- **May 11, 2017:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **May 11, 2017:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **May 11, 2017:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 76.
- **Apr 25, 2017:** Introduced in Senate
- **Apr 25, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.