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.

Summary (as of Jun 24, 2019)

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.

LegiList

CONGRESS, MADE CLEAR.

Search Every Federal Bill, Law, and Vote

LegiList is the fastest way to research Congress. Track any bill from introduction to enactment, see how every legislator voted, follow committee activity, and read the full text of every bill — all in one place, always up to date.

legilist.com

Free Course: Learn How Congress Actually Works

LegiList Learn is a free, self-paced course that walks through the entire legislative process — from drafting a bill to a presidential signature. Seven modules, plain language, no politics. Earn a certificate when you finish.

legilist.com/learn

Developer API: Build Apps on Legislative Data

The LegiList API gives developers direct access to bills, votes, legislators, committees, and more. Start free with 1,000 requests per day — no credit card required. Upgrade to Pro when you need to scale.

legilist.com/api

Public data belongs to the public. — legilist.com