

S 1463

Modernizing Therapeutic Equivalence Rating Determination Act

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Apr 29, 2021

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. (Apr 29, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/1463>

Sponsor

Name: Sen. Cassidy, Bill [R-LA]

Party: Republican • **State:** LA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Smith, Tina [D-MN]	D · MN		Apr 29, 2021

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 29, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Modernizing Therapeutic Equivalence Rating Determination Act

This bill requires the Food and Drug Administration (FDA) to provide a therapeutic equivalence rating for certain new drug applications if the applicant requests such a rating.

Upon request in the application, the FDA must provide such a rating for a new drug application that relies on information from studies not conducted by the applicant and that the applicant does not have a right to reference or use (commonly referred to as a 505(b)(2) application). The FDA must provide the rating no later than 30 days after the application's approval.

(A drug is a therapeutic equivalent of another if they produce the same clinical effect and have the same safety profile. Typically, for certain generic drugs, the FDA rates the therapeutic equivalence of that generic drug to another drug, such as the brand name version. Currently, an applicant seeking approval of a drug through a 505(b)(2) application typically only receives an equivalence rating by requesting one from the FDA in a separate petition.)

Actions Timeline

- **Apr 29, 2021:** Introduced in Senate
- **Apr 29, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.