

118TH CONGRESS
2D 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. PAUL, Mr. KING, Mr. BRAUN, Mr. WHITEHOUSE, Mr. KENNEDY, 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) **IN GENERAL.**—Not later than 180 days after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services, acting through the Commissioner of
6 Food and Drugs, shall publish a final rule to implement
7 section 505(z) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 355(z)).

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