

118TH CONGRESS
2D SESSION

H. R. 7248

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.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2024

Mr. CARTER of Georgia (for himself, Ms. BARRAGÁN, Mrs. HARSHBARGER, Mr. BUCHANAN, Mr. CARTER of Louisiana, Mr. WALTZ, Ms. DeLAURO, Mr. NEHLS, Mr. GOODEN of Texas, Mr. CRENSHAW, and Mr. FITZPATRICK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 may—

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 relating 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).

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