

117TH CONGRESS  
2D SESSION

# S. 5002

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## AN ACT

To allow for alternatives to animal testing for purposes of  
drug and biological product applications.

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 2.0”.

4 **SEC. 2. ALTERNATIVES TO ANIMAL TESTING.**

5       (a) IN GENERAL.—Section 505 of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

7               (1) in subsection (i)—

8                       (A) in paragraph (1)(A), by striking “pre-  
9                       clinical tests (including tests on animals)” and  
10                      inserting “nonclinical tests”; and

11                     (B) in paragraph (2)(B), by striking “ani-  
12                     mal” and inserting “nonclinical tests”; and

13               (2) after subsection (y), by inserting the fol-  
14       lowing:

15       “(z) NONCLINICAL TEST DEFINED.—For purposes  
16 of this section, the term ‘nonclinical test’ means a test con-  
17 ducted in vitro, in silico, or in chemico, or a non-human  
18 in vivo test that occurs before or during the clinical trial  
19 phase of the investigation of the safety and effectiveness  
20 of a drug, and may include animal tests, or non-animal  
21 or human biology-based test methods, such as cell-based  
22 assays, microphysiological systems, or bioprinted or com-  
23 puter models.”.

24       (b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-  
25 TIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the

1 Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I))

2 is amended to read as follows:

3 “(bb) an assessment of tox-  
4 icity (which may rely on, or con-  
5 sist of, a study or studies de-  
6 scribed in item (aa) or (cc));  
7 and”.

Passed the Senate September 29, 2022.

Attest:

*Secretary.*

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