117TH CONGRESS
2D SESSION

S. 5002

AN ACT

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Modernization Act 2.0''.

SEC. 2. ALTERNATIVES TO ANIMAL TESTING.

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

(1) in subsection (i)—

(A) in paragraph (1)(A), by striking ''preclinical tests (including tests on animals)'' and inserting ''nonclinical tests''; and

(B) in paragraph (2)(B), by striking ''animal'' and inserting ''nonclinical tests''; and

(2) after subsection (y), by inserting the following:

''(z) NONCLINICAL TEST DEFINED.—For purposes of this section, the term 'nonclinical test' means a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug, and may include animal tests, or non-animal or human biology-based test methods, such as cell-based assays, microphysiological systems, or bioprinted or computer models.''.

(b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the

Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I)) is amended to read as follows:

"(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc)); and".

Passed the Senate September 29, 2022.

Attest:

Secretary.

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