

Union Calendar No. 614

119TH CONGRESS
2^D SESSION

H. R. 2821

[Report No. 119-706]

To require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to publish a final rule relating to nonclinical testing methods.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2025

Mr. CARTER of Georgia (for himself, Ms. BARRAGÁN, Mr. BUCHANAN, Ms. DELAURO, Mrs. HARSHBARGER, and Mr. CARTER of Louisiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 18, 2026

Additional sponsors: Mr. DOGGETT, Mr. NADLER, Mr. CAREY, Mr. FITZPATRICK, Ms. MALLIOTAKIS, Mr. CRENSHAW, Ms. CHU, Ms. SCHOLTEN, Mr. SOTO, Mr. GOLDMAN of New York, Mr. OBERNOLTE, Mr. GOTTHEIMER, Mr. CROW, Mr. LIEU, Ms. TENNEY, Mr. SMITH of New Jersey, Ms. NORTON, Ms. SALAZAR, Ms. LOIS FRANKEL of Florida, Mr. VALADAO, Mr. HARDER of California, Mr. FITZGERALD, Mr. BILIRAKIS, Ms. LEE of Florida, Mr. CALVERT, Mr. VINDMAN, Mr. POCAN, Mr. LAWLER, Mr. WEBER of Texas, Mr. NEGUSE, Mr. KRISHNAMOORTHY, Mr. KEAN, Ms. JOHNSON of Texas, Mrs. KIM, Mr. LANGWORTHY, and Mr. THANEDAR

JUNE 18, 2026

Committed to the Committee of the Whole House on the State of the Union
and ordered to be printed

A BILL

To require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to publish a final rule relating to nonclinical testing methods.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Modernization
5 Act 3.0”.

6 **SEC. 2. REGULATIONS ON NONCLINICAL TESTING METH-**
7 **ODS.**

8 (a) INTERIM FINAL RULE.—

9 (1) IN GENERAL.—In order to ensure imple-
10 mentation of the amendments to section 505(i) of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355(i)) made by section 3209(a) of the Con-
13 solidated Appropriations Act, 2023 (Public Law
14 117–328; 136 Stat. 5821), not later than 1 year
15 after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services, acting
17 through the Commissioner of Food and Drugs, shall
18 publish an interim final rule—

19 (A) to amend the sections of title 21, Code
20 of Federal Regulations, described in paragraph
21 (2) to replace any references to “animal” tests,
22 data, studies, models, and research with a ref-
23 erence to nonclinical tests, data, studies, mod-
24 els, and research; and

1 (B) to add the definition of “nonclinical
2 test” in section 505(z) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 355(z)) to
4 sections 312.3, 314.3, 315.2, and 601.31 of
5 title 21, Code of Federal Regulations.

6 (2) CFR SECTIONS DESCRIBED.—The sections
7 of title 21, Code of Federal Regulations, described
8 in this paragraph are the following:

- 9 (A) Section 312.22(c).
10 (B) Section 312.23(a)(3)(iv).
11 (C) Section 312.23(a)(5)(ii).
12 (D) Section 312.23(a)(5)(iii).
13 (E) Section 312.23(a)(8).
14 (F) Section 312.23(a)(8)(i).
15 (G) Section 312.23(a)(8)(ii).
16 (H) Section 312.23(a)(10)(i).
17 (I) Section 312.23(a)(10)(ii).
18 (J) Section 312.33(b)(6).
19 (K) Section 312.82(a).
20 (L) Section 312.88.
21 (M) Section 314.50(d)(2).
22 (N) Section 314.50(d)(2)(iv).
23 (O) Section 314.50(d)(5)(i).
24 (P) Section 314.50(d)(5)(vi)(a).
25 (Q) Section 314.50(d)(5)(vi)(b).

1 (R) Section 314.93(e)(2).

2 (S) Section 315.6(d).

3 (T) Section 330.10(a)(2).

4 (U) Section 601.35(d).

5 (V) Any other section necessary to ensure
6 regulatory consistency with the amendments to
7 section 505(i) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 355(i)) made by sec-
9 tion 3209(a) of the Consolidated Appropriations
10 Act, 2023 (Public Law 117–328; 136 Stat.
11 5821).

12 (3) EFFECTIVENESS OF INTERIM FINAL
13 RULE.—Notwithstanding subparagraph (B) of sec-
14 tion 553(b) of title 5, United States Code, the in-
15 terim final rule issued by the Secretary of Health
16 and Human Services under paragraph (1) shall be-
17 come immediately effective as an interim final rule
18 without requiring the Secretary of Health and
19 Human Services to demonstrate good cause therefor.

20 (b) TECHNICAL AMENDMENT.—Section 505 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
22 is amended by designating the second subsection (z) (re-
23 lating to clinical trial diversity action plans), as added by
24 section 3601(a) of the Health Extenders, Improving Ac-
25 cess to Medicare, Medicaid, and CHIP, and Strengthening

1 Public Health Act of 2022 (division FF of Public Law
2 117–328), as subsection (aa).

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