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(Original Signature of Member)

118TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to establish a process for the qualification of nonclinical testing methods to reduce and replace the use of animals in nonclinical research, improve the predictivity of nonclinical testing methods, and reduce development time for a biological product or other drug, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. CARTER of Georgia introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to establish a process for the qualification of nonclinical testing methods to reduce and replace the use of animals in nonclinical research, improve the predictivity of nonclinical testing methods, and reduce development time for a biological product or other drug, and for other purposes.

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 3.0”.

4 **SEC. 2. NONCLINICAL TESTING METHODS QUALIFICATION**  
5 **PROCESS AT THE FOOD AND DRUG ADMINIS-**  
6 **TRATION.**

7 (a) IN GENERAL.—Subchapter A of chapter V of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
9 et seq.) is amended by inserting after section 507 the fol-  
10 lowing:

11 **“SEC. 507A. NONCLINICAL TESTING METHODS QUALIFICA-**  
12 **TION PROCESS.**

13 “(a) IN GENERAL.—

14 “(1) PROCESS DESCRIPTION.—The Secretary  
15 shall establish a process for the qualification of a  
16 nonclinical testing method, with respect to drugs,  
17 under which—

18 “(A) persons may request qualification of  
19 a nonclinical testing method for a particular  
20 context of use; and

21 “(B) the Secretary shall grant or deny  
22 such request in accordance with this section.

23 “(2) INITIATION.—The Secretary shall initiate  
24 the process under paragraph (1) not later than 1  
25 year after the date of enactment of this section.

1 “(b) ELIGIBLE NONCLINICAL TESTING METHODS.—

2 To be eligible for qualification under this section, a non-

3 clinical testing method shall—

4 “(1) be intended to replace or reduce animal

5 testing; and

6 “(2) either—

7 “(A) improve the predictivity of nonclinical

8 testing for safety and efficacy; or

9 “(B) reduce development time for a drug

10 (including any biological product).

11 “(c) QUALIFICATION OF NONCLINICAL TESTING

12 METHODS.—

13 “(1) PROCESS.—The Secretary shall establish a

14 process for submission of a request under subsection

15 (a).

16 “(2) CONTENTS.—At a minimum, a request

17 under subsection (a) shall include preliminary infor-

18 mation demonstrating that the nonclinical testing

19 method meets the criteria described in subsection (b)

20 in a particular context of use.

21 “(3) ADVICE REGARDING THE METHOD OF

22 NONCLINICAL TESTING.—The Secretary may facili-

23 tate the development and review of preliminary in-

24 formation submitted pursuant to paragraph (2) in a

25 request under subsection (a) by—

1           “(A) providing timely advice to, and inter-  
2           action with, the person submitting the request  
3           regarding the development of the method of  
4           nonclinical testing; and

5           “(B) involving senior managers and experi-  
6           enced staff of the Food and Drug Administra-  
7           tion, as appropriate, in a collaborative, cross-  
8           disciplinary review of the proposed method of  
9           nonclinical testing.

10          “(4) ENGAGEMENT OF EXTERNAL EXPERTS.—

11          In reviewing a request under subsection (a), the Sec-  
12          retary shall—

13                 “(A) through the use of cooperative agree-  
14                 ments or other appropriate mechanisms, consult  
15                 with biomedical research consortia and other  
16                 expert stakeholders with specific expertise in  
17                 nonclinical testing methods; and

18                 “(B) consider recommendations of bio-  
19                 medical research consortia or other qualified ex-  
20                 perts in deciding whether to grant or deny the  
21                 request.

22          “(5) REVIEW OF REQUESTS.—

23                 “(A) TIMING.—Not later than 180 cal-  
24                 endar days after the receipt of a request under

1 subsection (a), the Secretary shall determine  
2 whether to grant or deny the request.

3 “(B) DETERMINATION.—In reviewing a  
4 nonclinical testing method pursuant to a re-  
5 quest under subsection (a), the Secretary shall  
6 determine whether to grant or deny the request  
7 based on whether the method satisfies the cri-  
8 teria listed in subsection (b) as demonstrated  
9 by—

10 “(i) the information submitted in the  
11 request or supplements thereto; and

12 “(ii) any additional information pro-  
13 vided by external experts.

14 “(C) QUALIFICATION DECISION.—If the  
15 Secretary determines pursuant to subparagraph  
16 (B) that a nonclinical testing method satisfies  
17 the criteria listed in subsection (b), the Sec-  
18 retary shall grant the request for qualification  
19 of the method in a particular context of use.

20 “(d) EFFECTS OF QUALIFICATION.—If the Secretary  
21 qualifies a nonclinical testing method pursuant to a re-  
22 quest under this section—

23 “(1) the method shall be available for use by  
24 the holder of the qualification or a person authorized  
25 by such holder for drug development in the par-

1        ticular context of use for which the method is quali-  
2        fied; and

3            “(2) the Secretary shall—

4                    “(A) expedite the development and review  
5                    of an application submitted under section 505  
6                    of this Act or section 351 of the Public Health  
7                    Service Act, including supplemental applica-  
8                    tions, for drugs that are developed using the  
9                    qualified nonclinical testing method; and

10                    “(B) allow the holder of the qualification  
11                    or a person authorized by such holder to ref-  
12                    erence or rely upon, in an application submitted  
13                    under section 505 of this Act or section 351 of  
14                    the Public Health Service Act, including a sup-  
15                    plemental application, data and information  
16                    about the qualification of the nonclinical testing  
17                    method in the same context of use for which the  
18                    qualification was granted.

19            “(e) REVIEW OF APPLICATIONS UTILIZING QUALI-  
20        FIED NONCLINICAL TESTING METHODS.—The Secretary  
21        shall expedite the development and review of an applica-  
22        tion submitted under section 505 of this Act or section  
23        351 of the Public Health Service Act for drugs for which  
24        a nonclinical testing method qualified under this section  
25        is used.

1 “(f) TRANSPARENCY.—

2 “(1) SUBMISSION OF REPORT TO CONGRESS.—

3 Not later than 2 years after the date of enactment  
4 of this section and annually thereafter, the Secretary  
5 shall publish on the website of the Food and Drug  
6 Administration and submit to the Committee on  
7 Health, Education, Labor, and Pensions of the Sen-  
8 ate and the Committee on Energy and Commerce of  
9 the House of Representatives a report containing an  
10 evaluation of the process under this section.

11 “(2) CONTENTS OF REPORT.—Each report  
12 under paragraph (1) shall include—

13 “(A) for the period covered by the report—

14 “(i) the types of nonclinical testing  
15 methods qualified under the process;

16 “(ii) the number of requests for quali-  
17 fication under subsection (a), and the  
18 number of such requests that have been  
19 granted;

20 “(iii) the average number of calendar  
21 days for the review of requests under sub-  
22 section (a) before granting or denying such  
23 requests;

24 “(iv) an analysis of the factors that  
25 result in determinations to qualify or not

1           qualify a nonclinical testing method under  
2           this section; and

3                   “(v) the number of applications re-  
4           ceived under section 505 of this Act or sec-  
5           tion 351 of the Public Health Service Act  
6           that rely on a nonclinical testing method  
7           qualified under this section, and the num-  
8           ber of such applications approved; and

9                   “(B) for the period beginning on the date  
10          of enactment of this section through the end of  
11          the period covered by the report, the number of  
12          animals estimated to have been saved as a re-  
13          sult of the process under this section.

14          “(g) NONCLINICAL TESTING METHOD DEFINED.—  
15          In this section, the term ‘nonclinical testing method’ has  
16          the meaning given to such term in section 505(z) except  
17          that such term excludes any animal test.”.

18          (b) PUBLIC MEETING.— Not later than 180 days  
19          after the date of enactment of this Act, the Secretary of  
20          Health and Human Services shall publish in the Federal  
21          Register a notice to convene a public meeting to discuss  
22          and obtain input and recommendations from relevant  
23          stakeholders, including regulated industry, biomedical con-  
24          sortia, contract research organizations, and patients, re-  
25          garding—



1 (1) the goals and scope of the process under  
2 507A of the Federal Food, Drug, and Cosmetic Act,  
3 as added by subsection (a);

4 (2) a framework, procedures, and requirements  
5 for such process; and

6 (3) ways in which the Food and Drug Adminis-  
7 tration will support the use of nonclinical testing  
8 methods to replace or reduce the use of animals in  
9 nonclinical testing.

10 (c) FDA GUIDANCE.—

11 (1) NONCLINICAL TESTING METHODS QUALI-  
12 FICATION PROCESS.—The Secretary of Health and  
13 Human Services, acting through the Commissioner  
14 of Food and Drugs, shall—

15 (A) not later than 1 year after the date of  
16 the public meeting under subsection (b), pro-  
17 pose guidance on the goals and implementation  
18 of the process under section 507A of the Fed-  
19 eral Food, Drug, and Cosmetic Act, as added  
20 by subsection (a);

21 (B) provide a period for public comment  
22 on such proposed guidance; and

23 (C) not later than 1 year after the end of  
24 such public comment period, finalize such guid-  
25 ance.

1           (2) CONTENTS.—The guidance under para-  
2 graph (1) shall address—

3           (A) the process by which a person may re-  
4 quest qualification under section 507A of the  
5 Federal Food, Drug, and Cosmetic Act, as  
6 added by subsection (a);

7           (B) the eligibility criteria under subsection  
8 (b) of such section 507A;

9           (C) the information that a person request-  
10 ing such qualification is required to submit  
11 under subsection (c) of such section 507A; and

12           (D) how the Secretary intends to evaluate  
13 requests under such section 507A.

14 **SEC. 3. REGULATIONS ON NONCLINICAL TESTING METH-**  
15 **ODS.**

16           (a) IN GENERAL.—Not later than 90 days after the  
17 date of enactment of this Act, the Secretary of Health and  
18 Human Services, acting through the Commissioner of  
19 Food and Drugs, shall initiate a rulemaking under section  
20 553 of title 5, United States Code, to implement section  
21 505(z) of the Federal Food, Drug, and Cosmetic Act (21  
22 U.S.C. 355(z)).

23           (b) TECHNICAL AMENDMENT.—Section 505 of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
25 is amended by designating the second subsection (z) (re-

1 lating to clinical trial diversity action plans), as added by  
2 section 3601(a) of the Health Extenders, Improving Ac-  
3 cess to Medicare, Medicaid, and CHIP, and Strengthening  
4 Public Health Act of 2022 (division FF of Public Law  
5 117–328), as subsection (aa).