HR 7377

Modernizing Therapeutic Equivalence Rating Determination Act

Congress: 117 (2021–2023, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 4, 2022
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 5, 2022)
Official Text: https://www.congress.gov/bill/117th-congress/house-bill/7377

Sponsor

Name: Rep. Curtis, John R. [R-UT-3]
Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Craig, Angie [D-MN-2]	D · MN		Apr 4, 2022

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 5, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 4, 2022)

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 5, 2022:** Referred to the Subcommittee on Health.
- **Apr 4, 2022:** Introduced in House
- **Apr 4, 2022:** Referred to the House Committee on Energy and Commerce.