

## S 415

A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

**Congress:** 117 (2021–2023, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Feb 24, 2021

**Current Status:** Became Public Law No: 117-9.

**Latest Action:** Became Public Law No: 117-9. (Apr 23, 2021)

**Law:** 117-9 (Enacted Apr 23, 2021)

**Official Text:** <https://www.congress.gov/bill/117th-congress/senate-bill/415>

### Sponsor

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

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

### Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Marshall, Roger [R-KS]	R · KS		Feb 24, 2021
Sen. Smith, Tina [D-MN]	D · MN		Feb 24, 2021

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Discharged From	Mar 10, 2021

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

*No related bills are listed.*

This bill provides statutory authority for the existing Food and Drug Administration (FDA) practice of defining *active ingredient* more narrowly as *active moiety* in certain situations, such as when determining whether a new drug is entitled to a market exclusivity period or providing priority review of drugs for treating rare pediatric diseases.

Generally, the FDA defines *active moiety* as the core molecule or ion in a drug responsible for the relevant physiological or pharmacological action. By contrast, the FDA defines an *active ingredient* as a component in a drug that is intended to furnish pharmacological activity or other direct effect. The FDA's existing practice of interpreting *active ingredient* as *active moiety* in certain situations, as statutorily authorized by this bill, tends to exclude some drugs from market exclusivity.

The bill replaces references to *active ingredient* with *active moiety* in various statutes authorizing FDA activities.

### Actions Timeline

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- **Apr 23, 2021:** Signed by President.
- **Apr 23, 2021:** Became Public Law No: 117-9.
- **Apr 20, 2021:** Presented to President.
- **Apr 14, 2021:** Mr. Pallone moved to suspend the rules and pass the bill.
- **Apr 14, 2021:** Considered under suspension of the rules. (consideration: CR H1755-1756)
- **Apr 14, 2021:** DEBATE - The House proceeded with forty minutes of debate on S. 415.
- **Apr 14, 2021:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H1755)
- **Apr 14, 2021:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H1755)
- **Apr 14, 2021:** Motion to reconsider laid on the table Agreed to without objection.
- **Mar 12, 2021:** Received in the House.
- **Mar 12, 2021:** Held at the desk.
- **Mar 11, 2021:** Message on Senate action sent to the House.
- **Mar 10, 2021:** Senate Committee on Health, Education, Labor, and Pensions discharged by Unanimous Consent.(consideration: CR S1435)
- **Mar 10, 2021:** Senate Committee on Health, Education, Labor, and Pensions discharged by Unanimous Consent. (consideration: CR S1435)
- **Mar 10, 2021:** Passed/agreed to in Senate: Passed Senate without amendment by Unanimous Consent.(text: CR S1435)
- **Mar 10, 2021:** Passed Senate without amendment by Unanimous Consent. (text: CR S1435)
- **Feb 24, 2021:** Introduced in Senate
- **Feb 24, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.