

H.R.2565 - FDA Modernization Act of 2021

117th Congress (2021-2022) | [Get alerts](#)

Sponsor: [Rep. Buchanan, Vern \[R-FL-16\]](#) (Introduced 04/15/2021)  
Committees: House - Energy and Commerce  
Latest Action: House - 04/16/2021 Referred to the Subcommittee on Health. ([All Actions](#))  
Tracker: Introduced Passed House Passed Senate To President Became Law

Summary(1) **Text(1)** Actions(3) Titles(2) Amendments(0) Cosponsors(16) Committees(1) Related Bills(0)

There is one version of the bill.

Text available as: XML/HTML (6KB) | [XML/HTML \(new window\) \(5KB\)](#) | [TXT \(3KB\)](#) | [PDF \(246KB\)](#) (PDF provides a complete and accurate display of this text.) ?

Shown Here:  
Introduced in House (04/15/2021)

117TH CONGRESS  
1ST SESSION

H. R. 2565

To amend the Federal Food, Drug, and Cosmetic Act to allow manufacturers and sponsors of a drug to use alternative testing methods to animal testing to investigate the safety and effectiveness of a drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 15, 2021

Mr. BUCHANAN (for himself, Mrs. LURIA, Ms. MACE, Ms. SHERRILL, and Mr. BRENDAN F. BOYLE of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow manufacturers and sponsors of a drug to use alternative testing methods to animal testing to investigate the safety and effectiveness of a drug, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “FDA Modernization Act of 2021”.

SEC. 2. ANIMAL TESTING ALTERNATIVES.

Section 505 of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 355](#)) is amended—

(1) in subsection (b)(5)(B)(i)(II), by striking “animal” and inserting “nonclinical tests or studies”;

(2) in subsection (i)—

(A) in paragraph (1)(A), by striking “(including tests on animals)”;

(B) in paragraph (2)(B), by striking “animal or human studies” and inserting “nonclinical tests or studies”; and

(3) after subsection (y), by inserting the following:

“(z) NONCLINICAL TEST OR STUDY DEFINED.—For purposes of this section, the term ‘nonclinical test or study’ means a test or study that is most likely to predict human response based on scientific evidence and occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test or study may include the following:

“(1) Cell-based assays.

“(2) Organ chips and microphysiological systems.

“(3) Sophisticated computer modeling.

“(4) Other human biology-based test methods.

“(5) Animal tests.”.