

119TH CONGRESS
1ST SESSION

S. 355

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “FDA Modernization
3 Act 3.0”.

4 **SEC. 2. REGULATIONS ON NONCLINICAL TESTING METH-**
5 **ODS.**

6 (a) INTERIM FINAL RULE.—

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

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

23 (B) to add the definition of “nonclinical
24 test” in section 505(z) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 355(z)) to

1 sections 312.3, 314.3, 315.2, and 601.31 of
 2 title 21, Code of Federal Regulations.

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

6 (A) Section 312.22(c).

7 (B) Section 312.23(a)(3)(iv).

8 (C) Section 312.23(a)(5)(ii).

9 (D) Section 312.23(a)(5)(iii).

10 (E) Section 312.23(a)(8).

11 (F) Section 312.23(a)(8)(i).

12 (G) Section 312.23(a)(8)(ii).

13 (H) Section 312.23(a)(10)(i).

14 (I) Section 312.23(a)(10)(ii).

15 (J) Section 312.33(b)(6).

16 (K) Section 312.82(a).

17 (L) Section 312.88.

18 (M) Section 314.50(d)(2).

19 (N) Section 314.50(d)(2)(iv).

20 (O) Section 314.50(d)(5)(i).

21 (P) Section 314.50(d)(5)(vi)(a).

22 (Q) Section 314.50(d)(5)(vi)(b).

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

24 (S) Section 315.6(d).

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

1 (U) Section 601.35(d).

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

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

17 (b) TECHNICAL AMENDMENT.—Section 505 of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
19 is amended by designating the second subsection (z) (re-
20 lating to clinical trial diversity action plans), as added by
21 section 3601(a) of the Health Extenders, Improving

- 1 Access to Medicare, Medicaid, and CHIP, and Strength-
- 2 ening Public Health Act of 2022 (division FF of Public
- 3 Law 117–328), as subsection (aa).

Passed the Senate December 16, 2025.

Attest:

Secretary.

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