

HR 3443

To clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved drug application, and for other purposes.

Congress: 116 (2019–2021, Ended)

Chamber: House

Policy Area: Health

Introduced: Jun 24, 2019

Current Status: Sponsor introductory remarks on measure. (CR E971)

Latest Action: Sponsor introductory remarks on measure. (CR E971) (Jul 24, 2019)

Official Text: <https://www.congress.gov/bill/116th-congress/house-bill/3443>

Sponsor

Name: Rep. DeGette, Diana [D-CO-1]

Party: Democratic • **State:** CO • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Dingell, Debbie [D-MI-12]	D · MI		Jun 24, 2019
Rep. Guthrie, Brett [R-KY-2]	R · KY		Jun 24, 2019
Rep. Latta, Robert E. [R-OH-5]	R · OH		Jun 24, 2019

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 25, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 HR 748	Related bill	Jul 23, 2020: Committee on Small Business and Entrepreneurship. Hearings held. Hearings printed: S.Hrg. 116-517.
116 HR 19	Related bill	Dec 19, 2019: Referred to the Subcommittee on Antitrust, Commercial, and Administrative Law.
116 S 2740	Related bill	Dec 14, 2019: Referred to the Subcommittee on Health.
116 HR 269	Related bill	Jan 10, 2019: Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 10.

Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019

This bill makes significant changes to the regulation by the Food and Drug Administration (FDA) of nonprescription (i.e., over-the-counter or OTC) drugs.

The bill establishes a new approval process for OTC medications. Specifically, it creates an FDA administrative order process for the evaluation of OTC products, replacing the present notice and comment rulemaking approach. Under the new process, the FDA may issue an administrative order determining that a specific OTC drug, class of drugs, or combination is generally regarded as safe and effective and not subject to the new drug application process. The FDA may also use the administrative order process to (1) determine that a drug, class of drugs, or combination poses an imminent hazard to the public health; or (2) require labeling changes to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug.

The bill provides for market exclusivity under certain circumstances. For drugs determined to be generally regarded as safe and effective pursuant to an administrative order requested by a sponsor (rather than initiated by the FDA), the requestor is granted 18 months of market exclusivity. This market exclusivity applies to an OTC drug with a new active ingredient or if the requestor conducted new human studies to get approval.

The bill allows a sponsor of a nonprescription sunscreen active ingredient or a combination of such ingredients that was subject to a proposed sunscreen order to transition to the administrative order process. Market exclusivity provisions also apply to new sunscreen active ingredients.

The FDA must establish a user fee program for OTC drugs.

Actions Timeline

- **Jul 24, 2019:** Sponsor introductory remarks on measure. (CR E971)
- **Jun 25, 2019:** Referred to the Subcommittee on Health.
- **Jun 24, 2019:** Introduced in House
- **Jun 24, 2019:** Referred to the House Committee on Energy and Commerce.