

119TH CONGRESS
1ST SESSION

S. _____

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 SENATE OF THE UNITED STATES

Mr. BOOKER (for himself, Mr. SCHMITT, Mr. KING, Mr. KENNEDY, Mr. WHITEHOUSE, Mr. MARSHALL, Mr. BLUMENTHAL, Mr. PAUL, and Mr. LUJÁN) introduced the following bill; which was read twice and referred to the Committee on _____

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”.

1 **SEC. 2. REGULATIONS ON NONCLINICAL TESTING METH-**
2 **ODS.**

3 (a) INTERIM FINAL RULE.—

4 (1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this Act, the Secretary of
6 Health and Human Services, acting through the
7 Commissioner of Food and Drugs, shall publish an
8 interim final rule pursuant to subsections (b) and
9 (c) to ensure implementation of the amendments to
10 section 505(i) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(i)) made by section
12 3209(a) of the Consolidated Appropriations Act,
13 2023 (Public Law 117–328; 136 Stat. 5821).

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

22 (b) INCLUSIONS.—

23 (1) IN GENERAL.—The interim final rule shall
24 replace any references to “animal” tests, data, stud-
25 ies, models, and research with a reference to non-
26 clinical tests, data, studies, models, and research in

1 the following sections of title 21, Code of Federal
2 Regulations:

3 (A) Section 312.22(c).

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

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

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

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

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

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

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

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

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

13 (K) Section 312.82(a).

14 (L) Section 312.88.

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

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

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

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

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

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

21 (S) Section 315.6(d).

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

23 (U) Section 601.35(d).

24 (V) Any other section necessary to ensure

25 regulatory consistency with the amendments to

1 section 505(i) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 355(i)) made by sec-
3 tion 3209(a) of the Consolidated Appropriations
4 Act, 2023 (Public Law 117–328; 136 Stat.
5 5821).

6 (2) ADDITIONAL CHANGES.—The Secretary
7 may make such additional changes to the sections of
8 title 21, Code of Federal Regulations, described in
9 subparagraphs (A) through (V) of paragraph (1) as
10 the Secretary determines appropriate to fully imple-
11 ment the replacement required under such para-
12 graph.

13 (c) DEFINITION OF NONCLINICAL TEST.—The defi-
14 nition of “nonclinical test” in section 505(z) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(z))
16 shall be added to sections 312.3, 314.3, 315.2, and 601.31
17 of title 21, Code of Federal Regulations.

18 (d) TECHNICAL AMENDMENT.—Section 505 of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
20 is amended by designating the second subsection (z) (re-
21 lating to clinical trial diversity action plans), as added by
22 section 3601(a) of the Health Extenders, Improving Ac-
23 cess to Medicare, Medicaid, and CHIP, and Strengthening
24 Public Health Act of 2022 (division FF of Public Law
25 117–328), as subsection (aa).