(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.

IN THE HOUSE OF REPRESENTATIVES

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

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.

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 3.0''.

SEC. 2. NONCLINICAL TESTING METHODS QUALIFICATION PROCESS AT THE FOOD AND DRUG ADMINISTRATION.

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

''SEC. 507A. NONCLINICAL TESTING METHODS QUALIFICATION PROCESS.

''(a) IN GENERAL.—

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

''(A) persons may request qualification of a nonclinical testing method for a particular context of use; and

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

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

''(b) ELIGIBLE NONCLINICAL TESTING METHODS.—To be eligible for qualification under this section, a nonclinical testing method shall—

''(1) be intended to replace or reduce animal testing; and

''(2) either—

''(A) improve the predictivity of nonclinical testing for safety and efficacy; or

''(B) reduce development time for a drug (including any biological product).

''(c) QUALIFICATION OF NONCLINICAL TESTING METHODS.—

''(1) PROCESS.—The Secretary shall establish a process for submission of a request under subsection (a).

''(2) CONTENTS.—At a minimum, a request under subsection (a) shall include preliminary information demonstrating that the nonclinical testing method meets the criteria described in subsection (b) in a particular context of use.

''(3) ADVICE REGARDING THE METHOD OF NONCLINICAL TESTING.—The Secretary may facilitate the development and review of preliminary information submitted pursuant to paragraph (2) in a request under subsection (a) by—

"(A) providing timely advice to, and interaction with, the person submitting the request regarding the development of the method of nonclinical testing; and

"(B) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the proposed method of nonclinical testing.

"(4) ENGAGEMENT OF EXTERNAL EXPERTS.—In reviewing a request under subsection (a), the Secretary may—

"(A) through the use of cooperative agreements or other appropriate mechanisms, consult with biomedical research consortia and other expert stakeholders with specific expertise in nonclinical testing methods; and

"(B) consider recommendations of biomedical research consortia or other qualified experts in deciding whether to grant or deny the request.

"(5) REVIEW OF REQUESTS.—

"(A) TIMING.—Not later than 180 calendar days after the receipt of a request under

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

''(B) DETERMINATION.—In reviewing a nonclinical testing method pursuant to a request under subsection (a), the Secretary shall determine whether to grant or deny the request based on whether the method satisfies the criteria listed in subsection (b) as demonstrated by—

''(i) the information submitted in the request or supplements thereto; and

''(ii) any additional information provided by external experts.

''(C) QUALIFICATION DECISION.—If the Secretary determines pursuant to subparagraph (B) that a nonclinical testing method satisfies the criteria listed in subsection (b), the Secretary shall grant the request for qualification of the method in a particular context of use.

''(d) EFFECTS OF QUALIFICATION.—If the Secretary qualifies a nonclinical testing method pursuant to a request under this section—

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

ticular context of use for which the method is qualified; and

''(2) the Secretary shall—

''(A) expedite the development and review of an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, for drugs that are developed using the qualified nonclinical testing method; and

''(B) allow the holder of the qualification or a person authorized by such holder to reference or rely upon, in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including a supplemental application, data and information about the qualification of the nonclinical testing method in the same context of use for which the qualification was granted.

''(e) REVIEW OF APPLICATIONS UTILIZING QUALIFIED NONCLINICAL TESTING METHODS.—The Secretary shall expedite the development and review of an application submitted under section 505 of this Act or section 351 of the Public Health Service Act for drugs for which a nonclinical testing method qualified under this section is used.

''(f) TRANSPARENCY.—

''(1) SUBMISSION OF REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section and annually thereafter, the Secretary shall publish on the website of the Food and Drug Administration and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing an evaluation of the process under this section.

''(2) CONTENTS OF REPORT.—Each report under paragraph (1) shall include—

''(A) for the period covered by the report—

''(i) the types of nonclinical testing methods qualified under the process;

''(ii) the number of requests for qualification under subsection (a), and the number of such requests that have been granted;

''(iii) the average number of calendar days for the review of requests under subsection (a) before granting or denying such requests;

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

qualify a nonclinical testing method under this section; and

''(v) the number of applications received under section 505 of this Act or section 351 of the Public Health Service Act that rely on a nonclinical testing method qualified under this section, and the number of such applications approved; and

''(B) for the period beginning on the date of enactment of this section through the end of the period covered by the report, the number of animals estimated to have been saved as a result of the process under this section.

''(g) NONCLINICAL TESTING METHOD DEFINED.— In this section, the term 'nonclinical testing method' has the meaning given to such term in section 505(z) except that such term excludes any animal test.''.

(b) PUBLIC MEETING.— Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice to convene a public meeting to discuss and obtain input and recommendations from relevant stakeholders, including regulated industry, biomedical consortia, contract research organizations, and patients, regarding—

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

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

(3) ways in which the Food and Drug Administration will support the use of nonclinical testing methods to replace or reduce the use of animals in nonclinical testing.

(c) FDA GUIDANCE.—

(1) NONCLINICAL TESTING METHODS QUALIFICATION PROCESS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(A) not later than 1 year after the date of the public meeting under subsection (b), propose guidance on the goals and implementation of the process under section 507A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

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

(C) not later than 1 year after the end of such public comment period, finalize such guidance.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) the process by which a person may request qualification under section 507A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

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

(C) the information that a person requesting such qualification is required to submit under subsection (c) of such section 507A; and

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

SEC. 3. REGULATIONS ON NONCLINICAL TESTING METHODS.

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

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

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