

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 2d Sess.

S. 5046

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.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. BOOKER (for himself and Mr. SCHMITT)

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

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.—Not later than 1 year after
10 the date of enactment of this Act, the Secretary of

1 Health and Human Services, acting through the
2 Commissioner of Food and Drugs, shall publish an
3 interim final rule pursuant to subsections (b) and
4 (c) to ensure implementation of the amendments to
5 section 505(i) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355(i)) made by section
7 3209(a) of the Consolidated Appropriations Act,
8 2023 (Public Law 117–328; 136 Stat. 5821).

9 (2) 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) INCLUSIONS.—

18 (1) IN GENERAL.—The interim final rule shall
19 replace any references to “animal” tests, data, stud-
20 ies, models, and research with a reference to non-
21 clinical tests, data, studies, models, and research in
22 the following sections of title 21, Code of Federal
23 Regulations:

24 (A) Section 312.22(c).

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

- 1 (C) Section 312.23(a)(5)(ii).
- 2 (D) Section 312.23(a)(5)(iii).
- 3 (E) Section 312.23(a)(8).
- 4 (F) Section 312.23(a)(8)(i).
- 5 (G) Section 312.23(a)(8)(ii).
- 6 (H) Section 312.23(a)(10)(i).
- 7 (I) Section 312.23(a)(10)(ii).
- 8 (J) Section 312.33(b)(6).
- 9 (K) Section 312.82(a).
- 10 (L) Section 312.88.
- 11 (M) Section 314.50(d)(2).
- 12 (N) Section 314.50(d)(2)(iv).
- 13 (O) Section 314.50(d)(5)(i).
- 14 (P) Section 314.50(d)(5)(vi)(a).
- 15 (Q) Section 314.50(d)(5)(vi)(b).
- 16 (R) Section 314.93(e)(2).
- 17 (S) Section 315.6(d).
- 18 (T) Section 330.10(a)(2).
- 19 (U) Section 601.35(d).
- 20 (V) Any other section necessary to ensure
- 21 regulatory consistency with the amendments to
- 22 section 505(i) of the Federal Food, Drug, and
- 23 Cosmetic Act (21 U.S.C. 355(i)) made by sec-
- 24 tion 3209(a) of the Consolidated Appropriations

1 Act, 2023 (Public Law 117–328; 136 Stat.
2 5821).

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

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

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