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(Original Signature of Member)

118TH CONGRESS  
1ST SESSION

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

To amend the Federal Food, Drug, and Cosmetic Act with respect to in vitro clinical tests, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act with respect to in vitro clinical tests, 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,*

3 **SECTION 1. SHORT TITLE.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Verifying Accurate Leading-edge IVCT Development Act  
6 of 2023” or the “VALID Act of 2023”.

7 **SEC. 2. DEFINITIONS.**

8 (a) IN GENERAL.—Section 201 of the Federal Food,  
9 Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

1 (1) by adding at the end the following:

2 “(ss)(1) The term ‘in vitro clinical test’ means an ar-  
3 ticle specified in subparagraph (2) that is intended to be  
4 used in the collection, preparation, analysis, or in vitro  
5 clinical examination of specimens taken or derived from  
6 the human body for the purpose of—

7 “(A) identifying or diagnosing a disease or con-  
8 dition;

9 “(B) providing information for diagnosing,  
10 screening, measuring, detecting, predicting,  
11 prognosing, analyzing, or monitoring a disease or  
12 condition, including by making a determination of  
13 an individual’s state of health; or

14 “(C) selecting, monitoring, or informing ther-  
15 apy or treatment for a disease or condition.

16 “(2) An article specified in this subparagraph is—

17 “(A) a test kit;

18 “(B) a test system;

19 “(C) a test protocol or laboratory test protocol;

20 “(D) an instrument (as defined in section  
21 587(11));

22 “(E) a specimen receptacle (as defined in sec-  
23 tion 587(17));

1           “(F) software, excluding software that is ex-  
2           cluded by section 520(o) from the definition of a de-  
3           vice under section 201(h), that—

4                   “(i) is a component or part of another in  
5           vitro clinical test or analyzes, processes, or in-  
6           terprets a signal or pattern from another in  
7           vitro clinical test; and

8                   “(ii) does not analyze, process, or interpret  
9           a signal, pattern, or medical image from a de-  
10          vice; and

11          “(G) subject to subparagraph (3), a component  
12          or part of a test kit, a test system, a test protocol  
13          or laboratory test protocol, an instrument, a speci-  
14          men receptacle, or software described in subpara-  
15          graph (F), whether alone or in combination, includ-  
16          ing reagents, calibrators, and controls.

17          “(3) Notwithstanding subparagraph (2)(G), an arti-  
18          cle intended to be used as a component or part of an in  
19          vitro clinical test described in subparagraph (1) is ex-  
20          cluded from the definition in subparagraph (1) if the arti-  
21          cle consists of any of the following:

22                   “(A) Blood, blood components, or human cells  
23          or tissues, from the time of acquisition, donation, or  
24          recovery of such article, including determination of  
25          donor eligibility, as applicable, until such time as the

1 article is released as a component or part of an in  
2 vitro clinical test by the establishment that collected  
3 such article.

4 “(B) An article used for invasive sampling, a  
5 needle, or a lancet, except to the extent such article,  
6 needle, or lancet is an integral component of an arti-  
7 cle for holding, storing, or transporting a specimen.

8 “(C) General purpose laboratory equipment.”;

9 (2) by adding at the end of paragraph (g) the  
10 following:

11 “(3) The term ‘drug’ does not include an in vitro clin-  
12 ical test.”; and

13 (3) in paragraph (h)(1), in the matter following  
14 clause (C), by striking “section 520(o)” and insert-  
15 ing “section 520(o) or an in vitro clinical test”.

16 (b) EXCLUSION FROM DEFINITION OF BIOLOGICAL  
17 PRODUCT.—Section 351(i)(1) of the Public Health Serv-  
18 ice Act (42 U.S.C. 262(i)(1)) is amended—

19 (1) by striking “(1) The term ‘biological prod-  
20 uct’ means” and inserting “(1)(A) The term ‘biologi-  
21 cal product’ means”; and

22 (2) by adding at the end the following:

23 “(B) The term ‘biological product’ does not in-  
24 clude an in vitro clinical test as defined in section

1 201(ss) of the Federal Food, Drug, and Cosmetic  
2 Act.”.

3 (c) IN VITRO CLINICAL TEST DEFINITION.—In this  
4 Act, the term “in vitro clinical test” has the meaning given  
5 such term in section 201(ss) of the Federal Food, Drug,  
6 and Cosmetic Act, as added by subsection (a).

7 **SEC. 3. REGULATION OF IN VITRO CLINICAL TESTS.**

8 The Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 301 et seq.) is amended—

10 (1) by amending the heading of chapter V to  
11 read as follows: “**DRUGS, DEVICES, AND IN**  
12 **VITRO CLINICAL TESTS**”; and

13 (2) by adding at the end of chapter V the fol-  
14 lowing:

15 **“Subchapter J—In Vitro Clinical Tests**

16 **“SEC. 587. DEFINITIONS.**

17 “In this subchapter:

18 “(1) ANALYTICAL VALIDITY.—The term ‘ana-  
19 lytical validity’ means, with respect to an in vitro  
20 clinical test, the ability of the in vitro clinical test,  
21 to identify, measure, detect, calculate, or analyze (or  
22 assist in such identification, measurement, detection,  
23 calculation, or analysis of) one or more analytes, bio-  
24 markers, substances, or other targets intended to be

1 identified, measured, detected, calculated, or ana-  
2 lyzed by the test.

3 “(2) APPLICABLE STANDARD.—The term ‘ap-  
4 plicable standard’, with respect to an in vitro clinical  
5 test, means a reasonable assurance of analytical and  
6 clinical validity for its indications for use, and a rea-  
7 sonable assurance of safety for individuals who come  
8 into contact with such in vitro clinical test, except  
9 that such term, with respect to specimen receptacles  
10 and test instruments, means a reasonable assurance  
11 of analytical validity for its indications for use and  
12 safety for individuals who come into contact with  
13 such specimen receptacle or test instrument.

14 “(3) CLINICAL USE.—The term ‘clinical use’  
15 means the operation, application, or functioning of  
16 an in vitro clinical test for the purpose for which it  
17 is intended as described in section 201(ss)(1).

18 “(4) CLINICAL VALIDITY.—The term ‘clinical  
19 validity’ means the ability of an in vitro clinical test  
20 to achieve the purpose for which it is intended as de-  
21 scribed in section 201(ss)(1).

22 “(5) COMPONENT OR PART.—The term ‘compo-  
23 nent or part’ means a substance, piece, part, raw  
24 material, software, firmware, labeling, or assembly,  
25 including reagents, that is intended to be included as

1 an aspect of an in vitro clinical test described in sec-  
2 tion 201(ss)(1).

3 “(6) DEVELOP.—The term ‘develop’, with re-  
4 spect to an in vitro clinical test, means—

5 “(A) designing, validating, producing,  
6 manufacturing, remanufacturing, labeling, ad-  
7 vertising, propagating, importing, or assembling  
8 an in vitro clinical test;

9 “(B) modifying an in vitro clinical test, in-  
10 cluding modifying the indications for use of the  
11 in vitro clinical test, or modifying an article to  
12 be an in vitro clinical test; or

13 “(C) establishing a test system as de-  
14 scribed or included in a test protocol developed  
15 by another entity unless such test protocol is  
16 listed as an in vitro clinical test in the com-  
17 prehensive test information system established  
18 under section 587T by that other entity.

19 “(7) DEVELOPER.—The term ‘developer’ means  
20 a person who engages in development as described in  
21 paragraph (6), except the term does not include a  
22 laboratory that—

23 “(A) is certified by the Secretary under  
24 section 353 of the Public Health Service Act;  
25 and

1           “(B) assembles for use solely within that  
2           laboratory, without otherwise developing, an in  
3           vitro clinical test appropriately listed in the  
4           comprehensive test information system estab-  
5           lished under section 587T by a different person.

6           “(8) FIRST-OF-A-KIND.—The term ‘first-of-a-  
7           kind’, with respect to an in vitro clinical test, means  
8           that such test has any novel combination of the ele-  
9           ments specified in paragraph (10) that differs from  
10          in vitro clinical tests that already are legally avail-  
11          able in the United States, except for such tests of-  
12          fered under section 587C(a)(3), 587C(a)(4), or  
13          587G.

14          “(9) HIGH-RISK.—The term ‘high-risk’, with  
15          respect to an in vitro clinical test or category of in  
16          vitro clinical tests, means that an undetected inac-  
17          curate result from such test, or such category of  
18          tests, when used as intended—

19                 “(A)(i) is reasonably likely to result in se-  
20                 rious or irreversible harm or death to a patient  
21                 or patients, or would otherwise cause serious  
22                 harm to the public health; or

23                 “(ii) is reasonably likely to result in the  
24                 absence, significant delay, or discontinuation of



1 life-supporting or life-sustaining medical treat-  
2 ment; and

3 “(B) mitigating measures are not able to  
4 be established and applied to prevent, mitigate,  
5 or detect the inaccurate result, or otherwise suf-  
6 ficiently mitigate the risk resulting from an un-  
7 detected inaccurate result described in subpara-  
8 graph (A), such that the test would be mod-  
9 erate-risk or low-risk.

10 “(10) INDICATIONS FOR USE.—The term ‘indi-  
11 cations for use’, with respect to an in vitro clinical  
12 test, means the following elements:

13 “(A) Substance or substances measured by  
14 the in vitro clinical test, such as an analyte,  
15 protein, or pathogen.

16 “(B) Test method.

17 “(C) Test purpose or purposes, as de-  
18 scribed in section 201(ss)(1).

19 “(D) Diseases or conditions for which the  
20 in vitro clinical test is intended for use, includ-  
21 ing intended patient populations.

22 “(E) Context of use, such as in a clinical  
23 laboratory, in a health care facility, prescription  
24 home use, over-the-counter use, or direct-to-  
25 consumer testing.

1 “(11) INSTRUMENT.—

2 “(A) IN GENERAL.—The term ‘instrument’  
3 means an analytical or pre-analytical instru-  
4 ment.

5 “(B) ANALYTIC INSTRUMENT.—The term  
6 ‘analytic instrument’ means an in vitro clinical  
7 test that is hardware intended by the developer  
8 to be used with one or more other in vitro clin-  
9 ical tests to generate a clinical test result, in-  
10 cluding software used to effectuate the  
11 functionality of the hardware.

12 “(C) PRE-ANALYTICAL INSTRUMENT.—The  
13 term ‘pre-analytical instrument’ means an in  
14 vitro clinical test that is hardware intended by  
15 the developer solely to generate an output for  
16 use exclusively with one or more analytical in-  
17 struments as defined in subparagraph (B) and  
18 which does not itself generate a clinical test re-  
19 sult. Such term may include software used to  
20 effectuate the hardware’s functionality.

21 “(12) INSTRUMENT FAMILY.—The term ‘instru-  
22 ment family’ means more than one instrument devel-  
23 oped by the same developer for which the developer  
24 demonstrates and documents, with respect to all  
25 such instruments, that all—

1           “(A) have the same basic architecture, de-  
2           sign, and performance characteristics;

3           “(B) have the same indications for use and  
4           capabilities;

5           “(C) share the same measurement prin-  
6           ciples, detection methods, and reaction condi-  
7           tions, as applicable; and

8           “(D) produce the same or similar analyt-  
9           ical results from samples of the same specimen  
10          type or types.

11          “(13) LABORATORY OPERATIONS.—The term  
12          ‘laboratory operations’—

13                 “(A) means the conduct of a laboratory ex-  
14                 amination or other laboratory procedure on ma-  
15                 terials derived from the human body, including  
16                 the conduct of an in vitro clinical test and asso-  
17                 ciated activities, that is—

18                         “(i) regulated under section 353 of  
19                         the Public Health Service Act; and

20                         “(ii) not related to the design, analyt-  
21                         ical validation, or clinical validation of an  
22                         in vitro clinical test; and

23           “(B) includes—

1                   “(i) performing pre-analytical and  
2                   post-analytical processes for an in vitro  
3                   clinical test;

4                   “(ii) standard operating procedures  
5                   and the conduct thereof; and

6                   “(iii) preparing reagents or other test  
7                   materials that do not meet the criteria for  
8                   being an in vitro clinical test for clinical  
9                   use.

10                  “(14) LOW-RISK.—The term ‘low-risk’, with re-  
11                  spect to an in vitro clinical test or category of in  
12                  vitro clinical tests, means that an undetected inac-  
13                  curate result from such in vitro clinical test, or such  
14                  category of in vitro clinical tests, when used as in-  
15                  tended—

16                         “(A) would cause only minimal or imme-  
17                         diately reversible harm, and would lead to only  
18                         a remote risk of adverse patient impact or ad-  
19                         verse public health impact; or

20                         “(B) sufficient mitigating measures are  
21                         able to be established and applied such that the  
22                         in vitro clinical test meets the standard de-  
23                         scribed in subparagraph (A).

24                  “(15) MITIGATING MEASURES.—The term  
25                  ‘mitigating measures’—

1           “(A) means controls, standards, and other  
2 requirements that the Secretary determines,  
3 based on evidence, are necessary—

4           “(i) for an in vitro clinical test, or a  
5 category of in vitro clinical tests, to meet  
6 the applicable standard; or

7           “(ii) to mitigate the risk of harm en-  
8 suing from an undetected inaccurate result  
9 or misinterpretation of a result; and

10          “(B) may include, as required by the Sec-  
11 retary, as appropriate, applicable requirements  
12 regarding labeling, conformance to performance  
13 standards and consensus standards, perform-  
14 ance testing, submission of clinical data, adver-  
15 tising, website posting of information, clinical  
16 studies, postmarket surveillance, user com-  
17 prehension studies, training, and confirmatory  
18 laboratory, clinical findings, the history of the  
19 developer, the role of a health professional in  
20 the testing process, such as integration of the  
21 testing laboratory into the direct medical care  
22 of the patient, including direct interaction be-  
23 tween the testing laboratory and treating physi-  
24 cian, or testing.

1           “(16) MODERATE-RISK.—The term ‘moderate-  
2 risk’, with respect to an in vitro clinical test or cat-  
3 egory of in vitro clinical tests—

4           “(A) means a test or category of tests that  
5 is not high-risk under the criteria under para-  
6 graph (9) or low-risk under the criteria under  
7 paragraph (14); and

8           “(B) may include a test or category of  
9 tests that, when used as intended, meet the cri-  
10 teria specified in paragraph (9)(A) for high-  
11 risk, but for which one or more mitigating  
12 measures are able to be established and applied  
13 to prevent, mitigate, or detect an inaccurate re-  
14 sult or otherwise sufficiently mitigate the risk  
15 resulting from an undetected inaccurate result,  
16 but are not sufficient such that the test is low-  
17 risk under the criteria in paragraph (14).

18           “(17) SPECIMEN RECEPTACLE.—The term  
19 ‘specimen receptacle’ means an in vitro clinical test  
20 intended for taking, collecting, holding, storing, or  
21 transporting of specimens derived from the human  
22 body or for preparation, analysis, or in vitro clinical  
23 examination for purposes described in section  
24 201(ss)(1).

25           “(18) TECHNOLOGY.—The term ‘technology’—

1           “(A) means a set of control mechanisms,  
2 energy sources, or operating principles—

3           “(i) that do not differ significantly  
4 among multiple in vitro clinical tests; and

5           “(ii) for which design and develop-  
6 ment (including analytical and clinical vali-  
7 dation, as applicable) of the tests would be  
8 addressed in a similar manner or through  
9 similar procedures; and

10          “(B) may include clot detection, colori-  
11 metric (non-immunoassay), electrochemical  
12 (non-immunoassay), enzymatic (non-  
13 immunoassay), flow cytometry, fluorometry  
14 (non-immunoassay), immunoassay, mass spec-  
15 trometry or chromatography, microbial culture,  
16 next generation sequencing, nephelometric or  
17 turbidimetric (non-immunoassay), singleplex or  
18 multiplex non-NGS nucleic acid analysis, slide-  
19 based technology, spectroscopy, and any other  
20 technology, as the Secretary determines appro-  
21 priate.

22          “(19) TEST.—The term ‘test’, unless otherwise  
23 provided, means an in vitro clinical test.

24          “(20) VALID SCIENTIFIC EVIDENCE.—The term  
25 ‘valid scientific evidence’—

1           “(A) means, with respect to an in vitro  
2           clinical test, evidence that—

3                   “(i) has been generated and evaluated  
4                   by persons qualified by training or experi-  
5                   ence to do so, using procedures generally  
6                   accepted by other persons so qualified; and

7                   “(ii) forms an appropriate basis for  
8                   concluding by qualified experts whether the  
9                   applicable standard has been met by the in  
10                  vitro clinical test; and

11               “(B) may include evidence described in  
12               subparagraph (A) consisting of—

13                   “(i) peer-reviewed literature;

14                   “(ii) clinical guidelines;

15                   “(iii) reports of significant human ex-  
16                  perience with an in vitro clinical test;

17                   “(iv) bench studies;

18                   “(v) case studies or histories;

19                   “(vi) clinical data;

20                   “(vii) consensus standards;

21                   “(viii) reference standards;

22                   “(ix) data registries;

23                   “(x) postmarket data;

24                   “(xi) real world data;

25                   “(xii) clinical trials; and



1           “(xiii) data collected in countries  
2           other than the United States if such data  
3           are demonstrated to be appropriate for the  
4           purpose of making a regulatory determina-  
5           tion under this subchapter.

6 **“SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.**

7           “(a) IN GENERAL.—No person shall introduce or de-  
8           liver for introduction into interstate commerce any in vitro  
9           clinical test, unless—

10           “(1) an approval of an application filed pursu-  
11           ant to subsection (a) or (b) of section 587B is effec-  
12           tive with respect to such in vitro clinical test;

13           “(2) the in vitro clinical test is offered under a  
14           technology certification order under section  
15           587D(b)(1); or

16           “(3) the test is exempt under sections 587C or  
17           587G from the requirements of section 587B.

18           “(b) TRANSFER OR SALE OF IN VITRO CLINICAL  
19           TESTS.—

20           “(1) TRANSFER AND ASSUMPTION OF REGU-  
21           LATORY OBLIGATIONS.—If ownership of an in vitro  
22           clinical test is sold or transferred in such manner  
23           that the developer transfers the regulatory submis-  
24           sions and obligations applicable under this sub-  
25           chapter with respect to the test, the transferee or

1 purchaser becomes the developer of the test and  
2 shall have all regulatory obligations applicable to  
3 such a test under this subchapter. The transferee or  
4 purchaser shall update the registration and listing  
5 information under section 587J for the in vitro clin-  
6 ical test.

7 “(2) TRANSFER OR SALE OF PREMARKET AP-  
8 PROVAL.—

9 “(A) NOTICE REQUIRED.—If a developer  
10 of an in vitro clinical test transfers or sells the  
11 approval of the in vitro clinical test, the trans-  
12 feror or seller shall—

13 “(i) submit a notice of the transfer or  
14 sale to the Secretary and update the reg-  
15 istration and listing information under sec-  
16 tion 587J for the in vitro clinical test; and

17 “(ii) submit a supplement to an appli-  
18 cation if required under section 587B(h).

19 “(B) EFFECTIVE DATE OF APPROVAL  
20 TRANSFER.—A transfer or sale described in  
21 subparagraph (A) shall become effective upon  
22 completion of a transfer or sale described in  
23 paragraph (1) or the approval of a supplement  
24 to an application under section 587B(h) if re-  
25 quired, whichever is later. The transferee or

1 purchaser shall update the registration and list-  
2 ing information under section 587J for the in  
3 vitro clinical test within 15 calendar days of the  
4 effective date of the transfer or sale.

5 “(3) TRANSFER OR SALE OF TECHNOLOGY CER-  
6 TIFICATION.—

7 “(A) REQUIREMENTS FOR TRANSFER OR  
8 SALE OF TECHNOLOGY CERTIFICATION.—An  
9 unexpired technology certification can be trans-  
10 ferred or sold if the transferee or purchaser—

11 “(i) is an eligible person under section  
12 587D(a)(2); and

13 “(ii) maintains, upon such transfer or  
14 sale, test design and quality requirements,  
15 processes and procedures under the scope  
16 of technology certification, and scope of the  
17 technology certification identified in the  
18 applicable technology certification order.

19 “(B) NOTICE REQUIRED.—If a developer  
20 of an in vitro clinical test transfers or sells a  
21 technology certification order that has not ex-  
22 pired, the transferor or seller shall submit a no-  
23 tice of the transfer or sale to the Secretary and  
24 shall update the registration and listing infor-  
25 mation under section 587J for all in vitro clin-

1           ical tests covered by the technology certifi-  
2           cation.

3           “(C) EFFECTIVE DATE OF TECHNOLOGY  
4           CERTIFICATION TRANSFER.—The transfer of a  
5           technology certification shall become effective  
6           upon completion of a transfer or sale described  
7           in subparagraph (A). The transferee or pur-  
8           chaser shall update the registration and listing  
9           information under section 587J for the in vitro  
10          clinical test within 30 calendar days of the ef-  
11          fective date of the technology certification  
12          transfer.

13          “(D) NEW TECHNOLOGY CERTIFICATION  
14          REQUIRED.—If the requirements of subpara-  
15          graph (A)(ii) are not met, the technology cer-  
16          tification order may not be transferred and the  
17          transferee or purchaser of an in vitro clinical  
18          test is required to submit an application for  
19          technology certification and obtain a technology  
20          certification order prior to offering the test for  
21          clinical use.

22          “(c) REGULATIONS.—The Secretary may issue regu-  
23          lations to implement this subchapter.

24          **“SEC. 587B. PREMARKET REVIEW.**

25          “(a) APPLICATION.—

1           “(1) FILING.—Any developer may file with the  
2           Secretary an application for premarket approval of  
3           an in vitro clinical test under this subsection.

4           “(2) TRANSPARENCY AND PREDICTABILITY.—If  
5           a developer files a premarket application under this  
6           section and provides any additional documentation  
7           required under section 587D, the in vitro clinical  
8           test that is the subject of the premarket application  
9           may be utilized as the representative in vitro clinical  
10          test reviewed by the Secretary to support a tech-  
11          nology certification order under section 587D.

12          “(3) APPLICATION CONTENT.—An application  
13          submitted under paragraph (1) shall include the fol-  
14          lowing, in such format as the Secretary specifies:

15                 “(A) General information regarding the in  
16                 vitro clinical test, including—

17                         “(i) the name and address of the ap-  
18                         plicant;

19                         “(ii) the table of contents for the ap-  
20                         plication and the identification of the infor-  
21                         mation the applicant claims as trade secret  
22                         or confidential commercial or financial in-  
23                         formation;

1 “(iii) a description of the test’s design  
2 and intended use, including the indications  
3 for use; and

4 “(iv) a description regarding test  
5 function and performance characteristics.

6 “(B) A summary of the data and informa-  
7 tion in the application for the in vitro clinical  
8 test, including—

9 “(i) a brief description of the foreign  
10 and domestic marketing history of the test,  
11 if any, including a list of all countries in  
12 which the test has been marketed and a  
13 list of all countries in which the test has  
14 been withdrawn from the market for any  
15 reason related to the ability of the in vitro  
16 clinical test to meet the applicable stand-  
17 ard, if known by the applicant;

18 “(ii) a description of benefit and risk  
19 considerations related to the in vitro clin-  
20 ical test, including a description of any ap-  
21 plicable adverse effects of the test on  
22 health and how such adverse effects have  
23 been, or will be, mitigated;

24 “(iii) a risk assessment of the test;  
25 and

1           “(iv) a description of how the data  
2           and information in the application con-  
3           stitute valid scientific evidence and support  
4           a showing that the test meets the applica-  
5           ble standard under section 587(2).

6           “(C) The signature of the developer filing  
7           the premarket application or an authorized rep-  
8           resentative.

9           “(D) A bibliography of applicable pub-  
10          lished reports and a description of any studies  
11          conducted, including any unpublished studies  
12          related to such test, that are known or that  
13          should reasonably be known to the applicant,  
14          and a description of data and information rel-  
15          evant to the evaluation of whether the test  
16          meets the applicable standard.

17          “(E) Applicable information regarding the  
18          methods used in, and the facilities or controls  
19          used for, the development of the test to dem-  
20          onstrate compliance with the applicable quality  
21          requirements under section 587K.

22          “(F) Information demonstrating compli-  
23          ance with any relevant and applicable—

24                  “(i) mitigating measures under sec-  
25                  tion 587E; and

1           “(ii) standards established or recog-  
2           nized under section 514 prior to the date  
3           of enactment of the VALID Act of 2023,  
4           or, after applicable standards are estab-  
5           lished or recognized under section 587R,  
6           with such standards.

7           “(G) Valid scientific evidence to support  
8           that the test meets the applicable standard,  
9           which shall include—

10           “(i) summary information for all sup-  
11           porting validation studies performed, in-  
12           cluding a description of the objective of the  
13           study, a description of the experimental de-  
14           sign of the study, a description of any limi-  
15           tations of the study, a brief description of  
16           how the data were collected and analyzed,  
17           a brief description of the results of each  
18           study, and conclusions drawn from each  
19           study;

20           “(ii) raw data for each study, which  
21           may include, as applicable, tabulations of  
22           data and results; and

23           “(iii) for nonclinical laboratory studies  
24           involving the test, if applicable, a state-  
25           ment that studies were conducted in com-



1           pliance with applicable good laboratory  
2           practices.

3           “(H) To the extent the application seeks  
4           authorization to make modifications to the test  
5           within the scope of the approval that are not  
6           otherwise permitted without premarket review  
7           under this subchapter, a proposed change pro-  
8           tocol that includes validation procedures and  
9           acceptance criteria for anticipated modifications  
10          that could be made to the test within the scope  
11          of the approval.

12          “(I) Proposed labeling, in accordance with  
13          the requirements of section 587L.

14          “(J) Such other data or information as the  
15          Secretary may require in accordance with the  
16          least burdensome requirements under section  
17          587AA(c).

18          “(4) REGULATION FOR PREMARKET AND AB-  
19          BREVIATED PREMARKET APPLICATIONS.—Not later  
20          than 3 years after the date of enactment of the  
21          VALID Act of 2023, the Secretary shall promulgate  
22          final regulations detailing the information to be pro-  
23          vided in a premarket application and abbreviated  
24          premarket application under this section.

1           “(5) REFUSE TO FILE A PREMARKET OR AB-  
2           BREViated PREMARKET APPLICATION.—The Sec-  
3           retary may refuse to file an application under this  
4           section only for lack of completeness or legibility of  
5           the application. If, after receipt of an application  
6           under this section, the Secretary refuses to file such  
7           an application, the Secretary shall provide to the de-  
8           veloper, within 45 calendar days of receipt of such  
9           application submitted under this subsection or with-  
10          in 30 calendar days of receipt of an application sub-  
11          mitted under subsection (b), a description of the rea-  
12          son for such refusal, and identify the information re-  
13          quired, if any, to allow for the filing of the applica-  
14          tion.

15           “(6) SUBSTANTIVE REVIEW FOR DEFICIENT AP-  
16          PLICATION.—If, after receipt of an application under  
17          this section, the Secretary determines that any por-  
18          tion of such application is materially deficient, the  
19          Secretary shall provide to the applicant a description  
20          of such material deficiencies and the information re-  
21          quired to resolve such deficiencies.

22           “(7) INSPECTIONS.—With respect to an appli-  
23          cation under paragraph (1), preapproval inspections  
24          authorized by an employee of the Food and Drug  
25          Administration or a person accredited under section

1       587Q need not occur unless requested by the Sec-  
2       retary.

3       “(b) ABBREVIATED PREMARKET REVIEW.—

4               “(1) IN GENERAL.—Any developer may file  
5       with the Secretary an application for abbreviated  
6       premarket approval for—

7                       “(A) an instrument;

8                       “(B) a specimen receptacle;

9                       “(C) an in vitro clinical test that is mod-  
10       erate-risk; or

11                      “(D) an in vitro clinical test that is deter-  
12       mined by the Secretary to be eligible for abbrevi-  
13       ated premarket review under section  
14       587F(a)(1)(B).

15       “(2) APPLICATION CONTENT.—An application  
16       under paragraph (1) shall include—

17                      “(A) the information required for applica-  
18       tions submitted under subsection (a)(3), except  
19       that applications under paragraph (1) need not  
20       include—

21                               “(i) quality requirement information;

22                               or

23                               “(ii) raw data, unless requested in  
24       writing by the Secretary, in accordance  
25       with the least burdensome requirements

1 under section 587AA(c), and with super-  
2 visory review and concurrence prior to  
3 issuance of such request; and

4 “(B) data, as applicable, to support soft-  
5 ware validation, electromagnetic compatibility,  
6 and electrical safety, and information dem-  
7 onstrating compliance with maintaining quality  
8 systems documentation.

9 “(3) SAFETY INFORMATION.—The developer of  
10 an in vitro clinical test specimen receptacle reviewed  
11 under this subsection shall maintain safety informa-  
12 tion for such specimen receptacle.

13 “(4) INSPECTIONS.—With respect to an appli-  
14 cation under paragraph (1), preapproval inspections  
15 shall not be required unless requested in writing by  
16 the Secretary, after supervisory review and concur-  
17 rence, because such inspection is considered nec-  
18 essary to complete the review.

19 “(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—

20 “(1) IN GENERAL.—A developer of an instru-  
21 ment family shall file with the Secretary an applica-  
22 tion for premarket approval of one version of an in-  
23 strument under this subsection. Any modified  
24 versions of the instrument that generate a new in-  
25 strument within the same instrument family shall be

1 exempt from premarket review requirements of this  
2 section, provided that the developer of such instru-  
3 ment or instrument family—

4 “(A) maintains documentation that the  
5 new instrument is part of the instrument fam-  
6 ily, as defined in section 587;

7 “(B) performs, documents, and maintains  
8 a risk assessment (as described in subsection  
9 (a)(3)(B)(iii)) of the new instrument compared  
10 to the instrument approved under subsection  
11 (b) and no new risks are identified;

12 “(C) performs, documents, and maintains  
13 validation and verification activities for the new  
14 instrument;

15 “(D) makes such documentation available  
16 to the Secretary upon request; and

17 “(E) registers and lists the new instrument  
18 in accordance with section 587J.

19 “(2) TEST KITS AND TEST PROTOCOLS.—With  
20 regard to a test kit or test protocol that is approved  
21 under this section for use on an approved instru-  
22 ment or an instrument exempt from premarket re-  
23 view, including an instrument within an instrument  
24 family under this section, a submission under this  
25 section shall not be required for such test kit or test

1 protocol in order for it to be used on a new instru-  
2 ment within its instrument family, provided that—

3 “(A) use of the test kit or test protocol  
4 with the new instrument does not—

5 “(i) change the claims for the test kit  
6 or test protocol, except as applicable,  
7 claims regarding an instrument or instru-  
8 ments that can be used with such test kit  
9 or test protocol;

10 “(ii) adversely affect performance of  
11 the test kit or test protocol; or

12 “(iii) cause the test kit or test pro-  
13 tocol to no longer conform with perform-  
14 ance standards required under section  
15 587R or comply with any applicable miti-  
16 gating measures under section 587E, con-  
17 ditions of approval under subsection  
18 (e)(2)(B), or restrictions under section  
19 587O;

20 “(B) the test developer does not identify  
21 any new risks for the test kit or test protocol  
22 when using the new instrument after con-  
23 ducting a risk assessment;

24 “(C) the test developer validates the use of  
25 the new instrument with the test kit or test

1 protocol and maintains validation documenta-  
2 tion;

3 “(D) the test kit or test protocol is not in-  
4 tended for use—

5 “(i) in settings for which a certificate  
6 of waiver is in effect under section 353 of  
7 the Public Health Service Act;

8 “(ii) without a prescription;

9 “(iii) at home; or

10 “(iv) in testing donors, donations, and  
11 recipients of blood, blood components,  
12 human cells, tissues, cellular-based prod-  
13 ucts, or tissue-based products;

14 “(E) the test developer makes the docu-  
15 mentation described under subparagraph (C)  
16 available to the Secretary upon request; and

17 “(F) the test developer updates the listing  
18 information for the test kit or test protocol, as  
19 applicable.

20 “(d) AMENDMENTS TO AN APPLICATION.—An appli-  
21 cant shall amend an application submitted under sub-  
22 section (a), (b), or (f) if the applicant becomes aware of  
23 information that could reasonably affect an evaluation  
24 under subsection (e) of whether the approval standard has  
25 been met.

1           “(e) ACTION ON AN APPLICATION FOR PREMARKET  
2 APPROVAL.—

3           “(1) REVIEW.—

4                   “(A) DISPOSITION.—As promptly as pos-  
5 sible, but not later than 90 calendar days after  
6 an application under subsection (a) is accepted  
7 for submission (unless the Secretary determines  
8 that an extension is necessary to review one or  
9 more major amendments to the application), or  
10 not later than 60 calendar days after an appli-  
11 cation under subsection (b) is accepted for sub-  
12 mission or a supplemental application under  
13 subsection (f) is accepted for submission, the  
14 Secretary, after considering any applicable re-  
15 port and recommendations pursuant to advisory  
16 committees under section 587H, shall issue an  
17 order approving the application, unless the Sec-  
18 retary finds that the grounds for approval in  
19 paragraph (2) are not met.

20                   “(B) RELIANCE ON PROPOSED LABEL-  
21 ING.—In determining whether to approve or  
22 deny an application under paragraph (1), the  
23 Secretary shall rely on the indications for use  
24 included in the proposed labeling, provided that



1 such labeling is not false or misleading based on  
2 a fair evaluation of all material facts.

3 “(2) APPROVAL OF AN APPLICATION.—

4 “(A) IN GENERAL.—The Secretary shall  
5 approve an application submitted under sub-  
6 section (a) or (b) with respect to an in vitro  
7 clinical test if the Secretary finds that the ap-  
8 plicable standard is met, and—

9 “(i) the applicant is in compliance  
10 with applicable quality requirements in sec-  
11 tion 587K;

12 “(ii) the application does not contain  
13 a false statement or misrepresentation of  
14 material fact;

15 “(iii) based on a fair evaluation of all  
16 material facts, the proposed labeling is  
17 truthful and non-misleading and complies  
18 with the requirements of section 587L;

19 “(iv) the applicant permits, if re-  
20 quested, authorized employees of the Food  
21 and Drug Administration and persons ac-  
22 credited under section 587Q an oppor-  
23 tunity to inspect pursuant to section 704;

24 “(v) the test conforms with any appli-  
25 cable performance standards required

1 under section 587R and any applicable  
2 mitigating measures under section 587E;

3 “(vi) all nonclinical laboratory studies  
4 and clinical investigations involving human  
5 subjects that are described in the applica-  
6 tion were conducted in a manner that  
7 meets the applicable requirements of this  
8 subchapter; and

9 “(vii) other data and information the  
10 Secretary may require under subsection  
11 (a)(3)(J) support approval.

12 “(B) CONDITIONS OF APPROVAL.—An  
13 order approving an application pursuant to this  
14 section may require reasonable conditions of ap-  
15 proval for the in vitro clinical test, which may  
16 include conformance with applicable mitigating  
17 measures under section 587E, restrictions  
18 under section 587O, and performance standards  
19 under section 587R.

20 “(C) PUBLICATION.—The Secretary shall  
21 publish an order for each application approved  
22 pursuant to this paragraph on the public  
23 website of the Food and Drug Administration  
24 and make publicly available a summary of the  
25 data used to approve such application. In mak-

1           ing the order and summary publicly available,  
2           the Secretary shall not disclose any information  
3           that—

4                   “(i) is confidential commercial infor-  
5                   mation or trade secret information subject  
6                   to section 552(b)(4) of title 5, United  
7                   States Code, or section 1905 of title 18,  
8                   United States Code; or

9                   “(ii) could compromise national secu-  
10                  rity.

11           “(3) REVIEW OF DENIALS.—An applicant  
12           whose application submitted under this section has  
13           been denied approval under this subsection may, by  
14           petition filed not more than 60 calendar days after  
15           the date on which the applicant receives notice of  
16           such denial, obtain review of the denial in accord-  
17           ance with section 587P.

18           “(f) SUPPLEMENTS TO AN APPROVED APPLICA-  
19           TION.—

20                   “(1) RISK ANALYSIS.—Prior to implementing  
21                   any modification to an in vitro clinical test, the hold-  
22                   er of the application approved under subsection (e)  
23                   for such test shall perform risk analyses in accord-  
24                   ance with this subsection, unless such modification is  
25                   included in the change protocol submitted by the ap-

1 plicant and approved under this section or exempt  
2 under section 587C.

3 “(2) SUPPLEMENT REQUIREMENT.—

4 “(A) IN GENERAL.—If the holder of an ap-  
5 plication of an approved in vitro clinical test  
6 makes a modification to such in vitro clinical  
7 test, except as provided in subparagraph (C), or  
8 otherwise specified by the Secretary, the holder  
9 of the application approved under subsection (e)  
10 for an in vitro clinical test shall submit a sup-  
11 plemental application to the Secretary. The  
12 holder of the application may not implement  
13 such modification to the in vitro clinical test  
14 until such supplemental application is approved.  
15 The information required in a supplemental ap-  
16 plication is limited to what is needed to support  
17 the change.

18 “(B) CHANGE PROTOCOLS.—The holder of  
19 an approved application may submit under this  
20 paragraph a supplemental application to modify  
21 the change protocol for a test or to request a  
22 change protocol for a test.

23 “(C) EXCEPTIONS.—Notwithstanding sub-  
24 paragraphs (A) and (B), and so long as the  
25 holder of an approved application submitted

1 under subsection (a) or (b) for an in vitro clin-  
2 ical test does not add a manufacturing site, or  
3 change activities at an existing manufacturing  
4 site, with respect to the test, the holder of an  
5 approved application may, without submission  
6 of a supplemental application, implement the  
7 following modifications to the test:

8 “(i) Modifications in accordance with  
9 an approved change protocol under sub-  
10 section (a)(3)(H).

11 “(ii) Modifications that are exempt  
12 under section 587C(a)(6).

13 “(iii) Labeling changes that are ap-  
14 propriate to address a safety concern, ex-  
15 cept such labeling changes that include any  
16 of the following remain subject to subpara-  
17 graph (A):

18 “(I) A change to the indications  
19 for use of the test.

20 “(II) A change to the perform-  
21 ance claims made with respect to the  
22 test.

23 “(III) A change that adversely  
24 affects performance of the test.

1                   “(D) REPORTING FOR CERTAIN MODIFICA-  
2                   TIONS MADE PURSUANT TO A CHANGE PRO-  
3                   TOCOL.—The holder of an application approved  
4                   under subsection (e), with an approved change  
5                   protocol under subsection (a)(2)(H) for such in  
6                   vitro clinical test shall—

7                   “(i) report any modification to such  
8                   test made pursuant to such change pro-  
9                   tocol approved under subsection (a)(3)(H)  
10                  in a submission under section  
11                  587J(c)(2)(B); and

12                  “(ii) include in such report—

13                         “(I) a description of the modi-  
14                         fication;

15                         “(II) the rationale for imple-  
16                         menting such modification; and

17                         “(III) as applicable, a summary  
18                         of the evidence supporting that the  
19                         test, as modified, meets the applicable  
20                         standard, complies with performance  
21                         standards required under section  
22                         587Q, and complies with any miti-  
23                         gating measures established under  
24                         section 587E and any restrictions  
25                         under section 587O.

1           “(E) REPORTING FOR CERTAIN SAFETY  
2 RELATED LABELING CHANGES.—The holder of  
3 the application for an in vitro clinical test ap-  
4 proved under subsection (e) shall—

5           “(i) report to the Secretary any modi-  
6 fication to the test described in subpara-  
7 graph (C)(iii) not more than 30 days after  
8 the date on which the test, with the modi-  
9 fication, is introduced into interstate com-  
10 merce; and

11           “(ii) include in the report—

12           “(I) a description of the change  
13 or changes;

14           “(II) the rationale for imple-  
15 menting such change or changes; and

16           “(III) a description of how the  
17 change or changes were evaluated.

18           “(3) CONTENTS OF SUPPLEMENT.—Unless oth-  
19 erwise specified by the Secretary, a supplement  
20 under this subsection shall include—

21           “(A) for modifications other than manufac-  
22 turing site changes requiring a supplement—

23           “(i) a description of the modification;

24           “(ii) data relevant to the modification  
25 to demonstrate that the applicable stand-

1           ard is met, not to exceed data require-  
2           ments for the original submission;

3                   “(iii) acceptance criteria; and

4                   “(iv) any revised labeling; and

5           “(B) for manufacturing site changes—

6                   “(i) the information listed in subpara-  
7           graph (A); and

8                   “(ii) information regarding the meth-  
9           ods used in, or the facilities or controls  
10          used for, the development of the test to  
11          demonstrate compliance with the applicable  
12          quality requirements under section 587K.

13           “(4) ADDITIONAL DATA.—The Secretary may  
14          require, when necessary, data to evaluate a modifica-  
15          tion to an in vitro clinical test that is in addition to  
16          the data otherwise required under the preceding  
17          paragraphs if the data request is in accordance with  
18          the least burdensome requirements under section  
19          587AA(c).

20           “(5) CONDITIONS OF APPROVAL.—In an order  
21          approving a supplement under this subsection, the  
22          Secretary may require conditions of approval for the  
23          in vitro clinical test, including compliance with re-  
24          strictions under section 587O and conformance to  
25          performance standards under section 587R.



1           “(6) APPROVAL.—The Secretary shall approve  
2 a supplement under this subsection if—

3           “(A) the data demonstrate that the modi-  
4 fied in vitro clinical test meets the applicable  
5 standard; and

6           “(B) the holder of the application approved  
7 under subsection (e) for the test has dem-  
8 onstrated compliance with applicable quality  
9 and inspection requirements, as applicable and  
10 appropriate.

11          “(7) PUBLICATION.—The Secretary shall pub-  
12 lish on the public website of the Food and Drug Ad-  
13 ministration notice of any order approving a supple-  
14 ment under this subsection provided that doing so  
15 does not disclose any information that—

16           “(A) is trade secret or confidential com-  
17 mercial or financial information; or

18           “(B) could compromise national security.

19          “(8) REVIEW OF DENIAL.—An applicant whose  
20 supplement under this subsection has been denied  
21 approval may, by petition filed on or before the 60th  
22 calendar day after the date upon which the applicant  
23 receives notice of such denial, obtain review of the  
24 denial in accordance with section 587P.

1           “(g) WITHDRAWAL AND TEMPORARY SUSPENSION  
2 OF APPROVAL.—

3           “(1) ORDER WITHDRAWING APPROVAL.—

4                   “(A) IN GENERAL.—The Secretary may,  
5 after providing due notice and an opportunity  
6 for an informal hearing to the holder of an ap-  
7 proved application for an in vitro clinical test  
8 under this section, issue an order withdrawing  
9 approval of the application if the Secretary  
10 finds that—

11                           “(i) the grounds for approval under  
12 subsection (e) are no longer met;

13                           “(ii) there is a reasonable likelihood  
14 that the test would cause death or serious  
15 adverse health consequences, including by  
16 causing the absence, significant delay, or  
17 discontinuation of life-saving or life sus-  
18 taining medical treatment;

19                           “(iii) the holder of the approved appli-  
20 cation—

21                                   “(I) has failed to, or repeatedly  
22 or deliberately failed to, maintain  
23 records to make reports, as required  
24 under section 587M;

1                   “(II) has refused to permit ac-  
2                   cess to, or copying or verification of  
3                   such records, as required under sec-  
4                   tion 704;

5                   “(III) has not complied with the  
6                   requirements of section 587K; or

7                   “(IV) has not complied with any  
8                   mitigating measure required under  
9                   section 587E or restriction under sec-  
10                  tion 587O; or

11                  “(iv) the labeling of such in vitro clin-  
12                  ical test, based on a fair evaluation of all  
13                  material facts, is false or misleading in any  
14                  particular and was not corrected within a  
15                  reasonable time after receipt of written no-  
16                  tice from the Secretary of such fact.

17                  “(B) CONTENT.—An order under subpara-  
18                  graph (A) withdrawing approval of an applica-  
19                  tion shall state each ground for withdrawal and  
20                  shall notify the holder of such application 60  
21                  calendar days prior to issuing such order.

22                  “(C) PUBLICATION.—The Secretary shall  
23                  publish any order under subparagraph (A) on  
24                  the public website of the Food and Drug Ad-

1           ministration provided that doing so does not  
2           disclose—

3                   “(i) any information that is trade se-  
4                   cret or confidential commercial or financial  
5                   information; or

6                   “(ii) any other information that the  
7                   Secretary determines, if published, could  
8                   compromise national security.

9           “(2) ORDER OF TEMPORARY SUSPENSION.—If,  
10          after providing due notice and an opportunity for an  
11          informal hearing to the holder of an approved appli-  
12          cation for an in vitro clinical test under this section,  
13          the Secretary determines, based on scientific evi-  
14          dence, that there is a reasonable likelihood that the  
15          in vitro clinical test would cause death or serious ad-  
16          verse health consequences, such as by causing the  
17          absence, significant delay, or discontinuation of life-  
18          saving or life-sustaining medical treatment, the Sec-  
19          retary shall, by order, temporarily suspend the ap-  
20          proval of the application. If the Secretary issues  
21          such an order, the Secretary shall proceed expedi-  
22          tiously under paragraph (1) to withdraw approval of  
23          such application.

24                   “(3) APPEAL WITHDRAWING APPROVAL AND  
25          ORDERS OF TEMPORARY SUSPENSIONS.—An order of

1 withdrawal or an order of temporary suspension may  
2 be appealed under 587P.

3 **“SEC. 587C. EXEMPTIONS.**

4 “(a) IN GENERAL.—The following in vitro clinical  
5 tests are exempt from premarket review under section  
6 587B, and may be lawfully offered subject to other appli-  
7 cable requirements of this Act:

8 “(1) TESTS EXEMPT FROM SECTION 510(k).—

9 “(A) EXEMPTION.—An in vitro clinical  
10 test is exempt from premarket review under  
11 section 587B and may be lawfully offered sub-  
12 ject to the other applicable requirements of this  
13 Act, if the developer of the in vitro clinical  
14 test—

15 “(i) maintains documentation dem-  
16 onstrating that the test meets and con-  
17 tinues to meet the criteria set forth in sub-  
18 paragraph (B); and

19 “(ii) makes such documentation avail-  
20 able to the Secretary upon request.

21 “(B) CRITERIA FOR EXEMPTION.—An in  
22 vitro clinical test is exempt as specified in sub-  
23 paragraph (A) if such test—

1           “(i)(I)(aa) was offered for clinical use  
2 prior to the date of enactment of the  
3 VALID Act of 2023; and

4           “(bb) immediately prior to such date  
5 of enactment was exempt pursuant to sub-  
6 section (l) or (m)(2) of section 510 from  
7 the requirements for submission of a re-  
8 port under section 510(k); or

9           “(II)(aa) was not offered for clinical  
10 use prior to such date of enactment;

11           “(bb) is not an instrument; and

12           “(cc) falls within a category of tests  
13 that was exempt from the requirements for  
14 submission of a report under section  
15 510(k) as of such date of enactment (in-  
16 cluding class II devices and excluding class  
17 I devices described in section 510(l));

18           “(ii) meets the applicable standard as  
19 described in section 587(2);

20           “(iii) is not offered with labeling and  
21 advertising that is false or misleading; and

22           “(iv) is not likely to cause or con-  
23 tribute to serious adverse health con-  
24 sequences.

1           “(C) EFFECT ON SPECIAL CONTROLS.—  
2           For any in vitro clinical test, or category of in  
3           vitro clinical tests, that is exempt from pre-  
4           market review based on the criteria in subpara-  
5           graph (B), any special control that applied to a  
6           device within a predecessor category imme-  
7           diately prior to the date of enactment of the  
8           VALID Act of 2023 shall be deemed a miti-  
9           gating measure applicable under section 587E  
10          to an in vitro clinical test within the successor  
11          category, except to the extent such mitigating  
12          measure is withdrawn or changed in accordance  
13          with section 587E.

14          “(D) NEAR-PATIENT TESTING.—Not later  
15          than 1 year after the date of enactment of the  
16          VALID Act of 2023, the Secretary shall issue  
17          draft guidance indicating categories of tests  
18          that shall be exempt from premarket review  
19          under section 587B when offered for near-pa-  
20          tient testing (point of care), which were not ex-  
21          empt from submission of a report under section  
22          510(k) pursuant to subsection (l) or (m)(2) of  
23          section 510 and regulations imposing limita-  
24          tions on exemption for in vitro devices intended  
25          for near-patient testing (point of care).

1           “(2) LOW-RISK TESTS.—

2           “(A) EXEMPTION.—An in vitro clinical  
3 test is exempt from premarket review under  
4 section 587B and may be lawfully offered sub-  
5 ject to the other applicable requirements of this  
6 Act, including section 587J(b), if such test  
7 meets the definition of low-risk under section  
8 587 and if the developer of the test—

9           “(i) maintains documentation dem-  
10 onstrating that the in vitro clinical test  
11 meets and continues to meet the criteria  
12 set forth in subparagraph (B); and

13           “(ii) makes such documentation avail-  
14 able to the Secretary upon request.

15           “(B) CRITERIA FOR EXEMPTION.—An in  
16 vitro clinical test is exempt as specified in sub-  
17 paragraph (A) if—

18           “(i) the in vitro clinical test meets the  
19 applicable standard as described in 587(2);

20           “(ii) the labeling and advertising are  
21 not false or misleading;

22           “(iii) the in vitro clinical test is not  
23 likely to cause or contribute to serious ad-  
24 verse health consequences; and



1 “(iv) the in vitro clinical test falls  
2 within a category of tests listed as de-  
3 scribed in subparagraph (C).

4 “(C) LIST OF LOW-RISK TESTS.—

5 “(i) IN GENERAL.—The Secretary  
6 shall maintain, and make publicly available  
7 on the website of the Food and Drug Ad-  
8 ministration, a list of in vitro clinical tests,  
9 and categories of in vitro clinical tests,  
10 that are low-risk in vitro clinical tests for  
11 purposes of the exemption under this para-  
12 graph.

13 “(ii) INCLUSION.—The list under  
14 clause (i) shall consist of—

15 “(I) all in vitro clinical tests and  
16 categories of in vitro clinical tests that  
17 are exempt from premarket review  
18 pursuant to paragraph (1) or this  
19 paragraph; and

20 “(II) all in vitro clinical tests and  
21 categories of in vitro clinical tests that  
22 are designated by the Secretary pur-  
23 suant to subparagraph (D) as low-risk  
24 for purposes of this paragraph.

1           “(D) DESIGNATION OF TESTS AND CAT-  
2           EGORIES.—Without regard to subchapter II of  
3           chapter 5 of title 5, United States Code, the  
4           Secretary may designate, in addition to the  
5           tests and categories described in subparagraph  
6           (C)(i), additional in vitro clinical tests, and cat-  
7           egories of in vitro clinical tests, as low-risk in  
8           vitro clinical tests for purposes of the exemption  
9           under this paragraph. The Secretary may make  
10          such a designation on the Secretary’s own ini-  
11          tiative or in response to a request by a devel-  
12          oper pursuant to subsection (a) or (b) of section  
13          587F. In making such a designation for a test  
14          or category of tests, the Secretary shall con-  
15          sider—

16                   “(i) whether the test, or category of  
17                   tests, is low-risk;

18                   “(ii) the existence of and ability to de-  
19                   velop mitigating measures sufficient for  
20                   such test category to meet the low-risk  
21                   standard; and

22                   “(iii) such other factors as the Sec-  
23                   retary determines to be appropriate for the  
24                   protection of the public health.

25          “(3) HUMANITARIAN TEST EXEMPTION.—

1           “(A) IN GENERAL.—An in vitro clinical  
2 test that meets the criteria under subparagraph  
3 (B) is exempt from premarket review under sec-  
4 tion 587B and may be lawfully offered subject  
5 to the other applicable requirements of this sub-  
6 chapter, if the developer of the test—

7           “(i) maintains documentation (which  
8 may include literature citations in special-  
9 ized medical journals, textbooks, special-  
10 ized medical society proceedings, and gov-  
11 ernmental statistics publications, or, if no  
12 such studies or literature citations exist,  
13 credible conclusions from appropriate re-  
14 search or surveys) demonstrating that such  
15 test meets and continues to meet the cri-  
16 teria described in this subsection; and

17           “(ii) makes such documentation avail-  
18 able to the Secretary upon request.

19           “(B) CRITERIA FOR EXEMPTION.—An in  
20 vitro clinical test is exempt as described in sub-  
21 paragraph (A) if—

22           “(i) the in vitro clinical test is in-  
23 tended by the developer for use for a diag-  
24 nostic purpose for—

1                   “(I) a noncontagious disease or  
2                   condition that affects not more than  
3                   10,000 (or such other higher number  
4                   determined by the Secretary) individ-  
5                   uals in the United States per year; or

6                   “(II) a contagious disease or con-  
7                   dition that affects not more than  
8                   1,500 individuals in the United States  
9                   per year;

10                  “(ii) the in vitro clinical test meets  
11                  the applicable standard described in sec-  
12                  tion 587(2);

13                  “(iii) the labeling and advertising for  
14                  the in vitro clinical test are not false or  
15                  misleading;

16                  “(iv) the in vitro clinical test is not  
17                  likely to cause or contribute to serious ad-  
18                  verse health consequences; and

19                  “(v) the in vitro clinical test is not in-  
20                  tended for screening.

21                  “(C) EXCEPTION FOR CERTAIN TESTS.—

22                  An in vitro clinical test intended to inform the  
23                  use of a specific individual or specific type of bi-  
24                  ological product, drug, or device shall be eligible  
25                  for an exemption from premarket review under

1           this subsection only if, the developer submits a  
2           request under section 587F(e) for informal  
3           feedback and the Secretary determines that  
4           such in vitro clinical test is eligible for an ex-  
5           emption from premarket review under this sub-  
6           section.

7           “(4) CUSTOM TESTS AND LOW-VOLUME  
8           TESTS.—An in vitro clinical test is exempt from pre-  
9           market review under section 587B, quality require-  
10          ments under section 587K, and listing requirements  
11          under section 587J, and may be lawfully offered  
12          subject to the other applicable requirements of this  
13          Act, if—

14                 “(A) such in vitro clinical test—

15                         “(i) is a test protocol performed for  
16                         not more than 5 patients per year (or such  
17                         other higher number determined by the  
18                         Secretary), in a laboratory certified by the  
19                         Secretary under section 353 of the Public  
20                         Health Service Act that—

21                                 “(I) meets the requirements to  
22                                 perform tests of high-complexity in  
23                                 which the test protocol was developed;  
24                                 or

1                   “(II) meets the requirements to  
2                   perform tests of high-complexity with-  
3                   in the same corporate organization  
4                   and having common ownership by the  
5                   same parent corporation as the lab-  
6                   oratory in which such test protocol  
7                   was developed; or

8                   “(ii) is an in vitro clinical test devel-  
9                   oped to diagnose a unique pathology or  
10                  physical condition of a specific patient or  
11                  patients (including an in vitro clinical test  
12                  modified for such purpose), upon the pre-  
13                  scription or order of a health care practi-  
14                  tioner licensed to prescribe or order such  
15                  test, or a health care professional or other  
16                  specially qualified person designated under  
17                  regulations to prescribe or order such test,  
18                  for which no other in vitro clinical test is  
19                  commercially available in the United  
20                  States, and is—

21                   “(I) not intended for use with re-  
22                   spect to more than 5 (or such other  
23                   higher number determined by the Sec-  
24                   retary) other patients; and

1 “(II) not included in any test  
2 menu or template test report or other  
3 promotional materials, and is not oth-  
4 erwise advertised; and

5 “(B) the developer of the in vitro clinical  
6 test—

7 “(i) maintains documentation dem-  
8 onstrating that such test meets the appli-  
9 cable criteria described in subparagraph  
10 (A);

11 “(ii) makes such documentation, such  
12 as a prescription order requesting the cus-  
13 tom test for an individual patient, available  
14 to the Secretary upon request; and

15 “(iii) informs the Secretary, on an an-  
16 nual basis, in a manner prescribed by the  
17 Secretary by guidance, that such test was  
18 offered.

19 “(5) IN VITRO CLINICAL TESTS UNDER A TECH-  
20 NOLOGY CERTIFICATION ORDER.—An in vitro clin-  
21 ical test that is within the scope of a technology cer-  
22 tification order under section 587D is exempt from  
23 premarket review under section 587B.

24 “(6) MODIFIED TESTS.—

1           “(A) IN GENERAL.—An in vitro clinical  
2 test that is modified is exempt from premarket  
3 review under section 587B if—

4                   “(i) the modification is made by—

5                           “(I) the developer that obtained  
6 premarket approval for the unmodi-  
7 fied version of the test under section  
8 587B; or

9                           “(II) a clinical laboratory cer-  
10 tified by the Secretary under section  
11 353 of the Public Health Service Act  
12 that meets the requirements for per-  
13 forming high complexity testing, to a  
14 lawfully offered in vitro clinical test,  
15 including another developer’s lawfully  
16 offered in vitro clinical test, excluding  
17 investigational in vitro clinical tests  
18 offered under section 587S, and the  
19 modified test is performed—

20                           “(aa) in the same clinical  
21 laboratory in which it was devel-  
22 oped for which a certification is  
23 still in effect under section 353  
24 that meets the requirements to  
25 perform tests of high complexity;



1           “(bb) by another clinical lab-  
2           oratory for which a certificate is  
3           in effect under section 353 that  
4           meets the requirements to per-  
5           form tests of high complexity, is  
6           within the same corporate organi-  
7           zation, and has common owner-  
8           ship by the same parent corpora-  
9           tion as the laboratory in which  
10          the test was developed; or

11          “(cc) by a clinical laboratory  
12          for which a certificate is in effect  
13          under section 353 that meets the  
14          requirements to perform tests of  
15          high complexity and is within a  
16          public health laboratory network  
17          coordinated or managed by the  
18          Centers for Disease Control and  
19          Prevention, if the test was devel-  
20          oped by the Centers for Disease  
21          Control and Prevention or an-  
22          other laboratory within such pub-  
23          lic health laboratory network;

24          “(ii) the modification does not—

1           “(I) constitute a significant  
2 change to the indications for use, ex-  
3 cept for changes to a specimen type,  
4 as specified in the guidance issued  
5 under subparagraph (E);

6           “(II) cause the test to no longer  
7 comply with applicable mitigating  
8 measures under section 587E or re-  
9 strictions under section 587O;

10           “(III) significantly change per-  
11 formance claims or significantly and  
12 adversely change performance, unless  
13 provided for under an approved  
14 change protocol under section  
15 587B(a)(3)(H); or

16           “(IV) constitute an adverse  
17 change in the safety of the in vitro  
18 clinical test for individuals who come  
19 in contact with the in vitro clinical  
20 test;

21           “(iii) the test meets the applicable  
22 standard as described in section 587(2);

23           “(iv) the labeling and advertising are  
24 not false or misleading; and

1                   “(v) the test is not likely to cause or  
2                   contribute to serious adverse health con-  
3                   sequences.

4                   “(B) CERTAIN MODIFICATIONS.—A modi-  
5                   fication to extend specimen stability is exempt  
6                   from premarket review under section 587B if  
7                   the modified test meets the requirements in  
8                   clauses (ii) through (v) of subparagraph (A).

9                   “(C) MODIFICATIONS UNDER A CHANGE  
10                  PROTOCOL.—Notwithstanding       subparagraph  
11                  (A), a modification made under a change pro-  
12                  tocol pursuant to subsection (a)(2)(H) of sec-  
13                  tion 587B is exempt from review under such  
14                  section.

15                  “(D) DOCUMENTATION.—A person who  
16                  modifies an in vitro clinical test in a manner  
17                  that is a modification described in this para-  
18                  graph shall—

19                       “(i) document the modification that  
20                       was made and the basis for determining  
21                       that the modification, considering the  
22                       changes individually and collectively, is a  
23                       type of modification described in subpara-  
24                       graph (A), (B), or (C); and

1                   “(ii) provide such documentation to  
2                   the Secretary upon request or inspection.

3                   “(E) GUIDANCE.—Not later than 30  
4                   months after the date of enactment of the  
5                   VALID Act of 2023, the Secretary shall issue  
6                   guidance regarding the in vitro clinical tests  
7                   that are modified and exempt from premarket  
8                   review under section 587B pursuant to this  
9                   paragraph. Such guidance shall include consid-  
10                  erations for changes to a specimen type that  
11                  may be made by a developer without the re-  
12                  quirement of premarket review under 587B.

13                  “(b) MANUAL TESTS.—

14                  “(1) EXEMPTION.—An in vitro clinical test is  
15                  exempt from all requirements of this subchapter if  
16                  the output of such in vitro clinical test is the result  
17                  of direct, manual observation, without the use of  
18                  automated instrumentation or software for inter-  
19                  mediate or final interpretation, by a qualified labora-  
20                  tory professional, and such in vitro clinical test—

21                  “(A) is developed and used within a single  
22                  clinical laboratory for which a certificate is in  
23                  effect under section 353 of the Public Health  
24                  Service Act that meets the requirements under

1 section 353 for performing high-complexity test-  
2 ing;

3 “(B) is not a specimen receptacle, instru-  
4 ment, or an in vitro clinical test that includes  
5 an instrument or specimen receptacle that is  
6 not approved under or exempt from section  
7 587B;

8 “(C) is not a high-risk test, or is a high-  
9 risk test that the Secretary has determined  
10 meets at least one condition in paragraph (2)  
11 and is otherwise appropriate for this exemption;  
12 and

13 “(D) is not intended for testing donors,  
14 donations, or recipients of blood, blood compo-  
15 nents, human cells, tissues, cellular-based prod-  
16 ucts, or tissue-based products.

17 “(2) HIGH-RISK TEST LIMITATION OR CONDI-  
18 TION.—A high-risk test may be exempt under para-  
19 graph (1) from the requirements of this subchapter  
20 only if—

21 “(A) no components or parts of such test,  
22 including any reagent, is introduced into inter-  
23 state commerce under the exemption under sub-  
24 section (e), and any article for taking or deriv-  
25 ing specimens from the human body used in

1 conjunction with the test remains subject to the  
2 requirements of this subchapter; or

3 “(B) the test has been developed in accord-  
4 ance with the applicable test design and quality  
5 requirements under section 587K.

6 “(c) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

7 “(1) IN GENERAL.—The provisions of this sub-  
8 chapter shall not apply to a test intended by the de-  
9 veloper to be used solely for public health surveil-  
10 lance activities.

11 “(2) EXCLUSION.—An in vitro clinical test used  
12 for public health surveillance activities is not ex-  
13 cluded from the provisions of this subchapter pursu-  
14 ant to this subsection if such test is intended for use  
15 in making clinical decisions for individual patients.

16 “(d) GENERAL LABORATORY EQUIPMENT.—As set  
17 forth in section 201(ss)(3)(C), general purposes laboratory  
18 equipment is not an in vitro clinical tests and is not sub-  
19 ject to the requirements of this subchapter.

20 “(e) COMPONENTS AND PARTS.—

21 “(1) IN GENERAL.—Subject to paragraph (2), a  
22 component or part described in section  
23 201(ss)(2)(G) is—

1           “(A) exempt from the requirements of this  
2           subchapter if it is intended for further develop-  
3           ment as described in paragraph (3); or

4           “(B) subject to the requirements of this  
5           subchapter and regulated based on its risk  
6           when used as intended by the developer, not-  
7           withstanding its subsequent use by a developer  
8           as a component, part, or raw material of an-  
9           other in vitro clinical test.

10          “(2) INAPPLICABILITY TO OTHER TESTS.—Not-  
11          withstanding paragraph (1), an in vitro clinical test  
12          that is described in section 201(ss)(1)(B) and that  
13          uses a component or part described in such subpara-  
14          graph shall be subject to the requirements of this  
15          subchapter, unless the test is otherwise exempt  
16          under this section.

17          “(3) FURTHER DEVELOPMENT.—A component,  
18          part, or raw material (as described in paragraph  
19          (1)) is intended for further development (for pur-  
20          poses of such paragraph) if—

21                 “(A) it is intended solely for use in the de-  
22                 velopment of another in vitro clinical test; and

23                 “(B) in the case of such a test that is in-  
24                 troduced or delivered for introduction into  
25                 interstate commerce after the date of enactment

1 of the VALID Act of 2023, the labeling of such  
2 test bears the following statement: ‘This prod-  
3 uct is intended solely for further development of  
4 an in vitro clinical test and is exempt from  
5 FDA regulation. This product must be evalu-  
6 ated by the in vitro clinical test developer if it  
7 is used with or in the development of an in vitro  
8 clinical test.’.

9 “(f) GENERAL EXEMPTION AUTHORITY.—The Sec-  
10 retary may, by order published in the Federal Register  
11 following notice and an opportunity for comment, exempt  
12 a class of persons from any section under this subchapter  
13 upon a finding that such exemption is appropriate for the  
14 protection of the public health and other relevant consider-  
15 ations.

16 “(g) OTHER EXEMPTIONS.—An in vitro clinical test  
17 that is intended solely for use in forensic analysis or law  
18 enforcement activity is exempt from the requirements of  
19 this subchapter. An in vitro clinical test that is intended  
20 for use in making clinical decisions for individual patients,  
21 or whose individually identifiable results may be reported  
22 back to an individual patient or the patient’s health care  
23 provider, even if also intended for forensic analysis or law  
24 enforcement purposes, is not intended solely for forensic



1 analysis or law enforcement for purposes of this sub-  
2 section.

3 “(h) REVOCATION.—

4 “(1) IN GENERAL.—The Secretary may revoke  
5 any exemption under this section with respect to in  
6 vitro clinical tests with the same indications for use  
7 if new clinical information indicates that the exemp-  
8 tion of an in vitro clinical test or tests from pre-  
9 market review under section 587B has a reasonable  
10 probability of severe adverse health consequences, in-  
11 cluding the absence, delay, or discontinuation of ap-  
12 propriate medical treatment.

13 “(2) PROCESS.—Any action under paragraph  
14 (1) shall be made by publication of a notice of such  
15 proposed action on the website of the Food and  
16 Drug Administration, the consideration of comments  
17 to a public docket on such proposal, and publication  
18 of a final action on such website within 60 calendar  
19 days of the close of the comment period posted to  
20 such public docket, notwithstanding subchapter II of  
21 chapter 5 of title 5, United States Code.

22 “(i) PRE-ANALYTICAL INSTRUMENT.—A pre-analyt-  
23 ical instrument is exempt from premarket review under  
24 section 587B and may be lawfully offered subject to the

1 other applicable requirements of this Act, if either of the  
2 following applies:

3           “(1) Such instrument provides additional infor-  
4 mation regarding the sample or performs an action  
5 on the sample but is not preparing or processing the  
6 sample and does not perform any function of an an-  
7 alytical instrument. Such types of pre-analytical in-  
8 struments include barcode readers, sample movers,  
9 and sample identifiers.

10           “(2) Such instrument processes or prepares the  
11 sample prior to use on an analytical instrument,  
12 does not perform any function of an analytical in-  
13 strument, and does not select, isolate, or prepare a  
14 part of a sample based on specific properties. Such  
15 types of pre-analytical instruments may include sam-  
16 ple mixers, DNA extractors and those used to dilute  
17 samples.

18 **“SEC. 587D. TECHNOLOGY CERTIFICATION.**

19           “(a) DEFINITIONS.—In this section:

20           “(1) ELIGIBLE IN VITRO CLINICAL TEST.—The  
21 term ‘eligible in vitro clinical test’ means an in vitro  
22 clinical test that is not—

23           “(A) a component or part of an in vitro  
24 clinical test as described in section  
25 201(ss)(2)(G) unless it is a component or part

1 and is regulated based on its own risk under  
2 section 587C(e)(1)(B) or as part of an other-  
3 wise eligible in vitro clinical test;

4 “(B) an instrument under section  
5 201(ss)(2)(D) or an in vitro clinical test that  
6 includes an instrument that is subject to section  
7 587B, but is not approved under, or exempt  
8 from, section 587B;

9 “(C) a specimen receptacle under section  
10 201(ss)(2)(E) or an in vitro clinical test that  
11 includes a specimen receptacle that is subject to  
12 section 587B, but is not approved under, or ex-  
13 empt from, section 587B;

14 “(D) an in vitro clinical test, including re-  
15 agents used in such tests, intended for use for  
16 testing donors, donations, and recipients of  
17 blood, blood components, human cells, tissues,  
18 cellular-based products, or tissue-based prod-  
19 ucts;

20 “(E) high-risk;

21 “(F) a combination product, unless such  
22 test has been determined to be eligible to be in-  
23 troduced into interstate commerce under a tech-  
24 nology certification order pursuant to the regu-  
25 latory pathway designation process described in

1 section 587F, or as described in subsection (k),  
2 and the drug or biological product constituent  
3 part complies with the requirements of section  
4 503(g) applicable to the drug or biological prod-  
5 uct; or

6 “(G) a first-of-a-kind in vitro clinical test,  
7 unless such test has been determined to be eli-  
8 gible to be introduced into interstate commerce  
9 under a technology certification order pursuant  
10 to the regulatory pathway designation process  
11 described in section 587F, or as described in  
12 subsection (k).

13 “(2) ELIGIBLE PERSON.—The term ‘eligible  
14 person’ means an in vitro clinical test developer un-  
15 less such developer—

16 “(A) is a laboratory subject to section 353  
17 of the Public Health Service Act and does not  
18 have in effect a certificate applicable to the cat-  
19 egory of laboratory examination or other proce-  
20 dure;

21 “(B) was a laboratory, or an owner or op-  
22 erator or any employee of a laboratory, found  
23 to have committed a significant violation of sec-  
24 tion 353 of the Public Health Service Act that  
25 resulted in a suspended, revoked, or limited cer-

1           tificate within the 2-year period preceding the  
2           date of the submission of the application for a  
3           technology certificate under subsection (c) and  
4           such violation has not been resolved; or

5           “(C) has been found to have submitted in-  
6           formation to the Secretary, or otherwise dis-  
7           seminated information, that—

8           “(i) made false or misleading state-  
9           ments relevant to the requirements of this  
10          subchapter; or

11          “(ii) violated any requirement of this  
12          Act, where such violation exposed individ-  
13          uals to serious risk of illness, injury, or  
14          death, unless—

15          “(I) such violation has been re-  
16          solved; or

17          “(II) such violation is not perti-  
18          nent to any in vitro clinical test within  
19          the scope of the technology certifi-  
20          cation that such developer seeks.

21          “(b) APPLICABILITY.—

22          “(1) IN GENERAL.—An in vitro clinical test is  
23          not subject to section 587B and may be introduced  
24          into interstate commerce if the in vitro clinical  
25          test—

1 “(A) is an eligible in vitro clinical test;

2 “(B) is developed by an eligible person;

3 “(C) falls within the scope of a technology  
4 certification order issued under this section and  
5 that is in effect;

6 “(D) complies with the conditions of the  
7 technology certification order, including with  
8 applicable mitigating measures under section  
9 587E, restrictions under section 587O, and per-  
10 formance standards under section 587R; and

11 “(E) meets the applicable standard de-  
12 scribed in section 587(2).

13 “(2) SCOPE.—

14 “(A) IN GENERAL.—Subject to subpara-  
15 graph (B), the scope of a technology certifi-  
16 cation order issued under this section shall  
17 apply to one or more technologies with multiple  
18 in vitro clinical tests utilizing a technology that  
19 does not significantly differ in control mecha-  
20 nisms, energy sources, or operating principles  
21 and for which development, including design,  
22 and analytical and clinical validation, of the in  
23 vitro clinical tests would be addressed through  
24 similar procedures, and be no broader than—

25 “(i) a single technology type; or

1                   “(ii) a fixed combination of tech-  
2                   nologies.

3                   “(B) TECHNOLOGY TYPE.—A technology  
4                   type described in this paragraph may include  
5                   clot detection, colorimetric (non-immunoassay),  
6                   electrochemical (non-immunoassay), enzymatic  
7                   (non-immunoassay), flow cytometry,  
8                   fluorometry (non-immunoassay), immunoassay,  
9                   mass spectrometry or chromatography, micro-  
10                  bial culture, next generation sequencing,  
11                  nephelometric or turbidimetric (non-  
12                  immunoassay), singleplex or multiplex non-NGS  
13                  nucleic acid analysis, slide-based technology,  
14                  spectroscopy, and any other technology, as the  
15                  Secretary determines appropriate.

16                  “(c) APPLICATION FOR TECHNOLOGY CERTIFI-  
17                  CATION.—

18                  “(1) IN GENERAL.—A developer seeking a tech-  
19                  nology certification order shall submit an application  
20                  under this subsection, which shall contain the infor-  
21                  mation specified under paragraph (2).

22                  “(2) CONTENT OF APPLICATION.—A developer  
23                  that submits an application for a technology certifi-  
24                  cation shall include all necessary information to  
25                  make a showing that all eligible in vitro clinical tests

1 developed within the scope of the technology certifi-  
2 cation order will meet the applicable standard, in-  
3 cluding—

4 “(A) the name and address of the devel-  
5 oper;

6 “(B) a table of contents for the application  
7 and the identification of the information the de-  
8 veloper claims as trade secret or confidential  
9 commercial or financial information;

10 “(C) the signature of the individual filing  
11 the application or an authorized representative;

12 “(D) a statement identifying the scope of  
13 the proposed technology certification intended  
14 to be introduced into interstate commerce under  
15 the application;

16 “(E) information establishing that the de-  
17 veloper submitting the application is an eligible  
18 person;

19 “(F) quality procedures showing that eligi-  
20 ble in vitro clinical tests covered under the tech-  
21 nology certification will conform to the applica-  
22 ble quality requirements of section 587K with  
23 respect to—



1                   “(i) design controls, including related  
2                   purchasing controls and acceptance activi-  
3                   ties;

4                   “(ii) complaint investigation, adverse  
5                   event reporting, and corrections and re-  
6                   movals; and

7                   “(iii) process validation, as applicable;

8                   “(G) procedures for analytical and clinical  
9                   validation, including all procedures for valida-  
10                  tion, verification, and acceptance criteria, and  
11                  an explanation as to how such procedures, when  
12                  used, provide a showing that eligible in vitro  
13                  clinical tests within the proposed scope of the  
14                  technology certification order are analytically  
15                  and clinically valid;

16                  “(H) procedures that provide a showing  
17                  that in vitro clinical tests covered by the pro-  
18                  posed scope of the technology certification order  
19                  will be safe for individuals who come into con-  
20                  tact with in vitro clinical tests covered by such  
21                  order;

22                  “(I) a proposed listing submission under  
23                  section 587J(b) for in vitro clinical tests that  
24                  the developer intends to introduce into inter-  
25                  state commerce upon receiving a technology cer-

1           tification order, which shall not be construed to  
2           limit the developer from introducing additional  
3           tests not included in such submission under the  
4           same technology certification order;

5           “(J) information concerning one or more  
6           representative in vitro clinical tests, including—

7                   “(i) a test within the scope of the  
8                   technology certification application with  
9                   the appropriate analytical complexity at  
10                  the time of the submission of the applica-  
11                  tion under this section to serve as the rep-  
12                  resentative test;

13                   “(ii) the information specified in sub-  
14                   section (a) or (b) of section 587B, as ap-  
15                   plicable, for the representative in vitro clin-  
16                   ical test or tests, unless the Secretary de-  
17                   termines that such information is not nec-  
18                   essary;

19                   “(iii) a summary of a risk assessment  
20                   of the in vitro clinical test;

21                   “(iv) an explanation of the choice of  
22                   the representative in vitro clinical test or  
23                   tests for the technology certification applica-  
24                   tion and how such test adequately dem-  
25                   onstrates the range of procedures that the

1 developer includes in the application under  
2 subparagraphs (F), (G), (H), and (I); and

3 “(v) a brief explanation of the ways in  
4 which the procedures included in the appli-  
5 cation under subparagraphs (F), (G), (H),  
6 and (I) have been applied to the represent-  
7 ative in vitro clinical test or tests; and

8 “(K) such other information necessary to  
9 make a determination on a technology certifi-  
10 cation application as the Secretary may deter-  
11 mine necessary.

12 “(3) REFERENCE TO EXISTING APPLICA-  
13 TIONS.—With respect to the content requirements in  
14 the technology certification application described in  
15 paragraph (2), a developer may incorporate by ref-  
16 erence any content of an application previously sub-  
17 mitted by the developer.

18 “(d) ACTION ON AN APPLICATION FOR TECHNOLOGY  
19 CERTIFICATION.—

20 “(1) SECRETARY RESPONSE.—

21 “(A) IN GENERAL.—As promptly as prac-  
22 ticable, and not later than 90 days after receipt  
23 of an application under subsection (c), the Sec-  
24 retary shall—

1           “(i) if the Secretary finds that all of  
2           the grounds in paragraph (3) are met,  
3           issue a technology certification order  
4           granting the application, which—

5                   “(I) may include reasonable con-  
6                   ditions of certification; and

7                   “(II) shall specify the scope of  
8                   the technology certification; or

9           “(ii) deny the application, if the Sec-  
10          retary finds (and sets forth the basis of  
11          such finding as part of or accompanying  
12          such denial) that one or more grounds for  
13          granting the application specified in para-  
14          graph (3) are not met.

15          “(B) EXTENSION.—The timeline described  
16          in subparagraph (A) may be extended by mu-  
17          tual agreement between the Secretary and the  
18          applicant.

19          “(2) DEFICIENT APPLICATIONS.—

20                   “(A) IN GENERAL.—If, after receipt of an  
21                   application under this section, the Secretary de-  
22                   termines that any portion of such application is  
23                   deficient, the Secretary, not later than 60 days  
24                   after receipt of such application, shall provide  
25                   to the applicant a description of such defi-

1           iciencies and identify the information required to  
2           resolve such deficiencies.

3           “(B) CONVERTING TO PREMARKET APPLI-  
4           CATIONS.—When responding to the deficiency  
5           letter, the developer may convert the application  
6           for technology certification under subsection (c)  
7           into a premarket application under section  
8           587B.

9           “(3) TECHNOLOGY CERTIFICATION ORDER.—  
10          The Secretary shall issue an order granting a tech-  
11          nology certification under this section if, on the  
12          basis of the information submitted to the Secretary  
13          as part of the application and any other information  
14          with respect to such applicant, the Secretary finds  
15          that—

16                 “(A) there is a showing that in vitro clin-  
17                 ical tests within the scope of the technology cer-  
18                 tification order will meet the applicable stand-  
19                 ard;

20                 “(B) the methods used in, and the facili-  
21                 ties or controls used for, the development of eli-  
22                 gible in vitro clinical tests covered by the pro-  
23                 posed scope of the technology certification con-  
24                 form to the applicable requirements of section  
25                 587K with respect to—

1 “(i) design controls, including related  
2 purchasing controls and acceptance activi-  
3 ties;

4 “(ii) complaint investigation, adverse  
5 event reporting, and corrections and re-  
6 movals; and

7 “(iii) process validation, as applicable;

8 “(C) based on a fair evaluation of all mate-  
9 rial facts, the applicant’s proposed labeling and  
10 advertising are not false or misleading in any  
11 particular;

12 “(D) the application does not contain a  
13 false statement of material fact;

14 “(E) there is a showing that the represent-  
15 ative in vitro clinical test or tests—

16 “(i) meet the applicable standard; and

17 “(ii) reasonably represent the range of  
18 procedures required to be submitted in the  
19 application;

20 “(F) the applicant has agreed to permit,  
21 upon request, authorized employees of the Food  
22 and Drug Administration or persons accredited,  
23 or recognized under this Act, an opportunity to  
24 inspect at a reasonable time and in a reason-  
25 able manner the facilities and all pertinent

1 equipment, finished and unfinished materials,  
2 containers, and labeling therein, including all  
3 things (including records, files, papers, and con-  
4 trols) bearing on whether an in vitro clinical  
5 test is adulterated, misbranded, or otherwise in  
6 violation of this Act, and permits such author-  
7 ized employees or persons accredited under this  
8 Act to view and to copy and verify all records  
9 pertinent to the application and the in vitro  
10 clinical test; and

11 “(G) based on other data and information  
12 the Secretary may require under subsection  
13 (c)(2)(K), the Secretary finds that such data  
14 and information support granting a technology  
15 certification order.

16 “(4) REVIEW OF DENIALS.—An applicant  
17 whose application has been denied under this sub-  
18 section may obtain review of such denial under sec-  
19 tion 587P.

20 “(e) SUPPLEMENTS.—

21 “(1) SUPPLEMENTAL APPLICATIONS.—

22 “(A) IN GENERAL.—With respect to any of  
23 the following changes related to a technology  
24 certification order, a supplemental application  
25 to a technology certification order shall be sub-

1           mitted by the holder of the technology certifi-  
2           cation order describing such proposed changes,  
3           and the in vitro clinical test with such changes  
4           may not be introduced into interstate commerce  
5           until a technology certification order for such  
6           supplemental application is granted:

7                   “(i) Any significant change to the pro-  
8                   cedures provided in support of the applica-  
9                   tion for technology certification submitted  
10                  under subparagraph (G) or (H) of sub-  
11                  section (c)(2).

12                  “(ii) Any significant change to the  
13                  procedures provided in support of the ap-  
14                  plication for technology certification sub-  
15                  mitted under subparagraph (F) of sub-  
16                  section (c)(2).

17                  “(B) SECRETARY ACTION ON SUPPLE-  
18                  MENTAL APPLICATIONS.—Any action by the  
19                  Secretary on a supplemental application shall  
20                  be in accordance with subsection (d), and any  
21                  order resulting from such supplement shall be  
22                  treated as an amendment to a technology cer-  
23                  tification order.

24                  “(2) CONTENT OF APPLICATION.—



1           “(A) IN GENERAL.—A supplemental appli-  
2 cation for a change to an in vitro clinical test  
3 under a technology certification order shall—

4           “(i) contain all necessary information  
5 to make a showing that any in vitro clin-  
6 ical test affected by such change that is  
7 within the scope of the technology certifi-  
8 cation order will meet the applicable stand-  
9 ard; and

10           “(ii) be limited to such information  
11 that is needed to support the change.

12           “(B) CONTENT.—Unless otherwise speci-  
13 fied by the Secretary, a supplemental applica-  
14 tion under this subsection shall include—

15           “(i) a description of the change, in-  
16 cluding a rationale for implementing such  
17 change;

18           “(ii) a description of how the change  
19 was evaluated;

20           “(iii) data from a representative in  
21 vitro clinical test or tests that supports a  
22 showing that, in using the modified proce-  
23 dure or procedures, all eligible in vitro clin-  
24 ical tests within the scope of the tech-

1 nology certification will meet the applicable  
2 standard;

3 “(iv) as applicable, information to  
4 demonstrate that the modified procedure  
5 or procedures submitted under subsection  
6 (c)(2)(F) continue to conform to applicable  
7 requirements under section 587K; and

8 “(v) any other information requested  
9 by the Secretary.

10 “(3) CHANGES IN RESPONSE TO A PUBLIC  
11 HEALTH RISK.—

12 “(A) IN GENERAL.—If the holder of a  
13 technology certification makes a change to an  
14 in vitro clinical test or tests to address a poten-  
15 tial risk to public health by adding a new speci-  
16 fication or test method, such holder may imme-  
17 diately implement such change and shall submit  
18 a notification for such change to the Secretary  
19 within 30 days.

20 “(B) CONTENT.—Any notification to the  
21 Secretary under this paragraph shall include—

22 “(i) a summary of the relevant  
23 change;

24 “(ii) the rationale for implementing  
25 such change;

1           “(iii)(I) if such a change necessitates  
2           a change to the procedures reviewed as  
3           part of the granted technology certification  
4           order, the modified procedures; or

5           “(II) if the procedures were not  
6           changed, an explanation as to why they  
7           were not changed; and

8           “(iv) if such a change necessitates a  
9           change to the procedures reviewed as part  
10          of the granted technology certification  
11          order, data from a representative in vitro  
12          clinical test or tests that support a showing  
13          that, in using the modified procedures, all  
14          eligible in vitro clinical tests within the  
15          scope of the technology certification will  
16          meet the applicable standard.

17          “(f) TEMPORARY HOLD.—

18                 “(1) IN GENERAL.—Subject to the process  
19                 specified in paragraph (2), and based on one or  
20                 more findings under paragraph (4), the Secretary  
21                 may issue a temporary hold prohibiting any holder  
22                 of a technology certification order issued under this  
23                 section from introducing into interstate commerce  
24                 an in vitro clinical test that was not previously the  
25                 subject of a listing under section 587J. The tem-

1       porary hold shall identify the grounds for the tem-  
2       porary hold under paragraph (4) and the rationale  
3       for such finding.

4           “(2) PROCESS FOR ISSUING A TEMPORARY  
5       HOLD.—If the Secretary makes a finding that a  
6       temporary hold may be warranted based on one or  
7       more grounds specified in paragraph (4), the Sec-  
8       retary shall promptly notify the holder of the tech-  
9       nology certification order of such finding and pro-  
10      vide 30 calendar days for the developer to come into  
11      compliance with or otherwise resolve the finding.

12          “(3) WRITTEN REQUESTS.—Any written re-  
13      quest to the Secretary from the holder of a tech-  
14      nology certification order that a temporary hold  
15      under paragraph (1) be removed shall receive a deci-  
16      sion, in writing and specifying the reasons therefore,  
17      within 90 days after receipt of such request. Any  
18      such request shall include information to support the  
19      removal of the temporary hold.

20          “(4) GROUNDS FOR TEMPORARY HOLD.—The  
21      Secretary may initiate a temporary hold under this  
22      subsection upon a finding that the holder of a tech-  
23      nology certification order—

1           “(A) is not in compliance with the condi-  
2           tions of the technology certification order pur-  
3           suant to subsection (b)(1)(D);

4           “(B) offers one or more in vitro clinical  
5           tests with advertising or labeling that is false or  
6           misleading;

7           “(C) has reported a correction or removal  
8           of an in vitro clinical test that is offered under  
9           a technology certification order under this sec-  
10          tion and has failed to demonstrate that the  
11          issue or issues causing the correction or re-  
12          moval does not adversely impact the ability of  
13          other in vitro clinical tests offered under the  
14          same technology certification order to meet the  
15          applicable standard; or

16          “(D) has introduced into interstate com-  
17          merce an in vitro clinical test under a tech-  
18          nology certification order and such test is adul-  
19          terated or misbranded, based on a determina-  
20          tion by the Secretary, and has failed to dem-  
21          onstrate that the issue or issues causing the  
22          adulteration or misbranding does not adversely  
23          impact the ability of other in vitro clinical tests  
24          offered under the same technology certification

1           granted under this section to meet the applica-  
2           ble standard.

3           “(g) WITHDRAWAL.—The Secretary may, after due  
4 notice and opportunity for an informal hearing, issue an  
5 order withdrawing a technology certification order includ-  
6 ing all tests introduced into interstate commerce under the  
7 technology certification order if the Secretary finds that—

8           “(1) the application, supplement, or report  
9           under subsection (h) contains false or misleading in-  
10          formation or fails to reveal a material fact;

11          “(2) such holder fails to correct false or mis-  
12          leading labeling or advertising upon the request of  
13          the Secretary;

14          “(3) in connection with a technology certifi-  
15          cation, the holder provides false or misleading infor-  
16          mation to the Secretary; or

17          “(4) the holder of such technology certification  
18          order fails to correct the grounds for a temporary  
19          hold within a timeframe specified in the temporary  
20          hold order.

21          “(h) REPORTS TO CONGRESS.—

22          “(1) IN GENERAL.—Not later than 1 year after  
23          the effective date of the VALID Act of 2023, and  
24          annually thereafter for the next 4 years, the Sec-  
25          retary shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and  
2 the Committee on Energy and Commerce of the  
3 House of Representatives, and make publicly avail-  
4 able, including through posting on the website of the  
5 Food and Drug Administration, a report containing  
6 the information described in paragraph (2).

7 “(2) CONTENT.—

8 “(A) IN GENERAL.—Each report under  
9 paragraph (1) shall address, at a minimum—

10 “(i) the total number of applications  
11 for technology certifications filed, issued,  
12 withdrawn, and denied;

13 “(ii) the total number of technology  
14 certification orders the Secretary put on  
15 temporary hold under subsection (h) and  
16 the number of technology certification or-  
17 ders withdrawn under subsection (i);

18 “(iii) the types of technologies for  
19 which the Secretary issued technology cer-  
20 tification orders;

21 “(iv) the total number of holders of  
22 technology certification orders that are in  
23 effect; and

24 “(v) the total number of in vitro clin-  
25 ical test categories that required premarket

1 review under section 587B that were reded-  
2 igned as eligible in vitro clinical tests  
3 under this section.

4 “(B) FINAL REPORT.—The fifth report  
5 submitted under paragraph (1) shall include a  
6 summary of, and responses to, comments raised  
7 in the docket.

8 “(C) PERFORMANCE REPORTS.—The re-  
9 ports required under this section may be issued  
10 with performance reports as required under sec-  
11 tion 9 of the VALID Act of 2023.

12 “(i) PUBLIC MEETING AND INPUT.—

13 “(1) PUBLIC DOCKET.—Not later than 30 days  
14 after the date of enactment of the VALID Act of  
15 2023, the Secretary shall establish a public docket to  
16 receive comments concerning recommendations for  
17 implementation of this section, including criteria and  
18 procedures for subsections (c) through (h). The pub-  
19 lic docket shall remain open for at least 1 year after  
20 the establishment of the public docket.

21 “(2) PUBLIC MEETING.—Not later than 180  
22 days after the date of enactment of the VALID Act  
23 of 2023, the Secretary shall convene a public meet-  
24 ing to which stakeholders from organizations rep-  
25 resenting patients and consumers, academia, and the



1 in vitro clinical test industry are invited to discuss  
2 the technology certification process including appli-  
3 cation requirements, inspections, alignment with  
4 third-party accreditors, and the definition of the  
5 term ‘technology’ under section 587.

6 “(j) REGULATIONS.—The Secretary shall issue regu-  
7 lations regarding the technology certification process, in-  
8 cluding describing criteria or procedures relating to tech-  
9 nology certification under this section, which shall be sub-  
10 ject to public comment for a minimum of 60 days from  
11 issuance prior to finalizing such regulations after consid-  
12 ering the comments received. The regulation shall include  
13 an outline of the application process, opportunities to meet  
14 with officials of the Food and Drug Administration, and  
15 plans to streamline inspections.

16 “(k) NOTIFICATION.—

17 “(1) IN GENERAL.—Notwithstanding subsection  
18 (a)(1), a first-of-a-kind in vitro clinical test or a  
19 combination product that meets the definition of a  
20 moderate-risk test under section 587 may be intro-  
21 duced into interstate commerce under a technology  
22 certification order that has been issued by the Sec-  
23 retary, subject to other applicable requirements if—

24 “(A) the developer provides notification to  
25 the Secretary 60 days prior to introducing such

1 tests into interstate commerce that includes in-  
2 formation demonstrating that the test is mod-  
3 erate-risk and within the scope of the applicable  
4 technology certification order; and

5 “(B) the Secretary has not issued a notifi-  
6 cation to the developer under paragraph (2) be-  
7 fore such time has elapsed.

8 “(2) NOTIFICATION FROM SECRETARY.—The  
9 Secretary shall issue a notification to the developer  
10 that such test may not be introduced into interstate  
11 commerce under such order if the Secretary deter-  
12 mines that—

13 “(A) such test—

14 “(i) does not meet the definition of a  
15 moderate-risk test under section 587;

16 “(ii) is not eligible to be introduced  
17 into interstate commerce under any of sub-  
18 paragraphs (A) through (E) of subsection  
19 (a)(1); or

20 “(iii) is not eligible to be introduced  
21 into interstate commerce under the ref-  
22 erenced technology certification order  
23 issued by the Secretary because it is not  
24 within the scope of the technology certifi-  
25 cation order under subsection (b)(2); or

1           “(B) based on the information included in  
2           the notification submitted by the developer pur-  
3           suant to this subsection, there is insufficient in-  
4           formation for the Secretary to make the deter-  
5           minations described in clauses (i), (ii), and (iii)  
6           of subparagraph (A).

7   **“SEC. 587E. MITIGATING MEASURES.**

8           “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

9           “(1) ESTABLISHING, CHANGING, OR WITH-  
10          DRAWING.—

11           “(A) ESTABLISHMENT.—The Secretary  
12           may establish and require, on the basis of evi-  
13           dence, mitigating measures for any in vitro clin-  
14           ical test or category of in vitro clinical tests  
15           with the same indications for use that is intro-  
16           duced or delivered for introduction into inter-  
17           state commerce after the Secretary establishes  
18           any such mitigating measures.

19           “(B) METHODS OF ESTABLISHMENT.—The  
20           Secretary may establish mitigating measures—

21           “(i) under the process set forth in  
22           subparagraph (D);

23           “(ii) as provided under section 587F;

24           or

1 “(iii) through a premarket approval or  
2 technology certification order, which may  
3 establish mitigating measures for an indi-  
4 vidual in vitro clinical test or a category of  
5 in vitro clinical tests.

6 “(C) METHODS OF CHANGE OR WITH-  
7 DRAWAL.—The Secretary may change or with-  
8 draw mitigating measures—

9 “(i) under the process set forth in  
10 subparagraph (D); or

11 “(ii) as provided under section 587F.

12 “(D) PROCESS FOR ESTABLISHMENT,  
13 CHANGE, OR WITHDRAWAL.—Notwithstanding  
14 subchapter II of chapter 5 of title 5, United  
15 States Code, the Secretary may, upon the ini-  
16 tiative of the Secretary or upon petition of an  
17 interested person, establish, change, or with-  
18 draw mitigating measures for an in vitro clin-  
19 ical test or category of in vitro clinical tests  
20 by—

21 “(i) publishing a proposed order in  
22 the Federal Register;

23 “(ii) providing an opportunity for  
24 public comment for a period of not less  
25 than 30 60 calendar days; and

1           “(iii) after consideration of any com-  
2           ments submitted, publishing a final order  
3           in the Federal Register that responds to  
4           the comments submitted, and which shall  
5           include a reasonable transition period.

6           “(E) EFFECT OF MITIGATING MEASURES  
7           ON GRANDFATHERED TESTS.—A mitigating  
8           measure shall not be required by the Secretary  
9           for an in vitro clinical test subject to section  
10          587G(a).

11          “(2) IN VITRO CLINICAL TESTS PREVIOUSLY  
12          CLEARED OR EXEMPT AS DEVICES WITH SPECIAL  
13          CONTROLS.—

14               “(A) IN GENERAL.—Any special controls  
15               applicable to an in vitro clinical test previously  
16               cleared or exempt under section 510(k), or clas-  
17               sified under section 513(f)(2) prior to date of  
18               enactment of the VALID Act of 2023, including  
19               any such special controls established during the  
20               period beginning on the date of enactment of  
21               the VALID Act of 2023 and ending on the ef-  
22               fective date of such Act (as described in section  
23               5(b) of such Act)—

1 “(i) shall continue to apply to such in  
2 vitro clinical test after such effective date;  
3 and

4 “(ii) are deemed to be mitigating  
5 measures as of the effective date specified  
6 in section 5(a)(1)(A) of the VALID Act of  
7 2023.

8 “(B) CHANGES.—Notwithstanding sub-  
9 paragraph (A), the Secretary may establish,  
10 change, or withdraw mitigating measures for  
11 such tests or category of tests using the proce-  
12 dures under paragraph (1).

13 “(b) DOCUMENTATION.—

14 “(1) IN VITRO CLINICAL TESTS SUBJECT TO  
15 PREMARKET REVIEW.—The developer of an in vitro  
16 clinical test subject to premarket review under sec-  
17 tion 587B and to which mitigating measures apply  
18 shall maintain documentation in accordance with the  
19 applicable quality requirements under section 587K  
20 and make such documentation available to the Sec-  
21 retary upon request or inspection.

22 “(2) OTHER TESTS.—The developer of an in  
23 vitro clinical test that is offered under a technology  
24 certification order or other exemption from pre-

1 market review under section 587B and to which  
2 mitigating measures apply shall—

3 “(A) maintain documentation in accord-  
4 ance with the applicable quality requirements  
5 under section 587K demonstrating that such  
6 mitigating measures continue to be met fol-  
7 lowing a test modification by the developer;

8 “(B) make such documentation available to  
9 the Secretary upon request or inspection; and

10 “(C) include in the performance summary  
11 for such test a brief description of how such  
12 mitigating measures are met, if applicable.

13 **“SEC. 587F. REGULATORY PATHWAY DESIGNATION.**

14 “(a) **PATHWAY DETERMINATIONS.—**

15 “(1) **IN GENERAL.—**After considering available  
16 evidence with respect to an in vitro clinical test or  
17 category of in vitro clinical tests with the same in-  
18 tended use, including the identification, establish-  
19 ment under paragraph (4), and implementation of  
20 mitigating measures under section 587E, as appro-  
21 priate, the Secretary may, upon the initiative of the  
22 Secretary or upon request of a developer, determine  
23 that—

1           “(A) such in vitro clinical test is high-risk  
2 and subject to premarket review under section  
3 587B;

4           “(B) such in vitro clinical tests, including  
5 a first-of-a-kind test, is moderate-risk and sub-  
6 ject to abbreviated premarket review under sec-  
7 tion 587B(b) or technology certification under  
8 section 587D(a)(1); or

9           “(C) such in vitro clinical test, including a  
10 first-of-a-kind test is low-risk or otherwise ex-  
11 empt from premarket review under section  
12 587B.

13           “(2) REQUESTS.—

14           “(A) SUBMISSIONS BY DEVELOPERS.—

15           “(i) ABBREVIATED PREMARKET RE-  
16 VIEW; TECHNOLOGY CERTIFICATION.—A  
17 developer submitting a request that the  
18 Secretary make a determination as de-  
19 scribed in paragraph (1)(B) shall submit  
20 information to support that the in vitro  
21 clinical test is moderate-risk or propose  
22 mitigating measures, if applicable, that  
23 would support such a determination.

24           “(ii) LOW-RISK; EXEMPT FROM PRE-  
25 MARKET REVIEW.—A developer submitting



1 a request that the Secretary make a deter-  
2 mination as described in paragraph (1)(C)  
3 shall submit information that the in vitro  
4 clinical test is low-risk, or otherwise appro-  
5 priate for exemption from premarket re-  
6 view under section 587B and propose miti-  
7 gating measures, if applicable, that would  
8 support such a determination.

9 “(B) RESPONSE BY THE SECRETARY.—  
10 Not later than 30 days after receiving a request  
11 under clause (i) or (ii) of subparagraph (A), the  
12 Secretary shall provide a timely response de-  
13 scribing whether or not the Secretary will ini-  
14 tiate the process for making a determination  
15 under paragraph (1)(B) or (1)(C) as described  
16 in paragraph (4).

17 “(3) SUFFICIENCY OF MITIGATING MEAS-  
18 URES.—When determining whether mitigating meas-  
19 ures for an in vitro clinical test, or category of in  
20 vitro clinical tests, are sufficient to make such test  
21 moderate-risk or low-risk, the Secretary shall take  
22 into account the following:

23 “(A) The degree to which the technology  
24 for the intended use of the in vitro clinical test  
25 is well-characterized, taking into consideration

1 factors that include one or more of the fol-  
2 lowing:

3 “(i) Peer-reviewed literature.

4 “(ii) Practice guidelines.

5 “(iii) Consensus standards.

6 “(iv) Recognized standards of care.

7 “(v) Use of such technology, including  
8 historical use.

9 “(vi) Multiple scientific publications  
10 by different authors.

11 “(vii) Adoption by the scientific or  
12 clinical community.

13 “(viii) Real world evidence.

14 “(B) Whether the criteria for performance  
15 of the test are well-established to be sufficient  
16 for the intended use.

17 “(C) The clinical circumstances under  
18 which the in vitro clinical test is used, including  
19 whether the in vitro clinical test is the sole de-  
20 terminate for the diagnosis or treatment of the  
21 targeted disease, and the availability of other  
22 tests (such as confirmatory or adjunctive tests)  
23 or relevant material standards.

24 “(D) Whether such mitigating measures  
25 sufficiently mitigate the risk of harm such that

1 the test or category of tests is moderate-risk or  
2 low-risk.

3 “(4) PROCESS.—

4 “(A) IN GENERAL.—For a test that is not  
5 first-of-a-kind, any action under paragraph (1)  
6 shall be made by publication of a notice of such  
7 proposed action on the website of the Food and  
8 Drug Administration, the consideration of com-  
9 ments to a public docket on such proposal, and  
10 publication of a final action on such website  
11 within 60 calendar days of the close of the com-  
12 ment period posted to such public docket, not-  
13 withstanding subchapter II of chapter 5 of title  
14 5, United States Code.

15 “(B) PROCESS FOR FIRST-OF-A-KIND  
16 TEST.—In the case of an in vitro clinical test  
17 that is first-of-a-kind, the process is as follows:

18 “(i) Any determination that the test is  
19 subject to premarket approval or abbrevi-  
20 ated premarket review under subpara-  
21 graph (A) or (B) of paragraph (1) shall be  
22 published on the website of the Food and  
23 Drug Administration, notwithstanding sub-  
24 clause II of chapter 5 of title 5, United  
25 States Code, only after the in vitro clinical

1 test is approved under section 587B. Until  
2 that time, the determination shall not be  
3 binding on other in vitro clinical tests.

4 “(ii) Any determination other than  
5 those made under clause (i) shall be made  
6 by publication of a notice of final action on  
7 the website of the Food and Drug Admin-  
8 istration, notwithstanding subchapter II of  
9 chapter 5 of title 5, United States Code.

10 “(5) NO EFFECT ON GRANDFATHERING DETER-  
11 MINATIONS.—A determination under paragraph (1)  
12 shall have no effect on the applicability of section  
13 587G to an in vitro clinical tests.

14 “(b) TRANSITION PERIOD.—Upon a decision by the  
15 Secretary to change a regulatory pathway designation, or  
16 reclassifies an in vitro clinical test, or category of in vitro  
17 clinical tests, the Secretary shall provide an appropriate  
18 transition period with respect to any new requirements.

19 “(c) APPEALS.—A decision by the Secretary under  
20 this section shall be deemed a significant decision subject  
21 to appeal under section 587P.

22 “(d) ADVISORY COMMITTEE.—The Secretary may re-  
23 quest recommendations from an advisory committee under  
24 section 587H pursuant to carrying out this section.

1       “(e) REQUEST FOR INFORMAL FEEDBACK.—Before  
2 submitting a premarket application or technology certifi-  
3 cation application for an in vitro clinical test—

4           “(1) the developer of the test may submit to the  
5 Secretary a written request for a meeting, con-  
6 ference, or written feedback to discuss and provide  
7 information relating to the regulation of such in  
8 vitro clinical test which may include—

9           “(A) the submission process and the type  
10 and amount of evidence expected to dem-  
11 onstrate the applicable standard;

12           “(B) which regulatory pathway is appro-  
13 priate for an in vitro clinical test; and

14           “(C) an investigation plan for an in vitro  
15 clinical test, including a clinical protocol; and

16           “(2) upon receipt of such a request, the Sec-  
17 retary shall—

18           “(A) if a meeting is requested—

19           “(i) within 60 calendar days after  
20 such receipt, or within such time period as  
21 may be agreed to by the developer, meet or  
22 confer with the developer submitting the  
23 request; and

24           “(ii) within 15 calendar days after  
25 such meeting or conference, provide to the

1 developer a written record or response de-  
2 scribing the issues discussed and conclu-  
3 sions reached in the meeting or conference;  
4 and

5 “(B) if written feedback is requested, pro-  
6 vide feedback to the requestor within 75 days  
7 after such receipt.

8 **“SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.**

9 “(a) IN GENERAL.—Subject to subsection (d), an in  
10 vitro clinical test is exempt from the requirements of this  
11 subchapter specified in subsection (b) if—

12 “(1) the test was first offered for clinical use,  
13 and was not intended solely for investigational use,  
14 not later than 45 days after the date of enactment  
15 of the VALID Act of 2023;

16 “(2) the test was developed by a clinical labora-  
17 tory for which a certificate was in effect under sec-  
18 tion 353 of the Public Health Service Act that meets  
19 the requirements for performing tests of high com-  
20 plexity;

21 “(3) the test is performed—

22 “(A) in the same clinical laboratory in  
23 which the test was developed for which a certifi-  
24 cation is still in effect under section 353 of the

1 Public Health Service Act that meets the re-  
2 quirements to perform tests of high complexity;

3 “(B) by another clinical laboratory for  
4 which a certificate is in effect under section 353  
5 of such Act that meets the requirements to per-  
6 form tests of high complexity, and that is with-  
7 in the same corporate organization and having  
8 common ownership by the same parent corpora-  
9 tion as the laboratory in which the test was de-  
10 veloped; or

11 “(C) in the case of a test that was devel-  
12 oped by the Centers for Disease Control and  
13 Prevention or another laboratory in a public  
14 health laboratory network coordinated or man-  
15 aged by the Centers for Disease Control and  
16 Prevention, by a clinical laboratory for which a  
17 certificate is in effect under section 353 of such  
18 Act that meets the requirements to perform  
19 tests of high complexity, and that is within a  
20 public health laboratory network coordinated or  
21 managed by the Centers for Disease Control  
22 and Prevention;

23 “(4) the test does not have in effect an ap-  
24 proval under section 515, a clearance under section  
25 510(k), an authorization under section 513(f)(2), or

1 an exemption under section 520(m), or licensure  
2 under section 351 of the Public Health Service Act;

3 “(5) any modification to the test on or after the  
4 date that is 45 days after the date of enactment of  
5 the VALID Act of 2023 is made by the initial devel-  
6 oper, conforms with section 587C(a)(6)(A)(ii), and  
7 does not meet the criteria in subsection (d)(1);

8 “(6) when used as an investigational in vitro  
9 clinical test, such test complies with section 587S, as  
10 applicable;

11 “(7) the test is offered with an order from an  
12 authorized person as required under section 353 of  
13 the Public Health Service Act, and was offered with  
14 a prescription required under section 809.30(f) of  
15 title 21, Code of Federal Regulations prior to the ef-  
16 fective date of this subchapter;

17 “(8) the test is not for use with home specimen  
18 collection, unless the specimen is collected with a  
19 collection container, receptacle, or kit that—

20 “(A) has been approved, cleared, or au-  
21 thorized by the Secretary for home specimen  
22 collection and the collection is performed pursu-  
23 ant to the approved, cleared, or authorized la-  
24 beling, including any indication for use as pre-  
25 scription use or over-the-counter use, or



1           “(B) is exempt from premarket review and  
2           its use is consistent with applicable limitations  
3           on the exemption;

4           “(9) the test is not a specimen receptacle or in-  
5           strument;

6           “(10) each test report for the test bears a  
7           statement that reads as follows: ‘This in vitro clin-  
8           ical test was introduced into commerce prior to the  
9           application of the VALID Act and is exempt from  
10          FDA premarket review.’; and

11          “(11) the developer of the test—

12                 “(A) maintains documentation dem-  
13                 onstrating that the test meets and continues to  
14                 meet the criteria set forth in this subsection;  
15                 and

16                 “(B) makes such documentation available  
17                 to the Secretary upon request.

18          “(b) EXEMPTIONS APPLICABLE TO GRAND-  
19 FATHERED TESTS.—An in vitro clinical test that meets  
20 the criteria specified in subsection (a) is exempt from pre-  
21 market review under 587B, labeling requirements under  
22 587L, and test design requirements and quality require-  
23 ments under 587K, and may be lawfully offered subject  
24 to the other applicable requirements of this Act.

1           “(c) MODIFICATIONS.—In the case of an in vitro clin-  
2 ical test that meets the criteria specified in subsection (a),  
3 such test continues to qualify for the exemptions described  
4 in subsection (b) if the test is modified and the modifica-  
5 tion is of a type described in subsection (a)(5), and the  
6 person modifying such in vitro clinical test—

7           “(1) documents each such modification and  
8 maintains documentation of the basis for such deter-  
9 mination;

10           “(2) provides such documentation relating to  
11 the change to the Secretary upon request or inspec-  
12 tion; and

13           “(3) does not modify the in vitro clinical test  
14 such that it no longer meets the criteria under sub-  
15 section (a).

16           “(d) REQUEST FOR INFORMATION.—

17           “(1) CRITERIA.—The criteria described in this  
18 paragraph are any of the following:

19           “(A) There is a lack of valid scientific evi-  
20 dence to support that the in vitro clinical test  
21 is analytically valid or clinically valid.

22           “(B) Such in vitro clinical test is being of-  
23 fered by its developer with any false or mis-  
24 leading analytical or clinical claims.

1           “(C) It is probable that such in vitro clin-  
2           ical test will cause serious adverse health con-  
3           sequences.

4           “(2) PROCESS.—

5           “(A) WRITTEN REQUEST FOR INFORMA-  
6           TION.—The Secretary may issue a written re-  
7           quest to a developer identifying specific sci-  
8           entific concerns, based on credible information,  
9           with an in vitro clinical test, which indicate that  
10          one or more of the criteria described in para-  
11          graph (1) apply to such in vitro clinical test.  
12          Such written request shall include specific infor-  
13          mation requests pertaining to such criteria.

14          “(B) DEADLINE FOR SUBMITTING INFOR-  
15          MATION.—Not later than 45 days after receiv-  
16          ing a request for information under subpara-  
17          graph (A)—

18                  “(i) the developer of an in vitro clin-  
19                  ical test—

20                          “(I) may seek a teleconference  
21                          prior to the submission of information  
22                          under subclause (II) to discuss the  
23                          Secretary’s request; and

24                          “(II) shall submit the informa-  
25                          tion requested pursuant to subpara-

1 graph (A), and may include in such  
2 submission a request for a teleconfer-  
3 ence; and

4 “(ii) the Secretary shall—

5 “(I) schedule a teleconference re-  
6 quested under clause (i)(I); and

7 “(II) hold a teleconference if re-  
8 quested within 10 days of the Sec-  
9 retary’s receipt of the information  
10 submitted under clause (i)(II).

11 “(C) REVIEW DEADLINE.—Upon receiving  
12 a submission under subparagraph (B), the Sec-  
13 retary shall—

14 “(i) review the submitted information  
15 within 45 calendar days of such receipt,  
16 which may include communication with the  
17 developer; and

18 “(ii) determine whether the criteria  
19 listed in paragraph (1) apply to the in  
20 vitro clinical test and communicate such  
21 determination to the developer as described  
22 in subparagraph (D).

23 “(D) COMMUNICATION AND RESULTS OF  
24 DETERMINATION.—The Secretary shall notify

1 the developer, in writing, of the Secretary’s de-  
2 termination under subparagraph (C), as follows:

3 “(i) If the Secretary determines that  
4 none of the criteria listed in paragraph (1)  
5 apply to the in vitro clinical test, such test  
6 shall be exempt from relevant requirements  
7 of this subchapter, as set forth in sub-  
8 section (b), subject to the criteria under  
9 subsection (a).

10 “(ii) If the Secretary determines that  
11 one or more of the criteria listed in para-  
12 graph (1) apply to the test but such a de-  
13 termination may be resolved within a rea-  
14 sonable time, and the test has not been  
15 previously subject to this subsection on the  
16 basis of the same or substantially similar  
17 scientific concerns identified in the written  
18 request issued under paragraph  
19 (d)(2)(A)—

20 “(I) the Secretary shall notify the  
21 developer of such a determination and  
22 allow the developer to seek a tele-  
23 conference to discuss the finding;

24 “(II) the developer shall submit  
25 information demonstrating resolution

1 of the determination within 15 days of  
2 receiving such notification; and

3 “(III) the Secretary shall make a  
4 determination within 30 days of the  
5 receipt of such submission of informa-  
6 tion as to whether the criteria under  
7 paragraph (1) continue to apply to the  
8 test and, if through such determina-  
9 tion the Secretary determines that—

10 “(aa) none of the criteria  
11 listed in paragraph (1) apply to  
12 the test, such test shall be ex-  
13 empt from relevant requirements  
14 of the subchapter as set forth in  
15 subsection (b), subject to applica-  
16 ble limitations; or

17 “(bb) one or more of the cri-  
18 teria listed in paragraph (1)  
19 apply to the in vitro clinical test,  
20 such test is not exempt as set  
21 forth in this section and shall not  
22 be offered unless approved under  
23 section 587B, or, upon a deter-  
24 mination by the Secretary pursu-  
25 ant to section 587F, offered

1 under a technology certification  
2 order under section 587D or of-  
3 fered as a low-risk test.

4 “(iii) If the Secretary determines that  
5 one or more of the criteria listed in para-  
6 graph (1) apply to the in vitro clinical test  
7 and clause (ii) does not apply, the in vitro  
8 clinical test is not exempt as set forth in  
9 this section and shall not be offered unless  
10 approved under section 587B, or upon a  
11 determination by the Secretary pursuant to  
12 section 587F, offered under a technology  
13 certification order under section 587D or  
14 offered as a low-risk test.

15 **“SEC. 587H. ADVISORY COMMITTEES.**

16 “(a) IN GENERAL.—The Secretary may establish ad-  
17 visory committees or use advisory committee panels of ex-  
18 perts established before the date of enactment of the  
19 VALID Act of 2023 (including a device classification  
20 panel under section 513) for the purposes of providing ex-  
21 pert scientific advice and making recommendations related  
22 to—

23 “(1) the approval of an application for an in  
24 vitro clinical test submitted under this subchapter,  
25 including for evaluating, as applicable, the analytical

1 validity, clinical validity, and safety of in vitro clin-  
2 ical tests;

3 “(2) the potential effectiveness of mitigating  
4 measures for a determination of the applicable regu-  
5 latory pathway under section 587F(b) or risk eval-  
6 uation for an in vitro clinical test or tests;

7 “(3) quality requirements under section 587K  
8 or applying such requirements to in vitro clinical  
9 tests developed or imported by developers;

10 “(4) appeals under section 587P; or

11 “(5) such other purposes as the Secretary de-  
12 termines appropriate.

13 “(b) APPOINTMENTS.—

14 “(1) VOTING MEMBERS.—The Secretary shall  
15 appoint to each committee established under sub-  
16 section (a), as voting members, individuals who are  
17 qualified by training and experience to evaluate in  
18 vitro clinical tests referred to the committee for the  
19 purposes specified in subsection (a), including indi-  
20 viduals with, to the extent feasible, scientific exper-  
21 tise in the development of such in vitro clinical tests,  
22 laboratory operations, and the use of in vitro clinical  
23 tests. The Secretary shall designate one member of  
24 each committee to serve as chair.



1           “(2) NONVOTING MEMBERS.—In addition to the  
2 individuals appointed pursuant to paragraph (1), the  
3 Secretary shall appoint to each committee estab-  
4 lished under subsection (a), as nonvoting members—

5           “(A) a representative of consumer inter-  
6 ests; and

7           “(B) a representative of interests of in  
8 vitro clinical test developers not directly af-  
9 fected by the matter to be brought before the  
10 committee.

11           “(3) LIMITATION.—No individual who is a reg-  
12 ular full-time employee of the United States and en-  
13 gaged in the administration of this Act may be a  
14 member of any advisory committee established under  
15 subsection (a).

16           “(4) EDUCATION AND TRAINING.—The Sec-  
17 retary shall, as appropriate, provide education and  
18 training to each new committee member before such  
19 member participates in a committee’s activities, in-  
20 cluding education regarding requirements under this  
21 Act and related regulations of the Secretary, and the  
22 administrative processes and procedures related to  
23 committee meetings.

24           “(5) MEETINGS.—The Secretary shall ensure  
25 that scientific advisory committees meet regularly

1 and at appropriate intervals so that any matter to  
2 be reviewed by such a committee can be presented  
3 to the committee not more than 60 calendar days  
4 after the matter is ready for such review. Meetings  
5 of the committee may be held using electronic or tel-  
6 ephonic communication to convene the meetings.

7 “(6) COMPENSATION.—Members of an advisory  
8 committee established under subsection (a), while at-  
9 tending meetings or conferences or otherwise en-  
10 gaged in the business of the advisory committee—

11 “(A) shall be entitled to receive compensa-  
12 tion at rates to be fixed by the Secretary, but  
13 not to exceed the daily equivalent of the rate in  
14 effect for positions classified above level GS–15  
15 of the General Schedule; and

16 “(B) may be allowed travel expenses as au-  
17 thorized by section 5703 of title 5, United  
18 States Code, for employees serving intermit-  
19 tently in the Government service.

20 “(c) GUIDANCE.—The Secretary may issue guidance  
21 on the policies and procedures governing advisory commit-  
22 tees established under subsection (a).

23 **“SEC. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

24 “(a) IN GENERAL.—The purpose of this section is  
25 to encourage the Secretary, and provide the Secretary with

1 sufficient authority, to apply efficient and flexible ap-  
2 proaches to expedite the development of, and prioritize the  
3 review of, in vitro clinical tests that represent break-  
4 through technologies.

5 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary  
6 shall establish a program to expedite the development of,  
7 and provide for the priority review of, in vitro clinical  
8 tests.

9 “(c) ELIGIBILITY.—The program developed under  
10 subsection (b) shall be available for any in vitro clinical  
11 test that—

12 “(1) provides or enables more effective treat-  
13 ment or diagnosis of life-threatening or irreversibly  
14 debilitating human disease or conditions; and

15 “(2) is a test—

16 “(A) that represents a breakthrough tech-  
17 nology;

18 “(B) for which no approved alternative in  
19 vitro clinical test exists, including no in vitro  
20 clinical test offered under a technology certifi-  
21 cation order;

22 “(C) that offers a clinically meaningful ad-  
23 vantage over existing alternative in vitro clinical  
24 tests that are approved (including in vitro clin-  
25 ical tests offered under a technology certifi-

1 cation order), including the potential to reduce  
2 or eliminate the need for hospitalization, im-  
3 prove patient quality of life, facilitate patients'  
4 ability to manage their own care (such as  
5 through self-directed personal assistance), or es-  
6 tablish long-term clinical efficiencies; or

7 “(D) the availability of which is in the best  
8 interest of patients or public health.

9 “(d) DESIGNATION.—

10 “(1) REQUEST.—To receive breakthrough des-  
11 ignation under this section, an applicant may re-  
12 quest that the Secretary designate the in vitro clin-  
13 ical test for expedited development and priority re-  
14 view. Any such request for designation may be made  
15 at any time prior to, or at the time of, the submis-  
16 sion of an application under section 587B or 587D,  
17 and shall include information demonstrating that the  
18 test meets the criteria described in subsection (c).

19 “(2) DETERMINATION.—Not later than 60 cal-  
20 endar days after the receipt of a request under para-  
21 graph (1), the Secretary shall determine whether the  
22 in vitro clinical test that is the subject of the request  
23 meets the criteria described in subsection (c). If the  
24 Secretary determines that the test meets the criteria,

1 the Secretary shall designate the test for expedited  
2 development and priority review.

3 “(3) REVIEW.—Review of a request under para-  
4 graph (1) shall be undertaken by a team that is  
5 composed of experienced staff and senior managers  
6 of the Food and Drug Administration.

7 “(4) WITHDRAWAL.—

8 “(A) IN GENERAL.—The designation of an  
9 in vitro clinical test under this subsection is  
10 deemed to be withdrawn, and such in vitro clin-  
11 ical test shall no longer be eligible for designa-  
12 tion under this section, if an application for ap-  
13 proval for such test under section 587B or  
14 587D is denied. Such test shall be eligible for  
15 breakthrough designation upon a new request  
16 for such designation.

17 “(B) EXCEPTION.—The Secretary may not  
18 withdraw a designation granted under this sub-  
19 section based on the subsequent approval or  
20 technology certification of another in vitro clin-  
21 ical test that—

22 “(i) is designated under this section;

23 or

24 “(ii) was given priority review under  
25 section 515B.

1           “(e) ACTIONS.—For purposes of expediting the devel-  
2 opment and review of in vitro clinical tests under this sec-  
3 tion, the Secretary may take the actions and additional  
4 actions set forth in paragraphs (1) and (2), respectively,  
5 of section 515B(e) when reviewing such tests. Any ref-  
6 erence or authorization in section 515B(e) with respect  
7 to a device shall be deemed a reference or authorization  
8 with respect to an in vitro clinical test for purposes of this  
9 section.

10           “(f) GUIDANCE.—Not later than 30 months after the  
11 date of enactment of the VALID Act of 2023, the Sec-  
12 retary shall issue final guidance on the implementation of  
13 this section. Such guidance shall—

14           “(1) set forth the process by which a person  
15 may seek a designation under subsection (d);

16           “(2) provide a template for request under sub-  
17 section (d);

18           “(3) identify the criteria the Secretary will use  
19 in evaluating a request for designation; and

20           “(4) identify the criteria and processes the Sec-  
21 retary will use to assign a team of staff, including  
22 team leaders, to review in vitro clinical tests des-  
23 ignated for expedited development and priority re-  
24 view, including any training required for such per-  
25 sonnel to ensure effective and efficient review.

1 “(g) RULES OF CONSTRUCTION.—Nothing in this  
2 section shall be construed to affect—

3 “(1) the criteria and standards for evaluating  
4 an application pursuant to section 587B or 587D,  
5 including the recognition of valid scientific evidence  
6 as described in section 587(20) and consideration  
7 and application of the least burdensome means de-  
8 scribed under section 587AA(e);

9 “(2) the authority of the Secretary with respect  
10 to clinical holds under section 587S;

11 “(3) the authority of the Secretary to act on an  
12 application pursuant to section 587B before comple-  
13 tion of an establishment inspection, as the Secretary  
14 determines appropriate; or

15 “(4) the authority of the Secretary with respect  
16 to postmarket surveillance under section 587X.

17 **“SEC. 587J. REGISTRATION AND LISTING.**

18 “(a) REGISTRATION REQUIREMENT.—

19 “(1) IN GENERAL.—Each person described in  
20 subsection (b)(1) shall—

21 “(A) during the period beginning on Octo-  
22 ber 1 and ending on December 31 of each year,  
23 register with the Secretary the name of such  
24 person, places of business of such person, all es-  
25 tablishments engaged in the activities specified

1 under this paragraph, the establishment reg-  
2 istration number of each such establishment,  
3 and a point of contact for each such establish-  
4 ment, including an electronic point of contact;  
5 and

6 “(B) submit an initial registration con-  
7 taining the information required under subpara-  
8 graph (A)—

9 “(i) in accordance with the timelines  
10 for submission under subsection (c), if the  
11 establishment is engaged in any activity  
12 described in subsection (b)(1) on the effec-  
13 tive date of this section, unless the Sec-  
14 retary establishes by guidance a date later  
15 than such date for all or a category of such  
16 establishments; or

17 “(ii) not later than 30 days prior to  
18 engaging in any activity described in sub-  
19 section (b)(1), if the establishment is not  
20 engaged in any activity described in this  
21 paragraph on the effective date of this sec-  
22 tion.

23 “(2) REGISTRATION NUMBERS.—The Secretary  
24 may assign a registration number to any person or  
25 an establishment registration number to any estab-



1        lishment registered in accordance with this section.  
2        Registration information shall be made publicly  
3        available by publication on the website maintained  
4        by the Food and Drug Administration, in accord-  
5        ance with subsection (d).

6            “(3) INSPECTION.—Each person or establish-  
7        ment that is required to be registered with the Sec-  
8        retary under this section shall be subject to inspec-  
9        tion pursuant to section 704.

10        “(b) LISTING INFORMATION FOR IN VITRO CLINICAL  
11        TESTS.—

12            “(1) IN GENERAL.—Each person who—

13                    “(A) is a developer; and

14                    “(B) introduces or proposes to begin the  
15        introduction or delivery for introduction into  
16        interstate commerce through an exemption  
17        under subsection (a)(1), (a)(2), (a)(3), or (g) of  
18        section 587C or section 587G or through the  
19        filing of an application under section 587B or  
20        section 587D,

21        shall submit a listing to the Secretary containing the  
22        information described in paragraph (2), or (4), as  
23        applicable, in accordance with the applicable sched-  
24        ule described under subsection (c). Such listing shall  
25        be prepared in such form and manner as the Sec-

1       retary may specify in guidance. Listing information  
2       shall be submitted through the comprehensive test  
3       information system in accordance with section 587T,  
4       as appropriate.

5           “(2) SUBMISSIONS.—Each developer submitting  
6       a listing under paragraph (1) shall electronically  
7       submit to the comprehensive test information system  
8       described in section 587T the following information,  
9       as applicable, for each in vitro clinical test for which  
10      such person is a developer in the form and manner  
11      prescribed by the Secretary, taking into account the  
12      least burdensome requirements under section  
13      587AA(c):

14           “(A) Name of the establishment and its es-  
15      tablishment registration number.

16           “(B) Contact information for the official  
17      correspondent for the listing.

18           “(C) Name (common name and trade  
19      name, if applicable) of the in vitro clinical test  
20      and its test listing number (when available).

21           “(D) The certificate number for any lab-  
22      oratory certified by the Secretary under section  
23      353 of the Public Health Service Act that  
24      meets the requirements to perform high-com-  
25      plexity testing and that is the developer of the

1 in vitro clinical test, and the certificate number  
2 under such section for any laboratory that is  
3 performing the test, is within the same cor-  
4 porate organization, and has common ownership  
5 by the same parent corporation.

6 “(E) Whether the in vitro clinical test is,  
7 as applicable, offered as a test approved under  
8 section 587B, offered under a granted tech-  
9 nology certification order, or offered as an ex-  
10 empt in vitro clinical test under section 587C or  
11 587G.

12 “(F) Indications for use information under  
13 section 587(10).

14 “(G) A brief summary of the analytical  
15 and clinical performance of the in vitro clinical  
16 test, and as applicable, the lot release criteria.

17 “(H) A brief description of conformance  
18 with any applicable mitigating measures, re-  
19 strictions, and standards.

20 “(I) Representative labeling for the in vitro  
21 clinical test, as appropriate.

22 “(3) TEST LISTING NUMBER.—The Secretary  
23 may assign a test listing number to each in vitro  
24 clinical test that is the subject of a listing under this  
25 section. The process for assigning test listing num-

1       bers may be established through guidance, and may  
2       include the recognition of standards, formats, or  
3       conventions developed by a third-party organization.

4               “(4) GRANDFATHERED TESTS.—A developer of-  
5       fering a test that is a grandfathered in vitro clinical  
6       test under section 587G(a) shall submit listing infor-  
7       mation required under subparagraphs (A) through  
8       (F) of paragraph (2), and may submit a statement  
9       of the performance specifications for such in vitro  
10      clinical tests.

11              “(5) EXEMPT TESTS.—A developer of an in  
12      vitro clinical test who introduces or proposes to  
13      begin the introduction or delivery for introduction  
14      into interstate commerce that is otherwise exempt  
15      from the requirement to submit listing information  
16      pursuant to an exemption under section 587C may  
17      submit listing information under this subsection.

18              “(c) TIMELINES FOR SUBMISSION OF LISTING IN-  
19      FORMATION.—

20              “(1) IN GENERAL.—The timelines for submis-  
21      sion of registration and listing under subsections (a)  
22      and (b) are as follows:

23              “(A) For an in vitro clinical test that was  
24      listed as a device under section 510(j) prior to  
25      the effective date of this section, a person shall

1 maintain a device listing under section 510  
2 until such time as the system for submitting  
3 the listing information required under sub-  
4 section (b) becomes available and thereafter  
5 shall submit the listing information not later  
6 than the later of 1 year after the system for  
7 submitting the listing under this section be-  
8 comes available or the effective date of this sec-  
9 tion.

10 “(B) For an in vitro clinical test that is  
11 subject to grandfathering under section  
12 587G(a) a person shall submit the listing infor-  
13 mation required under subsection (b)(4) within  
14 10 calendar days of offering the test after the  
15 effective date of this section.

16 “(C) For an in vitro clinical test that is  
17 not described in subparagraph (A) or (B), a  
18 person shall submit the required listing infor-  
19 mation as follows:

20 “(i) For an in vitro clinical test that  
21 is not exempt from premarket approval  
22 under section 587B, a person shall submit  
23 the required listing information, prior to  
24 offering the in vitro clinical test and not  
25 later than 30 business days after the date

1 of approval of the premarket approval ap-  
2 plication.

3 “(ii) For an in vitro clinical test that  
4 is exempt from premarket review under  
5 section 587C, the required listing informa-  
6 tion shall be submitted prior to offering  
7 the in vitro clinical test.

8 “(2) UPDATES.—

9 “(A) UPDATES AFTER CHANGES.—Each  
10 developer required to submit listing information  
11 under this section shall update such informa-  
12 tion within 10 business days of any change that  
13 causes any previously listed information to be  
14 inaccurate or incomplete.

15 “(B) ANNUAL UPDATES.—Each developer  
16 required to submit listing information under  
17 this section shall update its information annu-  
18 ally during the period beginning on October 1  
19 and ending on December 31 of each year.

20 “(d) PUBLIC AVAILABILITY OF LISTING INFORMA-  
21 TION.—

22 “(1) IN GENERAL.—Listing information sub-  
23 mitted pursuant to this section shall be made pub-  
24 licly available on the website of the Food and Drug  
25 Administration in accordance with paragraph (3).

1           “(2) CONFIDENTIALITY.—Listing information  
2           for an in vitro clinical test that is subject to pre-  
3           market approval or technology certification shall re-  
4           main confidential until such date as the in vitro clin-  
5           ical test receives the applicable premarket approval  
6           or the developer receives a technology certification  
7           order and for subsequent tests introduced under a  
8           technology certification order until their introduc-  
9           tion.

10           “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY  
11           REQUIREMENTS.—The public listing requirements of  
12           this subsection shall not apply to any registration  
13           and listing information submitted under subsection  
14           (a) or (b), if the Secretary determines that such in-  
15           formation—

16                   “(A) is a trade secret or confidential com-  
17                   mercial or financial information; or

18                   “(B) if posted, could compromise national  
19                   security.

20           “(e) SUBMISSION OF INFORMATION BY ACCREDITED  
21           PERSONS.—If agreed upon by the developer, the informa-  
22           tion required under this section may be submitted by a  
23           person accredited under section 587Q.

24           **“SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.**

25           “(a) APPLICABILITY.—

1           “(1) IN GENERAL.—Each developer shall estab-  
2           lish and maintain quality requirements in accord-  
3           ance with the applicable requirements set forth in  
4           subsection (b).

5           “(2) CERTIFIED LABORATORY REQUIRE-  
6           MENTS.—A developer shall establish and maintain  
7           quality requirement under subsection (b)(2) or  
8           (b)(3), as applicable, if such developer is a clinical  
9           laboratory certified by the Secretary under section  
10          353 of the Public Health Service Act that—

11                   “(A) is certified to perform high-com-  
12                   plexity testing;

13                   “(B) develops an in vitro clinical test that  
14                   is for use only—

15                           “(i) within the laboratory certified by  
16                           the Secretary under such section 353 in  
17                           which such test was developed; or

18                           “(ii) within another laboratory cer-  
19                           tified by the Secretary under such section  
20                           353 if such laboratory is—

21                                   “(I) within the same corporate  
22                                   organization and has common owner-  
23                                   ship by the same parent corporation  
24                                   as the laboratory in which the test  
25                                   was developed; or



1                   “(II) within a public health lab-  
2                   oratory network coordinated or man-  
3                   aged by the Centers for Disease Con-  
4                   trol and Prevention, if the test is de-  
5                   veloped by a public health laboratory  
6                   or the Centers for Disease Control  
7                   and Prevention; and

8                   “(C) does not manufacture, produce, or  
9                   distribute in vitro clinical tests other than lab-  
10                  oratory test protocols.

11                  “(3) REGULATIONS.—The Secretary shall pro-  
12                  mulgate quality system regulations implementing  
13                  this section. In promulgating such regulations under  
14                  this section, the Secretary shall consider whether,  
15                  and to what extent, international harmonization is  
16                  appropriate.

17                  “(4) QUALITY SYSTEMS FOR HYBRID DEVEL-  
18                  OPERS OF BOTH LABORATORY TEST PROTOCOLS AND  
19                  OTHER IN VITRO CLINICAL TESTS.—An entity that  
20                  develops both laboratory test protocols and other in  
21                  vitro clinical tests shall comply with subsection  
22                  (b)(1) for activities related to the development of  
23                  any in vitro clinical test that is not a laboratory test  
24                  protocol and with subsection (b)(2) or (b)(3), as ap-

1 plicable, for activities related to the development of  
2 any laboratory test protocol.

3 “(b) QUALITY REQUIREMENTS.—

4 “(1) IN GENERAL.—The quality requirements  
5 applicable under this section shall—

6 “(A) avoid duplication of regulations and  
7 guidance under section 353 of the Public  
8 Health Service Act, such that laboratories  
9 would not be subject to conflicting regulatory  
10 obligations with respect to the same activity;

11 “(B) not apply to laboratory operations;  
12 and

13 “(C) include, as applicable, subject to sub-  
14 paragraphs (A) and (B) and paragraphs (2)  
15 and (3)—

16 “(i) management responsibilities;

17 “(ii) quality audits;

18 “(iii) personnel;

19 “(iv) design controls;

20 “(v) document controls;

21 “(vi) purchasing controls;

22 “(vii) identification and traceability;

23 “(viii) production and process con-  
24 trols;

25 “(ix) acceptance activities;

- 1 “(x) nonconforming in vitro clinical  
2 tests;  
3 “(xi) corrective and preventive action;  
4 “(xii) labeling and packaging controls;  
5 “(xiii) handling, storage, distribution,  
6 and installation;  
7 “(xiv) complaints and records;  
8 “(xv) servicing; and  
9 “(xvi) statistical techniques.

10 “(2) EXCEPTION FOR LABORATORY TEST PRO-  
11 TOCOLS.—Developers that are developing test proto-  
12 cols for use as described in subsection (a)(2)(B)(i)  
13 are exempt from the requirements under paragraph  
14 (1)(C) except for the requirements described in  
15 clauses (iv), (ix), (xi), and (xiv) of such paragraph.

16 “(3) QUALITY REQUIREMENTS FOR CERTAIN  
17 LABORATORIES DISTRIBUTING LABORATORY TEST  
18 PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC  
19 HEALTH NETWORKS.—Quality requirements applica-  
20 ble to the developer who is distributing a laboratory  
21 test protocol as described in subsection (a)(2)(B)(ii)  
22 shall consist of the following:

- 23 “(A) Clauses (iv), (ix), (xi), (xiv), (xii) of  
24 paragraph (1)(B).

1           “(B) The requirement to maintain records  
2           of the laboratories to which the laboratory test  
3           protocol is distributed.

4           “(c) REGULATIONS.—In implementing quality re-  
5           quirements for test developers that participate in inter-  
6           national audit programs under this section, the Secretary  
7           shall—

8           “(1) for purposes of facilitating international  
9           harmonization, consider whether the developer par-  
10          ticipates in an international audit program in which  
11          the United States participates and recognizes com-  
12          pliance with, or conformance to, such standards rec-  
13          ognized by the Secretary; and

14          “(2) ensure a least burdensome approach de-  
15          scribed in section 587AA(c) by leveraging, to the ex-  
16          tent applicable, the quality assurance requirements  
17          applicable to developers certified by the Secretary  
18          under section 353 of the Public Health Service Act.

19   **“SEC. 587L. LABELING REQUIREMENTS.**

20          “(a) IN GENERAL.—An in vitro clinical test shall  
21          bear or be accompanied by labeling, as applicable, that  
22          meets the requirements set forth in subsections (b) and  
23          (c), unless such test is exempt under subsection (d) or (e).

24          “(b) LABELS.—

1           “(1) IN GENERAL.—The label of an in vitro  
2           clinical test, shall meet the requirements set forth in  
3           paragraph (2) if there is an immediate container to  
4           which the label is applied.

5           “(2) REGULATIONS.—The label of an in vitro  
6           clinical test shall state the name and place of busi-  
7           ness of its developer and meet the requirements set  
8           forth in regulations promulgated in accordance with  
9           this section.

10          “(c) LABELING.—

11           “(1) IN GENERAL.—Labeling of an in vitro clin-  
12           ical test, including labeling in the form of a package  
13           insert, website, standalone laboratory reference docu-  
14           ment, or other similar document shall include—

15           “(A) adequate directions for use and shall  
16           meet the requirements set forth in regulations  
17           promulgated under this section, except as pro-  
18           vided in subsection (d) or (e); and

19           “(B) the information described in para-  
20           graph (2), as applicable.

21           “(2) CONTENT.—Labeling of an in vitro clinical  
22           test shall include—

23           “(A) the test listing number that was pro-  
24           vided to the developer at the time of listing;

1           “(B) information to facilitate reporting an  
2           adverse event;

3           “(C) information regarding accessing the  
4           performance summary data displayed in the  
5           listing database for the test;

6           “(D) the indications for use of the in vitro  
7           clinical test; and

8           “(E) any warnings, contraindications, or  
9           limitations.

10          “(3) PUBLIC AVAILABILITY OF INFORMATION.—

11          The Secretary shall make all of the information de-  
12          scribed in paragraph (2) with respect to each in  
13          vitro clinical test available to the public, as applica-  
14          ble, in accordance with section 587T, except to the  
15          extent that the Secretary determines that such infor-  
16          mation—

17                 “(A) is trade secret or confidential com-  
18                 mercial or financial information; or

19                 “(B) if posted, could compromise national  
20                 security.

21          “(4) ADDITIONAL REQUIREMENTS.—Labeling  
22          for an in vitro clinical test used for  
23          immunoematology testing shall meet the applicable  
24          requirements set forth in part 660 of title 21, Code  
25          of Federal Regulations (or any successor regula-

1 tions), related to the labeling of blood grouping re-  
2 agents, reagent red blood cells, and anti-human  
3 globulin.

4 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-  
5 MENTS.—

6 “(1) IN GENERAL.—

7 “(A) IN GENERAL.—With respect to an in  
8 vitro clinical test that meets the criteria of sub-  
9 paragraph (B), the ‘state in one place’ regula-  
10 tions under section 809.10(b) of title 21, Code  
11 of Federal Regulations (or any successor regu-  
12 lations) may be satisfied by the laboratory post-  
13 ing such information on its website or in mul-  
14 tiple documents, if such documents are main-  
15 tained and accessible in one place.

16 “(B) APPLICABLE TESTS.—An in vitro  
17 clinical test meets the criteria of this subpara-  
18 graph if such test is—

19 “(i) developed by a laboratory cer-  
20 tified by the Secretary under section 353  
21 of the Public Health Service Act that  
22 meets the requirements to perform tests of  
23 high-complexity; and

24 “(ii) performed in—

1 “(I) the same laboratory in which  
2 such test was developed; or

3 “(II) by another laboratory cer-  
4 tified by the Secretary under section  
5 353 of the Public Health Service Act  
6 that—

7 “(aa) meets the require-  
8 ments to perform tests of high  
9 complexity; and

10 “(bb) is under common own-  
11 ership and control as the labora-  
12 tory that developed the test.

13 “(2) TEST INSTRUMENT LABELING.—Unless  
14 the instrument is the entire test system, the labeling  
15 for an instrument is not required to bear the infor-  
16 mation indicated in paragraphs (3), (4), (5), (7),  
17 (8), (9), (10), (11), (12), and (13) of section  
18 809.10(b) of title 21, Code of Federal Regulations  
19 (or any successor regulations).

20 “(3) REAGENT LABELING.—For purposes of  
21 compliance with subsection (c)(1), the labeling for a  
22 reagent intended for use as a replacement in an in  
23 vitro clinical test may be limited to that information  
24 necessary to identify the reagent adequately and to  
25 describe its proper use in the test.



1           “(4) INVESTIGATIONAL USE.—A shipment or  
2 other delivery of an in vitro clinical test for inves-  
3 tigational use pursuant to section 587S shall be ex-  
4 empt from the labeling requirements of subsections  
5 (b) and (c)(1) and from any standard promulgated  
6 through regulations, except as required under sec-  
7 tion 353 of the Public Health Service Act or section  
8 587R of this Act.

9           “(5) GENERAL PURPOSE LABORATORY RE-  
10 AGENTS.—The labeling of general purpose labora-  
11 tory reagents (such as hydrochloric acid) whose uses  
12 are generally known by persons trained in their use  
13 need not bear the directions for use required by sub-  
14 section (c)(1)(A).

15           “(6) OVER-THE-COUNTER TEST SPECIMEN RE-  
16 CEPTACLE LABELING.—The labeling for over-the-  
17 counter test specimen receptacles for drugs of abuse  
18 testing shall bear the name and place of business of  
19 the developer included in the registration under sec-  
20 tion 587J and any information specified in applica-  
21 ble regulations promulgated under this section, in  
22 language appropriate for the intended users.

23           “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-  
24 PILE.—

1           “(1) IN GENERAL.—The Secretary may grant  
2           an exception or alternative to any provision listed in  
3           this section, unless explicitly required by a statutory  
4           provision outside this subchapter, for specified lots,  
5           batches, or other units of an in vitro clinical test, if  
6           the Secretary determines that compliance with such  
7           labeling requirement could adversely affect the avail-  
8           ability of such products that are, or will be, included  
9           in the Strategic National Stockpile under section  
10          319F–2 of the Public Health Service Act.

11          “(2) REGULATIONS.—The Secretary may issue  
12          regulations amending section 809.11 of title 21,  
13          Code of Federal Regulations (or any successor regu-  
14          lation) to apply in full or in part to in vitro clinical  
15          tests and in vitro clinical test developers.

16          “(f) REGULATIONS.—The Secretary shall issue regu-  
17          lations related to standardized, general content and for-  
18          mat for in vitro clinical test labeling pursuant to this sub-  
19          section.

20          **“SEC. 587M. ADVERSE EVENT REPORTING.**

21          “(a) IN GENERAL.—Each in vitro clinical test devel-  
22          oper shall establish and maintain a system for establishing  
23          and maintaining records of adverse events and reporting  
24          adverse events in accordance with this section.

1       “(b) SUBMISSION OF INDIVIDUAL REPORTS.—A de-  
2     veloper shall submit an individual adverse event report not  
3     later than 5 calendar days after the developer receives or  
4     becomes aware of an adverse event that reasonably sug-  
5     gests that an in vitro clinical test may—

6               “(1) have caused or contributed to a patient or  
7     user death; or

8               “(2) present an imminent threat to public  
9     health.

10       “(c) SUBMISSION OF QUARTERLY REPORTS.—As ap-  
11     plicable, a developer shall submit quarterly reports that  
12     include any in vitro clinical test errors and serious injuries  
13     that occurred during the applicable quarter. Such quar-  
14     terly reports shall be submitted not later than the end of  
15     the quarter following the quarter in which the developer  
16     receives or becomes aware of such adverse events.

17       “(d) DEFINITIONS.—For the purposes of this sec-  
18     tion—

19               “(1) the term ‘in vitro clinical test error’ means  
20     a failure of an in vitro clinical test to meet its per-  
21     formance specifications, or to otherwise perform as  
22     intended by the developer, including an inaccurate  
23     result resulting from such failure; and

24               “(2) the term ‘serious injury’ means—

1           “(A) a significant delay in a diagnosis that  
2           results in the absence, delay, or discontinuation  
3           of critical medical treatment or that irreversibly  
4           or seriously and negatively alters the course of  
5           a disease or condition; or

6           “(B) an injury that—

7                   “(i) is life threatening;

8                   “(ii) results in permanent impairment  
9                   of a body function or permanent damage  
10                  to a body structure; or

11                  “(iii) necessitates medical or surgical  
12                  intervention to preclude permanent impair-  
13                  ment of a body function or permanent  
14                  damage to a body structure.

15           “(e) REGULATIONS.—The Secretary shall promulgate  
16 regulations to implement this section.

17 **“SEC. 587N. CORRECTIONS AND REMOVALS.**

18           “(a) REGULATIONS.—The Secretary shall promulgate  
19 regulations, or amend existing regulations, as appropriate,  
20 to implement this section.

21           “(b) REPORTS OF CORRECTIONS AND REMOVALS.—

22                   “(1) IN GENERAL.—Each in vitro clinical test  
23                   developer shall report to the Secretary any correc-  
24                   tion or removal of an in vitro clinical test under-

1 taken by such developer if the correction or removal  
2 was undertaken—

3 “(A) to reduce the risk to health posed by  
4 the in vitro clinical test; or

5 “(B) to remedy a violation of this Act  
6 caused by the in vitro clinical test which may  
7 present a risk to health.

8 “(2) EXCEPTION FOR IN VITRO CLINICAL TESTS  
9 OFFERED UNDER A TECHNOLOGY CERTIFICATION  
10 ORDER.—For any eligible test offered under a tech-  
11 nology certification order under section 587D, a cor-  
12 rection and removal report for any correction or re-  
13 moval of an in vitro clinical test should demonstrate  
14 that the issue or issues causing the correction or re-  
15 moval do not adversely impact the ability of other in  
16 vitro clinical tests offered under the same technology  
17 certification order to meet the applicable standard.

18 “(c) TIMING.—A developer shall submit any report  
19 required under this subsection to the Secretary within 15  
20 business days of initiating such correction or removal.

21 “(d) RECORDKEEPING.—A developer of an in vitro  
22 clinical test that undertakes a correction or removal of an  
23 in vitro clinical test which is not required to be reported  
24 under this subsection shall keep a record of such correc-  
25 tion or removal.

1       “(e) RECALL COMMUNICATIONS.—Upon the report-  
2 ing of a correction or removal by the developer—

3           “(1) the Secretary shall classify such correction  
4 or removal under this section within 45 calendar  
5 days; and

6           “(2) not later than 70 calendar days after the  
7 developer or other responsible party notifies the Sec-  
8 retary that it has completed a recall action, the Sec-  
9 retary shall provide the developer or other respon-  
10 sible party with a written statement closing the re-  
11 call action or stating the reasons the Secretary can-  
12 not close the recall at that time.

13 **“SEC. 5870. RESTRICTED IN VITRO CLINICAL TESTS.**

14       “(a) APPLICABILITY.—

15           “(1) IN GENERAL.—For the types of in vitro  
16 clinical tests described in paragraph (3), the Sec-  
17 retary may require, in issuing an approval of an in  
18 vitro clinical test under section 587B, granting a  
19 technology certification order under section 587D, or  
20 in issuing a determination under section 587F(a), or  
21 by issuing a regulation, that such test, or category  
22 of tests, be restricted to sale, distribution, or use  
23 upon such conditions as the Secretary may prescribe  
24 under paragraph (2).

1           “(2) CONDITIONS.— The Secretary may pre-  
2       scribe conditions under this section, based on avail-  
3       able evidence, with respect to an in vitro clinical test  
4       described in paragraph (3), that are determined to  
5       be needed due to the potential for harmful effect of  
6       such test (including any resulting absence, signifi-  
7       cant delay, or discontinuation of appropriate medical  
8       treatment), and are necessary to ensure that the test  
9       meets the applicable standard.

10           “(3) IN VITRO CLINICAL TESTS SUBJECT TO  
11       RESTRICTIONS.—The restrictions or conditions au-  
12       thorized under this section may be applied by the  
13       Secretary to any high-risk or moderate-risk in vitro  
14       clinical test, prescription home-use in vitro clinical  
15       test, direct-to-consumer in vitro clinical test, or over-  
16       the-counter in vitro clinical test.

17           “(b) LABELING AND ADVERTISING OF A RESTRICTED  
18       IN VITRO CLINICAL TEST.—The labeling and advertising  
19       of an in vitro clinical test to which restrictions apply under  
20       subsection (a) shall bear such appropriate statements of  
21       the restrictions as the Secretary may prescribe in an ap-  
22       proval under section 587B, an order under section 587D,  
23       a determination under section 587F(a), or in regulation,  
24       as applicable.

1 “(c) DEVICE RESTRICTIONS.—An in vitro clinical  
2 test that was offered as a restricted device prior to the  
3 date of enactment of this subchapter—

4 “(1) shall continue to comply with the applica-  
5 ble restrictions under section 515 or section 520(e)  
6 until this subchapter takes effect; and

7 “(2) except for in vitro clinical tests required to  
8 meet the requirements of section 809.30 of title 21,  
9 Code of Federal Regulations prior to the effective  
10 date of this subchapter specified in section  
11 5(a)(1)(A) of the VALID Act of 2023, such restric-  
12 tions described in paragraph (1) shall be deemed to  
13 be restrictions under this subchapter as of such ef-  
14 fective date.

15 **“SEC. 587P. APPEALS.**

16 “(a) SIGNIFICANT DECISION.—

17 “(1) IN GENERAL.—The Secretary shall—

18 “(A) maintain a substantive summary of  
19 the scientific and regulatory rationale for any  
20 significant decision of the Food and Drug Ad-  
21 ministration pursuant to section 587F, regard-  
22 ing—

23 “(i) the submission of an application  
24 for, or a review of, an in vitro clinical test  
25 under section 587B or section 587D;



1 “(ii) an exemption under section  
2 587C; or

3 “(iii) any requirements for mitigation  
4 measures to an in vitro clinical test or cat-  
5 egory of in vitro clinical tests; and

6 “(B) include in such summaries docu-  
7 mentation of significant controversies or dif-  
8 ferences of opinion and the resolution of such  
9 controversies or differences of opinion.

10 “(2) PROVISION OF DOCUMENTATION.—Upon  
11 request, the Secretary shall furnish a substantive  
12 summary described in paragraph (1) to the person  
13 who has made, or is seeking to make, a submission  
14 described in such paragraph.

15 “(3) APPLICATION OF LEAST BURDENSOME RE-  
16 QUIREMENTS.—The substantive summary required  
17 under this subsection shall include a brief statement  
18 regarding how the least burdensome requirements  
19 were considered and applied consistent with section  
20 587AA(c), as applicable.

21 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

22 “(1) REQUEST FOR SUPERVISORY REVIEW OF  
23 SIGNIFICANT DECISION.—A developer may request a  
24 supervisory review of the significant decision de-  
25 scribed in subsection (a)(1). Such review may be

1 conducted at the next supervisory level or higher  
2 above the agency official who made the significant  
3 decision.

4 “(2) SUBMISSION OF REQUEST.—A developer  
5 requesting a supervisory review under paragraph (1)  
6 shall submit such request to the Secretary not later  
7 than 30 days after the decision for which the review  
8 is requested and shall indicate in the request wheth-  
9 er such developer seeks an in-person meeting or a  
10 teleconference review.

11 “(3) TIMEFRAME.—The Secretary shall sched-  
12 ule an in-person or teleconference review, if so re-  
13 quested, not later than 30 days after such request  
14 is made. The Secretary shall issue a decision to the  
15 developer requesting a review under this subsection  
16 not later than 45 days after the request is made  
17 under paragraph (1), or, in the case of a developer  
18 who requests an in-person meeting or teleconference,  
19 30 days after such meeting or teleconference.

20 “(c) ADVISORY PANELS.—The process established  
21 under subsection (a) shall permit the appellant to request  
22 review by an advisory committee established under section  
23 587G when there is a dispute involving substantial sci-  
24 entific fact. If an advisory panel meeting is held, the Sec-  
25 retary shall make a determination under this subsection

1 not later than 45 days after the requested advisory com-  
2 mittee meeting has concluded.

3 “(d) **LEAST BURDENSOME REVIEW.**—Any developer  
4 who has submitted an application under section 587B or  
5 587D may request a supervisory review of a request for  
6 additional information during an evaluation of such sub-  
7 mission within 60 calendar days of receipt of the addi-  
8 tional information request from the Secretary.

9 “(e) **AVAILABILITY OF ALL REMEDIES.**—The proce-  
10 dures set forth in this section shall be in addition to, and  
11 not in lieu of, other remedies available to the developer.

12 **“SEC. 587Q. ACCREDITED PERSONS.**

13 “(a) **IN GENERAL.**—

14 “(1) **AUTHORIZATION.**—Beginning on the date  
15 of enactment of the VALID Act of 2023, the Sec-  
16 retary shall accredit persons for any of the following  
17 purposes:

18 “(A) Reviewing applications for premarket  
19 approval under section 587B and making find-  
20 ings with respect to such applications.

21 “(B) Reviewing applications for technology  
22 certification under section 587D and making  
23 recommendations to the Secretary with respect  
24 to such applications.

1           “(C) Conducting inspections as specified in  
2           subsection (c) of in vitro clinical test developers  
3           and other persons required to register pursuant  
4           to section 587J.

5           “(2) PERSONS SUBMITTING APPLICATIONS.—A  
6           person submitting an application for premarket ap-  
7           proval under section 587B or an application for  
8           technology certification under section 587D may  
9           submit such application to the Secretary or to a per-  
10          son accredited pursuant to subparagraph (A) or (B)  
11          of paragraph (1).

12          “(b) ACCREDITED PERSONS APPLICATION REVIEWS,  
13 FINDINGS AND RECOMMENDATIONS.—

14           “(1) REQUIREMENTS FOR PREMARKET APPLI-  
15          CATION.—

16           “(A) REVIEW, FINDING, AND REC-  
17          COMMENDATION REQUIREMENTS.—An accredited  
18          person receiving an application for premarket  
19          approval under section 587B shall either—

20           “(i) provide to the Secretary, together  
21          with the application for premarket ap-  
22          proval submitted by the applicant, a rec-  
23          ommendation based on a finding that the  
24          criteria for approval of the application  
25          under section 587B(e)(2)(A) are met and

1 issue a copy of such finding to the appli-  
2 cant, which finding shall plainly state—

3 “(I) the basis for the accredited  
4 person’s finding that the criteria  
5 under section 587B(e)(2)(A) are met;  
6 and

7 “(II) any proposed restrictions,  
8 mitigating measures, or conditions of  
9 approval under section 587B(e)(2)(B),  
10 as applicable; or

11 “(ii) provide a notification to the ap-  
12 plicant that the accredited person cannot  
13 find that the criteria for approval of the  
14 application under section 587B(e)(2)(A)  
15 are met and the reasons for such decision.

16 “(B) REQUESTING MISSING OR CLARI-  
17 FYING INFORMATION.—After receipt of an ap-  
18 plication from an accredited person under this  
19 section, the Secretary may request missing or  
20 clarifying information from the applicant con-  
21 cerning the application, which the accredited  
22 person shall promptly provide.

23 “(C) SECRETARY ACTION ON REC-  
24 OMMENDATION THAT APPROVAL CRITERIA ARE  
25 MET.—If the accredited person transmits a rec-

1           ommendation to the Secretary under subpara-  
2           graph (A)(i), then prior to the date that is 45  
3           calendar days after the transmittal date, the  
4           Secretary shall consider such recommendation  
5           and make a determination to—

6                   “(i) approve the application for pre-  
7                   market approval under section 587B(e)(2)  
8                   with appropriate restrictions, mitigating  
9                   measures, or conditions of approval, as ap-  
10                  plicable; or

11                   “(ii) deny approval of the application  
12                   by issuing a written notice that reflects ap-  
13                   propriate management input and concur-  
14                   rence to the accredited person and the ap-  
15                   plicant detailing the scientific basis for the  
16                   Secretary’s determination that the criteria  
17                   for issuance of an approval under section  
18                   587B(e)(2)(A) have not been met.

19                   “(D) EFFECT OF INACTION ON REC-  
20                   COMMENDATION.—If the Secretary fails to take  
21                   an action under subparagraph (C) the Sec-  
22                   retary shall—

23                   “(i) within 45 calendar days after the  
24                   transmittal date, provide written feedback  
25                   to the applicant that—

1           “(I) includes all outstanding  
2 issues with the application preventing  
3 the Secretary from taking an action  
4 under subparagraph (B);

5           “(II) reflects appropriate man-  
6 agement input and concurrence; and

7           “(III) includes action items for  
8 the Secretary, the applicant, or both,  
9 as appropriate, with an estimated date  
10 of completion for the Secretary and  
11 the applicant to complete their respec-  
12 tive tasks, as applicable; and

13           “(ii) promptly schedule a meeting or  
14 teleconference to discuss the feedback pro-  
15 vided under clause (i), unless the Secretary  
16 and applicant agree that the outstanding  
17 issues are adequately presented through  
18 written correspondence and a meeting or  
19 teleconference is not necessary.

20           “(2) REQUIREMENTS FOR TECHNOLOGY CER-  
21 TIFICATION.—

22           “(A) REVIEW AND RECOMMENDATION RE-  
23 QUIREMENTS.—An accredited person receiving  
24 an application for technology certification under  
25 section 587D shall either—

1           “(i) provide to the Secretary, together  
2           with the application for technology certifi-  
3           cation submitted by the applicant, a rec-  
4           ommendation that the criteria for issuance  
5           of a technology certification order under  
6           section 587D(d)(3) are met and issue a  
7           copy of such recommendation to the appli-  
8           cant, which recommendation shall plainly  
9           state the basis for the accredited person’s  
10          recommendation that the criteria under  
11          section 587D(d)(3) are met; or

12          “(ii) provide a notification to the ap-  
13          plicant that the accredited person cannot  
14          recommend that the criteria for issuance of  
15          a technology certification order under sec-  
16          tion 587D(d)(3) are met and the reasons  
17          for such decision.

18          “(B) REQUESTING MISSING OR CLARI-  
19          FYING INFORMATION.—After receipt of an ap-  
20          plication under this section, the accredited per-  
21          son may request missing or clarifying informa-  
22          tion from the applicant concerning the applica-  
23          tion, which the applicant shall promptly pro-  
24          vide.



1           “(C) SECRETARY ACTION ON REC-  
2           COMMENDATION FOR ISSUANCE OF A TECH-  
3           NOLOGY CERTIFICATION ORDER.—If the accred-  
4           ited person transmits a recommendation to the  
5           Secretary under clause (i) of subparagraph (A),  
6           then prior to the date that is 60 calendar days  
7           after the transmittal date the Secretary shall—

8                   “(i) issue the technology certification  
9                   order under section 587D(d)(3), consistent  
10                  with such recommendation from the ac-  
11                  credited person; or

12                   “(ii) deny approval of the application  
13                   by issuing a written notice to the accred-  
14                   ited person and the applicant detailing the  
15                   scientific basis for a determination by the  
16                   Secretary that the criteria for issuance of  
17                   a technology certification order under sec-  
18                   tion 587D(d)(3) have not been met.

19           “(c) REQUIREMENTS FOR INSPECTIONS.—

20                   “(1) IN GENERAL.—When conducting inspec-  
21                   tion, persons accredited under subsection (a)(1)(C)  
22                   shall record in writing their specific observations and  
23                   shall present their observations to the designated  
24                   representative of the inspected establishment.

1           “(2) INSPECTION REPORT REQUIREMENTS.—  
2           Each person accredited under subsection (a)(1)(C)  
3           shall prepare and submit to the Secretary an inspec-  
4           tion report in a form and manner designated by the  
5           Secretary for conducting inspections. Any statement  
6           or representation made by an employee or agent of  
7           an establishment to a person accredited to conduct  
8           inspections under subsection (a)(1)(C) shall be sub-  
9           ject to section 1001 of title 18, United States Code.

10           “(3) SAVINGS CLAUSE.—Nothing in this section  
11           affects the authority of the Secretary to inspect any  
12           in vitro clinical test developer or other person reg-  
13           istered under section 587J or recognize inspections  
14           conducted by auditing organizations as described  
15           under section 704(g)(15).

16           “(4) INSPECTION LIMITATIONS.—The Secretary  
17           shall ensure that inspections carried out under this  
18           section are not duplicative of inspections carried out  
19           under section 353 of the Public Health Service Act.  
20           Inspections under this section shall be limited to the  
21           data and information necessary—

22                   “(A) for routine surveillance activities of  
23                   facilities associated with an approved applica-  
24                   tion under section 587B or issuance of a tech-

1 nology certification order under section 587D;  
2 or

3 “(B) to meet the requirements for pre-  
4 market approval under section 587B or  
5 issuance of a technology certification order  
6 under section 587D, as applicable.

7 “(d) ACCREDITATION.—

8 “(1) ACCREDITATION PROGRAM.—The Sec-  
9 retary may provide for accreditation under this sec-  
10 tion through programs administered by the Food  
11 and Drug Administration, by other non-Federal gov-  
12 ernment agencies, or by qualified nongovernmental  
13 organizations. A person may be accredited for the  
14 review of applications submitted under sections  
15 587B as described in subsection (a)(1)(A), for the  
16 review of applications submitted under section 587D  
17 as described in subsection (a)(1)(B), and to conduct  
18 inspection activities under subsection (a)(1)(C), or  
19 for a subset of such reviews or activities.

20 “(2) ELIGIBLE PERSONS.—

21 “(A) MINIMUM QUALIFICATIONS.—An ac-  
22 credited person, at a minimum, shall—

23 “(i) not be an employee of the Federal  
24 Government;

1 “(ii) not engage in the activities of a  
2 developer, as defined in section 587(7);

3 “(iii) not be a person required to reg-  
4 ister under section 587J, unless such per-  
5 son has established sufficient processes  
6 and protocols to separate activities to de-  
7 velop in vitro clinical tests and the activi-  
8 ties for which such person would be ac-  
9 credited under subsection (a) and discloses  
10 applicable information under this section;

11 “(iv) not be owned or controlled by,  
12 and shall have no organizational, material,  
13 or financial affiliation with, an in vitro  
14 clinical test developer or other person re-  
15 quired to register under section 587J;

16 “(v) be a legally constituted entity  
17 permitted to conduct the activities for  
18 which it seeks accreditation;

19 “(vi) ensure that the operations of  
20 such person are in accordance with gen-  
21 erally accepted professional and ethical  
22 business practices; and

23 “(vii) include in its request for accred-  
24 itation a commitment to, at the time of ac-  
25 creditation and at any time it is per-

1 forming activities pursuant to this sec-  
2 tion—

3 “(I) certify that the information  
4 reported to the Secretary accurately  
5 reflects the data or protocol reviewed,  
6 and the documented inspection find-  
7 ings, as applicable;

8 “(II) limit work to that for which  
9 competence and capacity are available;

10 “(III) treat information received  
11 or learned, records, reports, and rec-  
12 ommendations as proprietary informa-  
13 tion of the person submitting such in-  
14 formation; and

15 “(IV) in conducting the activities  
16 for which the person is accredited in  
17 respect to a particular in vitro clinical  
18 test, protect against the use of any  
19 employee or consultant who has a fi-  
20 nancial conflict of interest regarding  
21 that in vitro clinical test.

22 “(B) WAIVER.—The Secretary may waive  
23 any requirements in clauses (i), (ii), (iii), or (iv)  
24 of subparagraph (A) upon making a determina-  
25 tion that such person has implemented other

1 appropriate controls sufficient to ensure a com-  
2 petent and impartial review.

3 “(3) ACCREDITATION PROCESS.—

4 “(A) ACCREDITATION PROCESS GUIDANCE  
5 AND REGULATIONS.—Not later than 180 days  
6 after the date of enactment of the VALID Act  
7 of 2023, the Secretary shall issue draft guid-  
8 ance specifying the process for submitting a re-  
9 quest for accreditation and reaccreditation  
10 under this section, including the form and con-  
11 tent of information to be submitted, including  
12 the criteria that the Secretary will consider to  
13 accredit or deny accreditation and, not later  
14 than 1 year after the close of the comment pe-  
15 riod for the draft guidance, issue final guid-  
16 ance.

17 “(B) RESPONSE TO REQUEST.—The Sec-  
18 retary shall respond to a request for accredita-  
19 tion or reaccreditation within 60 calendar days  
20 of the receipt of the request. The Secretary’s  
21 response may be to accredit or reaccredit the  
22 person, to deny accreditation, or to request ad-  
23 ditional information in support of the request.  
24 If the Secretary requests additional informa-  
25 tion, the Secretary shall respond within 60 cal-

1           endar days of receipt of such additional infor-  
2           mation to accredit or deny the accreditation.

3           “(C) TYPE OF ACCREDITATION.—The ac-  
4           creditation or reaccreditation of a person shall  
5           specify the particular activity or activities under  
6           subsection (a) for which such person is accred-  
7           ited, and shall include any limitation to certain  
8           eligible in vitro clinical tests.

9           “(D) PUBLIC LIST.—The Secretary shall  
10          publish on the website of the Food and Drug  
11          Administration a list of persons who are accred-  
12          ited under this section. Such list shall be up-  
13          dated on at least a monthly basis. The list shall  
14          specify the particular activity or activities under  
15          this section for which the person is accredited.

16          “(E) AUDIT.—The Secretary may audit  
17          the performance of persons accredited under  
18          this section for purposes of ensuring that such  
19          persons continue to meet the published criteria  
20          for accreditation, and may modify the scope or  
21          particular activities for which a person is ac-  
22          credited if the Secretary determines that such  
23          person fails to meet one or more criteria for ac-  
24          creditation.

1           “(F) SUSPENSION OR WITHDRAWAL.—The  
2           Secretary may suspend or withdraw accredita-  
3           tion of any person accredited under this section,  
4           after providing notice and an opportunity for an  
5           informal hearing, when such person is substan-  
6           tially not in compliance with the requirements  
7           of this section or the published criteria for ac-  
8           creditation, or poses a threat to public health,  
9           or fails to act in a manner that is consistent  
10          with the purposes of this section.

11          “(G) REACCREDITATION.—Accredited per-  
12          sons may be initially accredited for up to 3  
13          years. After expiration of such initial period,  
14          persons may be recredited for unlimited addi-  
15          tional 5-year periods, as determined by the Sec-  
16          retary.

17          “(e) COMPENSATION OF ACCREDITED PERSONS.—  
18          Compensation of an accredited person shall be determined  
19          by agreement between the accredited person and the per-  
20          son who engages the services of the accredited person, and  
21          shall be paid by the person who engages such services.

22          “(f) INTERNATIONAL HARMONIZATION.—Notwith-  
23          standing any other provision of this section, to facilitate  
24          international harmonization the Secretary may recognize  
25          persons accredited or recognized by governments, who



1 have also entered into information sharing agreements, in-  
2 cluding confidentiality commitments, with the Commis-  
3 sioner of Food and Drugs.

4 “(g) INFORMATION SHARING AGREEMENTS.—An ac-  
5 credited person may enter into an agreement with a test  
6 developer to provide information to the comprehensive test  
7 information system under section 587T, including any re-  
8 quirements under section 587J.

9 “(h) REPORTS.—Not later than 2 years after the ef-  
10 fective date of the VALID Act of 2023, and annually  
11 thereafter for the next 4 years, the Secretary shall post  
12 on the website of the Food and Drug Administration, a  
13 report describing the Secretary’s performance in imple-  
14 menting this section, including the Secretary’s progress in  
15 minimizing duplicative reviews of applications for which  
16 an accredited person finds the criteria for approval are  
17 met. Such reports shall include, for each period—

18 “(1) with regard to premarket approval applica-  
19 tions—

20 “(A) the total number of findings trans-  
21 mitted to the Secretary under subsection  
22 (b)(1)(A)(i);

23 “(B) the total number of determinations  
24 made by the Secretary under subsection

1 (b)(1)(B)(i) within 30 calendar days of the  
2 transmittal date to approve an application;

3 “(C) the total number of determinations  
4 made by the Secretary under subsection  
5 (b)(1)(B)(ii) within 30 calendar days of the  
6 transmittal date to deny approval of an applica-  
7 tion; and

8 “(D) the total number of applications that  
9 were approved and the total number of applica-  
10 tions that were denied approval, after the Sec-  
11 retary failed to make a determination within 30  
12 calendar days of the transmittal date under  
13 subsection (b)(1)(B); and

14 “(2) with regard to applications for technology  
15 certification—

16 “(A) the total number of recommendations  
17 transmitted to the Secretary under subsection  
18 (b)(2)(A)(i);

19 “(B) the total number of determinations  
20 made by the Secretary under subsection  
21 (b)(2)(B)(i) to issue a technology certification  
22 order, including determinations made within 30  
23 days of the transmittal date;

24 “(C) the total number of determinations  
25 made by the Secretary under subsection

1 (b)(2)(B)(ii) to deny the application for tech-  
2 nology certification, including determinations  
3 made within 30 calendar days of the trans-  
4 mittal date; and

5 “(D) the total number of technology cer-  
6 tification orders issued, and the total number of  
7 applications for technology certification that  
8 were denied, including applications denied after  
9 the Secretary failed to make a determination  
10 within 30 calendar days of the transmittal date  
11 under subsection (b)(2)(B).

12 **“SEC. 587R. RECOGNIZED STANDARDS.**

13 “(a) IN GENERAL.—The Secretary may recognize all  
14 or part of appropriate standards established by nationally  
15 or internationally recognized standards development orga-  
16 nizations for which a person may submit a declaration of  
17 conformity in order to meet a requirement under this sub-  
18 chapter to which that standard is applicable. Standards  
19 for in vitro diagnostic devices previously recognized under  
20 section 514(c) shall be considered recognized standards  
21 under this section. Recognized and proposed standards  
22 shall be accessible to the public at no charge. The applica-  
23 tion of any such consensus standard shall only apply pro-  
24 spectively. The Secretary shall issue regulations estab-

1 lishing the criteria and process, for such recognition and  
2 adoption.

3 “(b) AMENDMENT PROCESS.—The procedures estab-  
4 lished in this section or in regulation or guidance issued  
5 under this section shall apply to amendment of an existing  
6 standard.

7 **“SEC. 587S. INVESTIGATIONAL USE.**

8 “(a) IN GENERAL.—Subject to the conditions pre-  
9 scribed in subsections (c), (d), (e), (f), and (g), an in vitro  
10 clinical test for investigational use shall be exempt from  
11 the requirements of this subchapter, other than sections  
12 587A, 587P, 587T, and 587V. The Secretary may amend  
13 parts 50, 54, and 56 of title 21 of the Code of Federal  
14 Regulations to apply to in vitro clinical tests to permit  
15 the investigational use of such tests by experts qualified  
16 by scientific training and experience.

17 “(b) REGULATIONS.—

18 “(1) IN GENERAL.—Not later than 3 years  
19 after the date of enactment of the VALID Act of  
20 2023, the Secretary shall promulgate regulations to  
21 implement this section.

22 “(2) VARIATION.—The requirements in the reg-  
23 ulations promulgated under this section shall take  
24 into account variations based on—

1           “(A) the scope and duration of clinical  
2           testing to be conducted under investigation that  
3           is the subject of such application;

4           “(B) the number of human subjects that  
5           are to be involved in such testing;

6           “(C) the need to permit changes to be  
7           made to the in vitro clinical test involved during  
8           testing conducted in accordance with a plan re-  
9           quired under subsection (c)(6); or

10           “(D) whether the clinical testing of such in  
11           vitro clinical test is for the purpose of devel-  
12           oping data to obtain approval to offer such test.

13           “(c) APPLICATION FOR INVESTIGATIONAL USE.—  
14           The following shall apply with respect to in vitro clinical  
15           tests for investigational use:

16           “(1) SIGNIFICANT RISK AND OTHER STUD-  
17           IES.—In the case of an in vitro clinical test the in-  
18           vestigational use of which poses a significant risk to  
19           the human subject or involves an exception from in-  
20           formed consent for emergency research, a sponsor of  
21           an investigation of such a test seeking an investiga-  
22           tional use exemption shall submit to the Secretary  
23           an investigational use application with respect to the  
24           in vitro clinical test in accordance with paragraphs  
25           (3) and (4).

1           “(2) NON-SIGNIFICANT RISK STUDIES.—In the  
2 case of an in vitro clinical test, the investigational  
3 use of which is not described in paragraph (1)—

4           “(A) the sponsor of such investigation  
5 shall—

6           “(i) ensure such investigation is con-  
7 ducted in compliance with an investiga-  
8 tional plan approved by an institutional re-  
9 view committee and the labeling of the in  
10 vitro clinical test involved clearly and con-  
11 spicuously states, ‘For investigational use  
12 only’, as specified in paragraph (4)(A)(ii);

13           “(ii) ensure each investigator obtains  
14 informed consent as required under part  
15 50, 54, and 56 of title 21, Code of Federal  
16 Regulations (or any successor regulations),  
17 subject to the exceptions set forth in para-  
18 graph (6)(C);

19           “(iii) establish and maintain records  
20 with respect to all requirements in this  
21 subparagraph;

22           “(iv) maintain records and make re-  
23 ports as required by the Secretary pursu-  
24 ant to regulations issued under subsection  
25 (b); and

1           “(v) ensure that investigators monitor  
2           investigations, maintain records and make  
3           reports as required by the Secretary pursu-  
4           ant to regulations issued under subsection  
5           (b); and

6           “(B) the sponsor may rely on any excep-  
7           tion or exemption described in paragraph (4) or  
8           as established by the Secretary in regulations  
9           issued under subsection (b).

10          “(3) APPLICATION.—An investigational use ap-  
11          plication shall be submitted in such time and man-  
12          ner and contain such information as the Secretary  
13          may require in regulation, and shall include an in-  
14          vestigational plan for proposed clinical testing and  
15          assurances that the sponsor submitting the applica-  
16          tion will—

17               “(A) establish and maintain records rel-  
18               evant to the investigation of such in vitro clin-  
19               ical test; and

20               “(B) submit to the Secretary annual re-  
21               ports of data obtained as a result of the inves-  
22               tigational use of the in vitro clinical test during  
23               the period covered by the exemption that the  
24               Secretary reasonably determines will enable the  
25               Secretary—

1 “(i) to ensure compliance with the  
2 conditions for the exemption specified in  
3 paragraph (4);

4 “(ii) to review the progress of the in-  
5 vestigation involved; and

6 “(iii) to evaluate the ability to meet  
7 the applicable standard.

8 “(4) CONDITIONS FOR EXEMPTION.—An appli-  
9 cation for an investigational use exemption with re-  
10 spect to a significant risk study shall be granted if  
11 each of the following conditions is met:

12 “(A) The risks to the subjects of the in  
13 vitro clinical test are outweighed by the antici-  
14 pated benefits of the test to the subjects and  
15 the importance of the knowledge to be gained,  
16 and adequate assurance of informed consent is  
17 provided in accordance with paragraphs (6)(B)  
18 and (6)(C).

19 “(B) The proposed labeling for the in vitro  
20 clinical test involved clearly and conspicuously  
21 states ‘For investigational use only’.

22 “(C) Such other requirements the Sec-  
23 retary determines—

24 “(i) are necessary for the protection  
25 of the public health and safety; and



1                   “(ii) do not unduly delay investiga-  
2                   tion.

3                   “(5) COORDINATION WITH INVESTIGATIONAL  
4                   NEW DRUG APPLICATIONS.—Any requirement for  
5                   the submission of a report to the Secretary pursuant  
6                   to an application for an investigational new drug ex-  
7                   emption involving an in vitro clinical test shall su-  
8                   persede the reporting requirement under paragraph  
9                   (3)(B), but only to the extent the requirement with  
10                  respect to the application for exemption with respect  
11                  to the drug is duplicative of the reporting require-  
12                  ment under such paragraph.

13                  “(6) INVESTIGATIONAL PLAN, PROCEDURES,  
14                  AND CONDITIONS.—With respect to an investiga-  
15                  tional plan submitted under paragraph (3), the  
16                  sponsor submitting such plan shall—

17                         “(A) promptly notify the Secretary of the  
18                         approval or the suspension or termination of  
19                         the approval of such plan by an institutional re-  
20                         view committee;

21                         “(B) in the case of an in vitro clinical test  
22                         made available to investigators for clinical test-  
23                         ing, obtain agreements from each investigator  
24                         that any testing of the in vitro clinical test in-  
25                         volving human subjects will be under such in-

1           investigator’s supervision and in accordance with  
2           paragraph (C) and submit such agreements to  
3           the Secretary that ensure—

4                   “(i) all investigators will comply with  
5                   this section, regulations promulgated or re-  
6                   vised under this section, and applicable  
7                   human subjects regulations; and

8                   “(ii) the investigator will ensure  
9                   that—

10                           “(I) informed consent is obtained  
11                           as required under part 50 of title 21,  
12                           Code of Federal Regulations (or any  
13                           successor regulations), amended to  
14                           apply to in vitro clinical tests; and

15                           “(II) the requirements for insti-  
16                           tutional review board under part 56 of  
17                           title 21 of the Code of Federal Regu-  
18                           lations (or successor regulations),  
19                           amended to apply to in vitro clinical  
20                           tests, are met; and

21                           “(C) ensure that informed consent will be  
22                           obtained from each human subject (or the rep-  
23                           resentative of such subject) of proposed clinical  
24                           testing involving such in vitro clinical test, ex-

1           cept where, subject to such other conditions as  
2           the Secretary may prescribe—

3                   “(i) the proposed clinical testing poses  
4                   no more than minimal risk to the human  
5                   subject and includes appropriate safe-  
6                   guards to protect the rights, safety, and  
7                   welfare of the human subject; or

8                   “(ii) the investigator conducting or  
9                   supervising the clinical testing determines  
10                  in writing that there exists a life-threat-  
11                  ening situation involving the human sub-  
12                  ject of such testing which necessitates the  
13                  use of such in vitro clinical test and it is  
14                  not feasible to obtain informed consent  
15                  from the subject and there is not sufficient  
16                  time to obtain such consent from a rep-  
17                  resentative of such subject.

18                  “(7) CONCURRED BY LICENSED PHYSICIAN.—  
19                  The determination required by paragraph (6)(C)(ii)  
20                  shall be concurred in writing by a licensed physician  
21                  who is not involved in the testing of the human sub-  
22                  ject with respect to which such determination is  
23                  made unless immediate use of the in vitro clinical  
24                  test is required to save the life of the human subject

1 of such testing and there is not sufficient time to ob-  
2 tain such concurrence.

3 “(8) SIGNIFICANT RISK.—For purposes of this  
4 subsection, the term ‘significant risk’ means, with  
5 respect to an in vitro clinical test, that the use of  
6 such in vitro clinical test—

7 “(A) is of substantial importance in per-  
8 forming an activity or activities described in  
9 section 201(ss)(1) for, a serious or life-threat-  
10 ening disease or condition without confirmation  
11 of the diagnosis by a medically established diag-  
12 nostic product or procedure;

13 “(B) requires an invasive sampling proce-  
14 dure that presents a significant risk to the  
15 human subject, provided that routine  
16 venipuncture shall not be considered an invasive  
17 sampling procedure; or

18 “(C) otherwise presents a potential for se-  
19 rious risk to the health of a human subject.

20 “(d) REVIEW OF APPLICATIONS.—

21 “(1) IN GENERAL.—The Secretary may issue  
22 an order approving an investigation as proposed, ap-  
23 proving it with conditions or modifications, or dis-  
24 approving it.

1           “(2) FAILURE TO ACT.—Unless the Secretary,  
2           not later than 30 calendar days after the date of the  
3           submission of an application for an investigational  
4           use exemption that meets the requirements of sub-  
5           section (c), issues an order under paragraph (1) and  
6           notifies the sponsor submitting the application, the  
7           application shall be treated as approved as of such  
8           date without further action by the Secretary.

9           “(3) DENIAL.—The Secretary may deny an in-  
10          vestigational use application submitted under this  
11          subsection if the Secretary determines that the in-  
12          vestigation with respect to which the application is  
13          submitted does not conform to the requirements of  
14          subsection (c). A notification of such denial sub-  
15          mitted to the sponsor with respect to such a request  
16          shall contain the order of disapproval and a complete  
17          statement of the reasons for the Secretary’s denial  
18          of the application.

19          “(e) WITHDRAWAL OF EXEMPTION.—

20                 “(1) IN GENERAL.—The Secretary may, by ad-  
21                 ministrative order, withdraw an exemption approved  
22                 under this section with respect to an in vitro clinical  
23                 test, including an exemption treated as approved  
24                 based on the Secretary’s failure to act pursuant to  
25                 subsection (d)(2), if the Secretary determines that

1 an investigation conducted under such an exemption  
2 does not meet the applicable conditions under sub-  
3 section (c)(3) for such exemption.

4 “(2) OPPORTUNITY TO BE HEARD.—

5 “(A) IN GENERAL.—Subject to subpara-  
6 graph (B), an order withdrawing an investiga-  
7 tional use exemption granted under this section  
8 may be issued only after the Secretary provides  
9 the sponsor of the in vitro clinical test with an  
10 opportunity for an informal hearing.

11 “(B) EXCEPTION.—An order referred to in  
12 subparagraph (A) with respect to an investiga-  
13 tional use exemption granted under this section  
14 may be issued on a preliminary basis before the  
15 provision of an opportunity for an informal  
16 hearing if the Secretary determines that the  
17 continuation of testing under the exemption will  
18 result in an unreasonable risk to the public  
19 health. The Secretary will provide an oppor-  
20 tunity for an informal hearing promptly fol-  
21 lowing any preliminary action under this sub-  
22 paragraph.

23 “(f) CHANGES.—

24 “(1) IN GENERAL.—The regulations promul-  
25 gated under subsection (b) shall provide, with re-

1       spect to an in vitro clinical test for which an exemp-  
2       tion under this subsection is in effect, procedures  
3       and conditions under which changes are allowed  
4       without the additional approval of an application for  
5       an exemption or submission of a supplement to such  
6       an application. Such regulations shall provide that  
7       such a change may be made if—

8               “(A) the sponsor determines, on the basis  
9               of credible information (as defined in regula-  
10              tions) that the change meets the conditions  
11              specified in paragraph (2); and

12              “(B) the sponsor submits to the Secretary,  
13              not later than 5 calendar days after making the  
14              change, a notice of the change.

15              “(2) CONDITIONS.—The conditions specified in  
16       this paragraph are that—

17              “(A) in the case of developmental changes  
18              to an in vitro clinical test, including manufac-  
19              turing changes, the changes—

20                      “(i) do not constitute a significant  
21                      change in design or in basic principles of  
22                      operation;

23                      “(ii) do not affect the rights, safety,  
24                      or welfare of the human subjects involved  
25                      in the investigation; and

1           “(iii) are made in response to infor-  
2           mation gathered during the course of an  
3           investigation; and

4           “(B) in the case of changes to clinical pro-  
5           tocols applicable to the test, the changes do not  
6           affect—

7           “(i) the validity of data or information  
8           resulting from the completion of an ap-  
9           proved clinical protocol, or the relationship  
10          of likely patient risk to benefit relied upon  
11          to approve a product;

12          “(ii) the scientific soundness of a plan  
13          submitted under subsection (c)(3); or

14          “(iii) the rights, safety, or welfare of  
15          the human subjects involved in the inves-  
16          tigation.

17          “(g) CLINICAL HOLD.—

18           “(1) IN GENERAL.—At any time, the Secretary  
19           may impose a clinical hold with respect to an inves-  
20           tigation of an in vitro clinical test if the Secretary  
21           makes a written determination described in para-  
22           graph (2). The Secretary shall, in imposing such  
23           clinical hold, specify the basis for the clinical hold,  
24           including the specific information available to the  
25           Secretary which served as the basis for such clinical



1 hold, and confirm such determination in writing.  
2 The applicant may immediately appeal any such de-  
3 termination pursuant to section 587P.

4 “(2) DETERMINATION.—

5 “(A) IN GENERAL.—For purposes of para-  
6 graph (1), a determination described in this  
7 subparagraph with respect to a clinical hold is  
8 a determination that, based on credible evi-  
9 dence, the in vitro clinical test involved rep-  
10 represents an unreasonable risk to the safety of  
11 the persons who are the subjects of the clinical  
12 investigation, taking into account the qualifica-  
13 tions of the clinical investigators, information  
14 about the in vitro clinical test, the design of the  
15 clinical investigation, the condition for which  
16 the in vitro clinical test is to be investigated,  
17 and the health status of the subjects involved.

18 “(B) REMOVAL OF CLINICAL HOLD.—Any  
19 written request to the Secretary from the spon-  
20 sor of an investigation that a clinical hold be re-  
21 moved shall receive a decision, in writing and  
22 specifying the reasons therefor, within 30 days  
23 after receipt of such request. Any such request  
24 shall include sufficient information to support  
25 the removal of such clinical hold.

1 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

2 “(a) ESTABLISHMENT.—Not later than 2 years after  
3 the date of enactment of the VALID Act of 2023, the Sec-  
4 retary shall make available a comprehensive test informa-  
5 tion system for in vitro clinical tests that is designed to—

6 “(1) provide a transparent interface on the  
7 website of the Food and Drug Administration for  
8 stakeholders, to the extent permitted by applicable  
9 law, which may include access to the—

10 “(A) regulatory pathway designation infor-  
11 mation for each in vitro clinical test or tests  
12 with the same indications for use;

13 “(B) registration and listing information  
14 provided by developers under section 587J, in-  
15 cluding the use of a link for labels;

16 “(C) adverse event reports submitted  
17 under section 587M, as appropriate;

18 “(D) reports of corrections and removals  
19 submitted under section 587N; and

20 “(E) other information pertaining to an in  
21 vitro clinical test or tests with the same indica-  
22 tions for use, as the Secretary determines ap-  
23 propriate; and

24 “(2) provide a secure portal for electronic sub-  
25 mission, including applications and other in vitro  
26 clinical test submissions, registration and listing in-

1 formation, and adverse event reports, which provides  
2 protections from unauthorized disclosure of informa-  
3 tion, including of—

4 “(A) trade secret or confidential commer-  
5 cial or financial information; and

6 “(B) information that could compromise  
7 national security.

8 “(b) **SUBMISSION FUNCTION.**—The comprehensive  
9 test information system shall serve as the electronic sub-  
10 mission service for test developers submitting information  
11 for applications under sections 587B and 587D.

12 **“SEC. 587U. PREEMPTION.**

13 “(a) **IN GENERAL.**—Except as provided in subsection  
14 (b), no State, Tribal, or local government (or political sub-  
15 division thereof) may establish or continue in effect any  
16 requirement—

17 “(1) that is different from, or in addition to,  
18 any requirement applicable to an in vitro clinical test  
19 under this Act; or

20 “(2) with respect to the analytical validity, clin-  
21 ical validity, or safety for individuals who come into  
22 contact with such an in vitro clinical test.

23 “(b) **EXCEPTIONS.**—Subsection (a) shall not be con-  
24 strued to affect the authority of a State, Tribal, or local  
25 government to do any of the following:

1           “(1) To license laboratory personnel, health  
2           care practitioners, or health care facilities or to reg-  
3           ulate any aspect of a health care practitioner-patient  
4           relationship.

5           “(2) To enforce laws of general applicability,  
6           such as zoning laws, environmental laws, labor laws,  
7           and general business laws.

8           “(3) To authorize laboratories to develop and  
9           perform an in vitro clinical test, pursuant to a law  
10          enacted by a State prior to January 1, 2022, as long  
11          as such law does not impose requirements that are  
12          different from any requirement applicable to an in  
13          vitro clinical test under this Act. If a State has en-  
14          acted such a law, the Secretary shall exempt such  
15          test for laboratories in that State from compliance  
16          with this subchapter.

17          “(c) CLARIFICATION.—Nothing in this section shall  
18          be construed to—

19                 “(1) modify any action for damages or the li-  
20                 ability of any person under the law of any State; or

21                 “(2) shift liability to health care practitioners  
22                 or other users.

23          **“SEC. 587V. ADULTERATION.**

24          “An in vitro clinical test shall be deemed to be adul-  
25          terated:

1           “(1) If it consists in whole or in part of any  
2 filthy, putrid, or decomposed substance.

3           “(2) If it has been developed, prepared, packed,  
4 or held under insanitary conditions whereby it may  
5 have been contaminated with filth, or whereby it  
6 may have been rendered injurious to health.

7           “(3) If its container or package is composed, in  
8 whole or in part, of any poisonous or deleterious  
9 substance which may render the contents injurious  
10 to health.

11           “(4) If it bears or contains, for purposes of  
12 coloring only, a color additive which is unsafe within  
13 the meaning of section 721(a).

14           “(5) If its analytical or clinical validity, as ap-  
15 plicable, or with respect to a specimen receptacle, its  
16 safety, falls below that which it purports or is rep-  
17 resented to possess.

18           “(6) If it is required to be, declared to be, pur-  
19 ports to be, or is represented as being, in conformity  
20 with any performance standard established or recog-  
21 nized under section 587R and is not in conformity  
22 with such standard.

23           “(7) If it is required to be in compliance with  
24 mitigating measures established under section 587E

1 and is not in conformity with such mitigating meas-  
2 ures.

3 “(8) If it fails to have in effect an approved  
4 premarket application under section 587B, unless  
5 such in vitro clinical test is in compliance with the  
6 requirements for—

7 “(A) offering without an approved pre-  
8 market application under section 587D(b)(1);

9 “(B) an exemption from premarket ap-  
10 proval under section 587C or 587G; or

11 “(C) investigational use pursuant to sec-  
12 tion 587S.

13 “(9) If it is not in conformity with any condi-  
14 tion established under section 587B or 587D.

15 “(10) If it purports to be an in vitro clinical  
16 test subject to an exemption under section 587C and  
17 it fails to meet or maintain any criteria, condition,  
18 or requirement of such exemption.

19 “(11) If it has been granted an exemption  
20 under section 587S for investigational use, and the  
21 person granted such exemption or any investigator  
22 who uses such in vitro clinical test under such ex-  
23 emption fails to comply with a requirement pre-  
24 scribed by or under such section.

1           “(12) If it fails to meet the quality require-  
2           ments prescribed in or established under section  
3           587K (as applicable), or the methods used in, or fa-  
4           cilities or controls used for, its development, pack-  
5           aging, storage, or installation are not in conformity  
6           with applicable requirements established under such  
7           section.

8           “(13) If it has been developed, processed, pack-  
9           aged, or held in any establishment, factory, or ware-  
10          house and the owner, operator or agent of such es-  
11          tablishment, factory, or warehouse delays, denies, or  
12          limits an inspection, or refuses to permit entry or in-  
13          spection.

14          “(14) If it is not in compliance with any restric-  
15          tion required under section 587O.

16 **“SEC. 587W. MISBRANDING.**

17          “An in vitro clinical test shall be deemed to be mis-  
18          branded:

19                 “(1) If its labeling is false or misleading in any  
20                 particular.

21                 “(2) If in a package form unless it bears a label  
22                 containing—

23                         “(A) the name and place of business of the  
24                         test developer, packager, or distributor; and

1           “(B) an accurate statement of the quantity  
2           of contents in terms of weight, measure, or nu-  
3           merical count, unless an exemption is granted  
4           by the Secretary by the issuance of guidance,  
5           such as with respect to small packages.

6           “(3) If any word, statement, or other informa-  
7           tion required by or under authority of this Act to  
8           appear on the label or labeling, including a test re-  
9           port, is not prominently placed thereon with such  
10          conspicuousness (as compared with other words,  
11          statements, designs, or devices, in the labeling) and  
12          in such terms as to render it likely to be read and  
13          understood by the ordinary individual under cus-  
14          tomary conditions of purchase and use.

15          “(4) Unless its labeling bears adequate direc-  
16          tions for use and such adequate warnings as are  
17          necessary for the protection of users of the in vitro  
18          clinical test and recipients of the results of such in  
19          vitro clinical test, including patients, consumers, do-  
20          nors, and related health care professionals. Required  
21          labeling for in vitro clinical tests intended for use in  
22          health care facilities, blood establishments, or by a  
23          health care professional may be made available solely  
24          by electronic means, provided that the labeling com-  
25          plies with all applicable requirements of law, and



1 that the test developer, or distributor affords such  
2 users the opportunity to request the labeling in  
3 paper form, and after such request, promptly pro-  
4 vides the requested information without additional  
5 cost.

6 “(5) If there is a reasonable probability that it  
7 could cause serious or adverse health consequences  
8 or death, including through absence, delay, or dis-  
9 continuation in diagnosis or treatment, when used in  
10 the manner prescribed, recommended, or suggested  
11 in the labeling thereof.

12 “(6) If it was developed, sterilized, packaged,  
13 repackaged, relabeled, installed, or imported in an  
14 establishment not duly registered under section  
15 587J or it was not included in a listing under sec-  
16 tion 587J, in accordance with timely reporting re-  
17 quirements under this subchapter.

18 “(7) In the case of any in vitro clinical test sub-  
19 ject to restrictions under section 587O, (1) if its ad-  
20 vertising is false or misleading in any particular, (2)  
21 if it is offered for clinical use, sold, distributed, or  
22 used in violation of such restrictions, or (3) unless  
23 the test developer or distributor includes in all ad-  
24 vertisements and other descriptive printed matter  
25 that such person issues or causes to be issued, a

1       brief statement of the indications for use of the in  
2       vitro clinical test and relevant warnings, precautions,  
3       side effects, and contraindications. This paragraph  
4       shall not be applicable to any printed matter that  
5       the Secretary determines to be labeling as defined in  
6       section 201(m).

7               “(8) If it is subject to a mitigating measure es-  
8       tablished under section 587E and does not bear such  
9       labeling as may be prescribed in such mitigating  
10      measure.

11              “(9) If it is subject to a standard established  
12      under section 587R and it does not bear such label-  
13      ing as may be prescribed in such standard.

14              “(10) Unless it bears such labeling as may be  
15      required by or established under an applicable label-  
16      ing requirement under this Act.

17              “(11) If there was a failure to comply with any  
18      requirement prescribed in or under section 587D,  
19      587J, 587K, 587L, 587M, 587N, 587X, 587Y,  
20      587Z, or to provide any report, material, or other in-  
21      formation required with respect to in vitro clinical  
22      tests under this subchapter.

23   **“SEC. 587X. POSTMARKET SURVEILLANCE.**

24              “(a) IN GENERAL.—

1           “(1) IN GENERAL.—In addition to other appli-  
2           cable requirements under this Act, the Secretary  
3           may issue an order requiring a developer of a high-  
4           risk or moderate-risk in vitro clinical test to conduct  
5           postmarket surveillance of such in vitro clinical test,  
6           if the failure of the in vitro clinical test is reasonably  
7           likely to result in serious adverse health con-  
8           sequences or death from use of such in vitro clinical  
9           test.

10           “(2) CONSIDERATION.—In determining whether  
11           to require a developer to conduct postmarket surveil-  
12           lance of an in vitro clinical test, the Secretary shall  
13           take into consideration the benefits and risks for the  
14           patient and the least burdensome requirements  
15           under section 587AA(c).

16           “(b) SURVEILLANCE APPROVAL.—

17           “(1) IN GENERAL.—Each developer required to  
18           conduct surveillance of an in vitro clinical test shall  
19           submit, within 30 days of receiving an order from  
20           the Secretary, a plan for the required surveillance.  
21           The Secretary, within 60 days of the receipt of such  
22           plan, shall determine if the person designated to  
23           conduct the surveillance has the appropriate quali-  
24           fications and experience to undertake such surveil-  
25           lance and if the plan will result in useful data that

1 can reveal unforeseen adverse events or other infor-  
2 mation necessary to protect the health of patients or  
3 the public.

4 “(2) **TIMELINE.**—The developer shall com-  
5 mence surveillance under this section not later than  
6 15 months after the day on which the Secretary or-  
7 ders such postmarket surveillance, unless the Sec-  
8 retary determines more time is needed to commence  
9 surveillance.

10 “(3) **PROSPECTIVE SURVEILLANCE.**—The Sec-  
11 retary may order a prospective surveillance period of  
12 up to 3 years. Any determination by the Secretary  
13 that a longer period is necessary shall be made by  
14 mutual agreement between the Secretary and the de-  
15 veloper or, if no agreement can be reached, upon the  
16 completion of a dispute resolution process pursuant  
17 to section 562.

18 **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

19 “(a) **IN GENERAL.**—All submissions to the Food and  
20 Drug Administration with respect to an in vitro clinical  
21 test, unless otherwise agreed to by the Secretary, shall—

22 “(1) be made electronically; and

23 “(2) with respect to the information required  
24 under sections 587B and 587D, utilize the system  
25 described in section 587T.

1       “(b) ELECTRONIC FORMAT.—Beginning on such date  
2 as the Secretary specifies in final guidance issued under  
3 subsection (c), submissions for in vitro clinical tests, in-  
4 cluding recommendations submitted by accredited and rec-  
5 ognized persons under section 587Q, and any appeals of  
6 action taken by the Secretary with respect to such submis-  
7 sions, shall be submitted in such electronic format as spec-  
8 ified by the Secretary in such guidance.

9       “(c) GUIDANCE.—The Secretary shall issue guidance  
10 implementing this section. Such guidance may—

11           “(1) provide standards for the electronic sub-  
12 mission required under subsection (a) or the submis-  
13 sion in electronic format required under subsection  
14 (b);

15           “(2) set forth criteria for waivers of, or exemp-  
16 tions from, the requirements of subsection (a) or (b);  
17 and

18           “(3) provide any other information for the effi-  
19 cient implementation and enforcement of this sec-  
20 tion.

21 **“SEC. 587Z. POSTMARKET REMEDIES.**

22       “(a) SAFETY NOTICE.—

23           “(1) IN GENERAL.—If the Secretary determines  
24 that an in vitro clinical test presents an unreason-  
25 able risk of substantial harm to the public health,

1 and notification under this subsection is necessary to  
2 eliminate the unreasonable risk of such harm and no  
3 more practicable means is available under the provi-  
4 sions of this Act (other than this section) to elimi-  
5 nate the risk, the Secretary may issue such order as  
6 may be necessary to ensure that adequate safety no-  
7 tice is provided in an appropriate form, by the per-  
8 sons and means best suited under the circumstances,  
9 to all health care professionals who prescribe, order,  
10 or use the in vitro clinical test and to any other per-  
11 son (including developers, importers, distributors, re-  
12 tailers, and users) who should properly receive such  
13 notice.

14 “(2) NOTICE TO INDIVIDUALS.—An order  
15 under this subsection shall require that the individ-  
16 uals subject to the risk with respect to which the  
17 order is to be issued be included in the persons to  
18 be notified of the risk unless the Secretary deter-  
19 mines that notice to such individuals would present  
20 a greater danger to the health of such individuals  
21 than no such notice. If the Secretary makes such a  
22 determination with respect to such individuals, the  
23 order shall require the health care professionals who  
24 prescribed, ordered, or used the in vitro clinical test  
25 provide notification to the individuals for whom the

1 health professionals prescribed, ordered, or used  
2 such test, of the risk presented by such in vitro clin-  
3 ical test and of any action which may be taken by  
4 or on behalf of such individuals to eliminate or re-  
5 duce such risk. Before issuing an order under this  
6 subsection, the Secretary shall consult with the per-  
7 sons required to give notice under the order.

8 “(b) REPAIR, REPLACEMENT, OR REFUND.—

9 “(1) DETERMINATION AFTER AN INFORMAL  
10 HEARING.—

11 “(A) IN GENERAL.—If, after affording op-  
12 portunity for an informal hearing, the Secretary  
13 determines that—

14 “(i) an in vitro clinical test presents  
15 an unreasonable risk of substantial harm  
16 to the public health;

17 “(ii) there are reasonable grounds to  
18 believe that the in vitro clinical test was  
19 not properly developed or manufactured  
20 considering the state of the art as it ex-  
21 isted at the time of its development;

22 “(iii) there are reasonable grounds to  
23 believe that the unreasonable risk was not  
24 caused by failure of a person other than a  
25 developer, importer, distributor, or retailer

1 of the in vitro clinical test to exercise due  
2 care in the installation, maintenance, re-  
3 pair, or use of the in vitro clinical test; and  
4 “(iv) the notice authorized by sub-  
5 section (a) would not by itself be sufficient  
6 to eliminate the unreasonable risk and ac-  
7 tion described in paragraph (2) of this sub-  
8 section is necessary to eliminate such risk,  
9 the Secretary may order the developer, im-  
10 porter, or any distributor of such in vitro clin-  
11 ical test, or any combination of such persons, to  
12 submit to him within a reasonable time a plan  
13 for taking one or more of the actions described  
14 in paragraph (2). An order issued under the  
15 preceding sentence which is directed to more  
16 than one person shall specify which person may  
17 decide which action shall be taken under such  
18 plan and the person specified shall be the per-  
19 son who the Secretary determines bears the  
20 principal, ultimate financial responsibility for  
21 action taken under the plan unless the Sec-  
22 retary cannot determine who bears such respon-  
23 sibility or the Secretary determines that the  
24 protection of the public health requires that  
25 such decision be made by a person (including a



1 health professional or user of the in vitro clin-  
2 ical test) other than the person the Secretary  
3 determines bears such responsibility.

4 “(B) SECRETARY APPROVAL OF PLAN.—  
5 The Secretary shall approve a plan submitted  
6 pursuant to an order issued under subpara-  
7 graph (A) unless the Secretary determines  
8 (after affording opportunity for an informal  
9 hearing) that the action or actions to be taken  
10 under the plan or the manner in which such ac-  
11 tion or actions are to be taken under the plan  
12 will not assure that the unreasonable risk with  
13 respect to which such order was issued will be  
14 eliminated. If the Secretary disapproves a plan,  
15 the Secretary shall order a revised plan to be  
16 submitted within a reasonable time. If the Sec-  
17 retary determines (after affording opportunity  
18 for an informal hearing) that the revised plan  
19 is unsatisfactory or if no revised plan or no ini-  
20 tial plan has been submitted to the Secretary  
21 within the prescribed time, the Secretary  
22 shall—

23 “(i) prescribe a plan to be carried out  
24 by the person or persons to whom the

1 order issued under subparagraph (A) was  
2 directed; or

3 “(ii) after affording an opportunity  
4 for an informal hearing, by order prescribe  
5 a plan to be carried out by a person who  
6 is a developer, importer, distributor, or re-  
7 tailer of the in vitro clinical test with re-  
8 spect to which the order was issued but to  
9 whom the order under subparagraph (A)  
10 was not directed.

11 “(2) ACTIONS ON A PLAN.—The actions that  
12 may be taken under a plan submitted under an  
13 order issued under paragraph (1)(A) are as follows:

14 “(A) To repair the in vitro clinical test so  
15 that it does not present the unreasonable risk  
16 of substantial harm with respect to which the  
17 order under paragraph (1)(A) was issued.

18 “(B) To replace the in vitro clinical test  
19 with a like or equivalent test which is in con-  
20 formity with all applicable requirements of this  
21 Act.

22 “(C) To refund the purchase price of the  
23 in vitro clinical test (less a reasonable allowance  
24 for use if such in vitro clinical test has been in  
25 the possession of the user for one year or more

1 at the time of notice ordered under subsection  
2 (a), or at the time the user receives actual no-  
3 tice of the unreasonable risk with respect to  
4 which the order was issued under paragraph  
5 (1)(A), whichever occurs first).

6 “(3) NO CHARGE.—No charge shall be made to  
7 any person (other than a developer, importer, dis-  
8 tributor, or retailer) for using a remedy described in  
9 paragraph (2) and provided under an order issued  
10 under paragraph (1), and the person subject to the  
11 order shall reimburse each person (other than a de-  
12 veloper, manufacturer, importer, distributor, or re-  
13 tailer) who is entitled to such a remedy for any rea-  
14 sonable and foreseeable expenses actually incurred  
15 by such person in using such remedy.

16 “(c) REIMBURSEMENT.—An order issued under sub-  
17 section (b)(1)(A) with respect to an in vitro clinical test  
18 may require any person who is a developer, importer, dis-  
19 tributor, or retailer of the in vitro clinical test to reimburse  
20 any other person who is a developer, importer, distributor,  
21 or retailer of such in vitro clinical test for such other per-  
22 son’s expenses actually incurred in connection with car-  
23 rying out the order if the Secretary determines such reim-  
24 bursement is required for the protection of the public  
25 health. Any such requirement shall not affect any rights

1 or obligations under any contract to which the person re-  
2 ceiving reimbursement or the person making such reim-  
3 bursement is a party.

4 “(d) RECALL AUTHORITY.—

5 “(1) IN GENERAL.—If the Secretary finds that  
6 there is a reasonable probability that an in vitro  
7 clinical test approved under section 587B or offered  
8 under a technology certification order under section  
9 587D would cause serious, adverse health con-  
10 sequences or death, including by the absence, signifi-  
11 cant delay, or discontinuation of appropriate medical  
12 treatment, the Secretary shall issue an order requir-  
13 ing the appropriate person (including the developers,  
14 importers, distributors, or retailers of the in vitro  
15 clinical test)—

16 “(A) to immediately cease distribution of  
17 such in vitro clinical test; and

18 “(B) to immediately notify health profes-  
19 sionals and applicable in vitro clinical test user  
20 facilities of the order and to instruct such pro-  
21 fessionals and facilities to cease use of such in  
22 vitro clinical test.

23 “(2) INFORMAL HEARING.—The order issued  
24 under paragraph (1)(A), shall provide the person  
25 subject to the order with an opportunity for an in-

1 formal hearing, to be held not later than 10 calendar  
2 days after the date of the issuance of the order, on  
3 the actions required by the order and on whether the  
4 order should be amended to require a recall of such  
5 in vitro clinical test. If, after providing an oppor-  
6 tunity for such a hearing, the Secretary determines  
7 that inadequate grounds exist to support the actions  
8 required by the order, the Secretary shall vacate the  
9 order.

10 “(3) AMENDED ORDER.—

11 “(A) IN GENERAL.—If, after providing an  
12 opportunity for an informal hearing under  
13 paragraph (2), the Secretary determines that  
14 the order should be amended to include a recall  
15 of the in vitro clinical test with respect to which  
16 the order was issued, the Secretary shall, except  
17 as provided in subparagraph (B), amend the  
18 order to require a recall. The Secretary shall  
19 specify a timetable in which the recall will occur  
20 and shall require periodic reports describing the  
21 progress of the recall.

22 “(B) REQUIREMENTS.—An amended order  
23 under subparagraph (A)—

24 “(i) shall not include recall of the in  
25 vitro clinical test from individuals;

1           “(ii) shall not include recall of an in  
2           vitro clinical test from test user facilities if  
3           the Secretary determines that the risk of  
4           recalling such in vitro clinical test from the  
5           facilities presents a greater health risk  
6           than the health risk of not recalling the in  
7           vitro clinical test from use; and

8           “(iii) shall provide for notice to indi-  
9           viduals subject to the risks associated with  
10          the use of such in vitro clinical test. In  
11          providing the notice required by this  
12          clause, the Secretary may use the assist-  
13          ance of health professionals who pre-  
14          scribed, ordered, or used such an in vitro  
15          clinical test for individuals.

16          “(4) CLARIFICATION.—The remedy provided by  
17          this subsection shall be in addition to remedies pro-  
18          vided by subsections (a), (b), and (c).

19          **“SEC. 587AA. APPLICABILITY.**

20          “(a) IN GENERAL.—An in vitro clinical test shall be  
21          subject to the requirements of this subchapter, except as  
22          otherwise provided in this subchapter. Laboratory oper-  
23          ations shall not be subject to the requirements of this sub-  
24          chapter.

1       “(b) INTERSTATE COMMERCE.—Any in vitro clinical  
2 test that is offered, including by making available for clin-  
3 ical use in the United States is deemed to be an act that  
4 constitutes introduction into interstate commerce for pur-  
5 poses of enforcing the requirements of this Act.

6       “(c) LEAST BURDENSOME REQUIREMENTS.—

7           “(1) IN GENERAL.—In carrying out this sub-  
8 chapter, the Secretary shall consider the least bur-  
9 densome means necessary to meet the applicable  
10 standard, and other regulatory requirements, as de-  
11 termined by the Secretary.

12           “(2) NECESSARY DEFINED.—For purposes of  
13 paragraph (1), the term ‘necessary’ means the min-  
14 imum required information that would support a de-  
15 termination by the Secretary that the application  
16 meet the applicable standard or regulatory require-  
17 ment, as determined by the Secretary.

18       “(d) SERVICE OF ORDERS.—Orders of the Secretary  
19 under this section with respect to applications under sub-  
20 section (a) or (b) of section 587B or supplements under  
21 subsection (f) of such section shall be served—

22           “(1) in person by any officer or employee of the  
23 Department of Health and Human Services des-  
24 ignated by the Secretary; or

1           “(2) by mailing the order by registered mail or  
2 certified mail or electronic equivalent addressed to  
3 the applicant at the last known address in the  
4 records of the Secretary.

5           “(e) LABORATORIES AND BLOOD AND TISSUE ES-  
6 TABLISHMENTS.—

7           “(1) RELATION TO LABORATORY CERTIFI-  
8 CATION PURSUANT TO SECTION 353 OF THE PUBLIC  
9 HEALTH SERVICE ACT.—Nothing in this subchapter  
10 shall be construed to modify the authority of the  
11 Secretary with respect to laboratories or clinical lab-  
12 oratories under section 353 of the Public Health  
13 Service Act.

14           “(2) AVOIDING DUPLICATION.—In imple-  
15 menting this subchapter, the Secretary shall avoid  
16 issuing or enforcing regulations or guidance that are  
17 duplicative of regulations or guidance under section  
18 353 of the Public Health Service Act such that lab-  
19 oratories would be subject to conflicting regulatory  
20 obligations with respect to the same activity.

21           “(3) BLOOD AND TISSUE.—Nothing in this sub-  
22 chapter shall be construed to modify the authority of  
23 the Secretary with respect to laboratories, establish-  
24 ments, or other facilities to the extent they are en-  
25 gaged in the propagation, manufacture, or prepara-



1       tion, including filling, labeling, packaging, and stor-  
2       age, of blood, blood components, human cells, tis-  
3       sues, or tissue products pursuant to any require-  
4       ments under this Act or section 351 or 361 of the  
5       Public Health Service Act.

6       “(f) NOT COMBINATION PRODUCT.—

7             “(1) IN GENERAL.—A product constituted of a  
8       device and an in vitro clinical test is not a combina-  
9       tion product and may be regulated as a device or as  
10      a device and in vitro clinical test, notwithstanding  
11      section 201(ss)(3).

12            “(2) GUIDANCE.—Not later than October 1,  
13      2026, the Secretary shall issue final guidance, after  
14      an opportunity for public comment, addressing the  
15      considerations for regulating a product described in  
16      paragraph (1). Such guidance shall take into ac-  
17      count the least burdensome requirements under sub-  
18      section (c).

19       “(g) PRACTICE OF MEDICINE.—Nothing in this sub-  
20      chapter shall be construed to limit or interfere with the  
21      authority of a health care practitioner to prescribe or ad-  
22      minister any lawfully offered in vitro clinical test for any  
23      condition or disease within a legitimate health care practi-  
24      tioner-patient relationship pursuant to applicable Federal  
25      or State law.

1       “(h) SALE, DISTRIBUTION, LABELING.—Nothing in  
2 this section shall be construed to limit the authority of  
3 the Secretary to establish or enforce restrictions on the  
4 sale, distribution, or labeling of an in vitro clinical test  
5 under this Act.

6       “(i) PROMOTION OF UNAPPROVED USES.—Nothing  
7 in this section shall be construed to alter any prohibition  
8 on the promotion of unapproved uses of legally offered in  
9 vitro clinical tests.

10       “(j) VOLUNTARY SUBMISSIONS.—Nothing in section  
11 587C shall be construed to prevent a developer developing  
12 a test described in such section, including an academic  
13 medical center laboratory described in subsection (a)(7)  
14 of such section, from filing an application under section  
15 587B or section 587D, or from adhering to the require-  
16 ments of section 587K with regard to a test protocol de-  
17 scribed in section 587K or for any other test or use of  
18 a test.

19       **“SEC. 587BB. JUDICIAL REVIEW.**

20       “(a) IN GENERAL.—Not later than 30 days after an  
21 order issued pursuant to sections 587B or 587D, any per-  
22 son adversely affected by such order may file a petition  
23 with the United States Court of Appeals for the District  
24 of Columbia or for the circuit wherein such person resides  
25 or has a principal place of business for judicial review of

1 such order, in accordance with the procedure set forth in  
2 section 517(a).

3 “(b) APPLICATION OF PROVISIONS.—Subsections (a)  
4 through (e) of section 517 shall apply with respect to a  
5 petition under subsection (a) of this section in the same  
6 manner such subsections apply to a petition under section  
7 517. Subsection (f) of section 517 shall apply to an order  
8 issued under section 587B or 587D.”

9 **SEC. 4. ENFORCEMENT AND OTHER PROVISIONS.**

10 (a) PROHIBITED ACTS.—Section 301 of the Federal  
11 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
12 ed—

13 (1) in paragraphs (a), (b), (c), (g), (h), (k), (q),  
14 (r), and (y), by inserting “in vitro clinical test,”  
15 after “device,” each place it appears;

16 (2) in paragraph (g), by inserting after “mis-  
17 branded” the following: “, and the development  
18 within any Territory of any in vitro clinical test that  
19 is adulterated or misbranded”;

20 (3) in paragraph (y), by inserting “or 587Q”  
21 after “section 523” each place it appears;

22 (4) in paragraph (ff), by striking “or device”  
23 and inserting “, device, or in vitro clinical test”; and

24 (5) by adding at the end, the following:

1           “(fff)(1) Forging, counterfeiting, simulating, or false-  
2 ly representing, or without proper authority using any  
3 mark, stamp, tag, label, or other identification upon any  
4 in vitro clinical test or container, packaging, or labeling  
5 thereof so as to render such in vitro clinical test a counter-  
6 feit in vitro clinical test.

7           “(2) Making, selling, disposing of, or keeping in pos-  
8 session, control, or custody, or concealing any punch, die,  
9 plate, stone, or other thing designed to print, imprint, or  
10 reproduce the trademark, trade name, or other identifying  
11 mark or imprint of another or any likeness of any of the  
12 foregoing upon any in vitro clinical test or container, pack-  
13 aging, or labeling thereof so as to render such in vitro  
14 clinical test a counterfeit in vitro clinical test.

15           “(3) The doing of any act which causes an in vitro  
16 clinical test to be a counterfeit in vitro clinical test, or  
17 the sale or dispensing, or the holding for sale or dis-  
18 pensing, of a counterfeit in vitro clinical test.

19           “(ggg)(1) The introduction or delivery for introduc-  
20 tion into interstate commerce of an in vitro clinical test  
21 in violation of section 587A(a).

22           “(2) The making of a false, fraudulent, or deceptive  
23 statement about an in vitro clinical test that is exempt  
24 from premarket review under section 587C.

1       “(3) The failure to maintain complete and accurate  
2 documentation for an exemption as required under section  
3 587C or the failure to provide labeling required under sec-  
4 tion 587L.

5       “(4) With respect to an in vitro clinical test, the sub-  
6 mission of any application, report, or listing under this  
7 Act that is false or misleading in any material respect.

8       “(5) The failure to comply with a condition of ap-  
9 proval, or restriction required under an approved applica-  
10 tion under section 587B; the failure to perform a risk  
11 analysis required by section 587B; the failure to submit  
12 an annual update required under section 587J(c)(2)(B);  
13 or the failure to complete postmarket surveillance as re-  
14 quired under section 587X.

15       “(6) The failure to comply with applicable require-  
16 ments to submit an application or report under section  
17 587D(e).

18       “(7) The failure to comply with applicable mitigating  
19 measures established under section 587E or to submit,  
20 maintain, or make available the documentation required  
21 under section 587E(b); or the failure to comply with appli-  
22 cable performance standards established under section  
23 587R.

24       “(8) The failure to register in accordance with section  
25 587J, the failure to provide information required under

1 section 587J(b), or the failure to maintain or submit infor-  
2 mation required under section 587J(c).

3 “(9) The failure to comply with requirements under  
4 section 587M or 587N, the failure to comply with a re-  
5 striction required under section 587O, or the failure to  
6 comply with labeling and advertising requirements under  
7 section 587O(b).

8 “(10) The failure to comply with the requirements  
9 of section 587Q.

10 “(11) The failure to comply with any requirement of  
11 section 587S; the failure to furnish any notification, infor-  
12 mation, material, or report required under section 587S;  
13 or the failure to comply with an order issued under section  
14 587S.

15 “(12) The failure to furnish information requested by  
16 the Secretary under 587G(d)(2).”.

17 (b) PENALTIES.—Section 303 of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

19 (1) in subsection (b)(8), by inserting “or coun-  
20 terfeit in vitro clinical test” after “counterfeit drug”;

21 (2) in subsection (c)—

22 (A) by striking “; or (5)” and inserting “;  
23 (5)”; and

24 (B) by inserting before the period at the  
25 end the following: “; or (6) for having violated

1 section 301(fff)(2) if such person acted in good  
2 faith and had no reason to believe that use of  
3 the punch, die, plate, stone, or other thing in-  
4 volved would result in an in vitro clinical test  
5 being a counterfeit in vitro clinical test, or for  
6 having violated section 301(fff)(3) if the person  
7 doing the act or causing it to be done acted in  
8 good faith and had no reason to believe that the  
9 in vitro clinical test was a counterfeit in vitro  
10 clinical test”; and

11 (3) in subsection (f)(1)—

12 (A) in subparagraph (A)—

13 (i) by inserting “or in vitro clinical  
14 tests” after “which relates to devices”;

15 (ii) by inserting “or section  
16 587Q(a)(1)” after “section 704(g)”; and

17 (iii) by inserting “or in vitro clinical  
18 tests, as applicable” before the period at  
19 the end of the second sentence; and

20 (B) in subparagraph (B)(i), by striking “or  
21 520(f)” and inserting “, 520(f), 587K, or  
22 587M,”.

23 (c) SEIZURE.—Section 304 of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

25 (1) in subsection (a)(2)—

1 (A) by striking “, and (E)” and inserting  
2 “, (E)”; and

3 (B) by inserting before the period at the  
4 end the following: “, and (F) Any in vitro clin-  
5 ical test that is a counterfeit in vitro clinical  
6 test, (G) Any container, packaging, or labeling  
7 of a counterfeit in vitro clinical test, and (H)  
8 Any punch, die, plate, stone, labeling, container,  
9 or other thing used or designed for use in mak-  
10 ing a counterfeit in vitro clinical test”;

11 (2) in subsection (d)(1), by inserting “in vitro  
12 clinical test,” after “device,”; and

13 (3) in subsection (g)—

14 (A) in paragraph (1), by inserting “, in  
15 vitro clinical test,” after “device” each place it  
16 appears; and

17 (B) in paragraph (2)—

18 (i) in subparagraph (A), by inserting  
19 “, in vitro clinical test,” after “device”;  
20 and

21 (ii) in subparagraph (B), by inserting  
22 “or in vitro clinical test” after “device”  
23 each place it appears.

24 (d) DEBARMENT, TEMPORARY DENIAL OF AP-  
25 PROVAL, AND SUSPENSION.—Section 306 of the Federal



1 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is  
2 amended by adding at the end the following:

3 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-  
4 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND  
5 REVIEWS.—

6 “(1) IN GENERAL.—If the Secretary finds that  
7 a person has been convicted of a felony for a viola-  
8 tion of section 301(gg) or 301(fff)(1), the Secretary  
9 shall debar such person from being accredited under  
10 section 587Q and from carrying out activities under  
11 an agreement described in section 803(b).

12 “(2) DEBARMENT PERIOD.—The Secretary  
13 shall debar a person under paragraph (1) for the fol-  
14 lowing periods:

15 “(A) The period of debarment of a person  
16 (other than an individual) shall not be less than  
17 1 year or more than 10 years, but if an act  
18 leading to a subsequent debarment under such  
19 paragraph occurs within 10 years after such  
20 person has been debarred under such para-  
21 graph, the period of debarment shall be perma-  
22 nent.

23 “(B) The debarment of an individual shall  
24 be permanent.

1           “(3) TERMINATION OF DEBARMENT; JUDICIAL  
2 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),  
3 (e), (i), (j), and (l)(1) apply with respect to a person  
4 (other than an individual) or an individual who is  
5 debarred under paragraph (1) to the same extent  
6 and in the same manner as such subsections apply  
7 with respect to a person who is debarred under sub-  
8 section (a)(1), or an individual who is debarred  
9 under subsection (a)(2), respectively.”.

10       (e) EXPANDED ACCESS TO UNAPPROVED THERAPIES  
11 AND DIAGNOSTICS.—Section 561 of the Federal Food,  
12 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-  
13 ed—

14           (1) in subsections (a) through (d)—

15               (A) by striking “or investigational devices”  
16 each place it appears and inserting “, investiga-  
17 tional devices, or investigational in vitro clinical  
18 tests”; and

19               (B) by striking “or investigational device”  
20 each place it appears (other than the second  
21 such place in paragraph (3)(A)) of subsection  
22 (c) and inserting “, investigational device, or  
23 investigational in vitro clinical test”;

1 (2) in subsection (b)(4) by striking “or 520(g)”  
2 each place it appears and inserting “, 520(g), or  
3 587S”;

4 (3) in subsection (c)—

5 (A) by amending the subsection heading to  
6 read: “TREATMENT INVESTIGATIONAL NEW  
7 DRUG APPLICATIONS, TREATMENT INVESTIGA-  
8 TIONAL DEVICE EXEMPTIONS, AND TREAT-  
9 MENT INVESTIGATIONAL IN VITRO CLINICAL  
10 TEST EXEMPTIONS.”;

11 (B) in paragraph (3)(A), by striking “or  
12 investigational device exemption in effect under  
13 section 520(g)” and inserting “, investigational  
14 device exemption in effect under section 520(g),  
15 or investigational in vitro clinical test exemption  
16 under section 587S”;

17 (C) by striking “or treatment investiga-  
18 tional device exemption” each place it appears  
19 and inserting “, treatment investigational device  
20 exemption, or treatment investigational in vitro  
21 clinical test exemption”;

22 (D) in paragraph (5), by striking “or  
23 520(g)” and inserting “, 520(g), or 587S”; and

1           (E) in the matter following paragraph (7)  
2           by striking “or 520(g)” each place it appears  
3           and inserting “, 520(g), or 587S”; and  
4           (4) by amending subsection (e) to read as fol-  
5           lows:

6           “(e) DEFINITIONS.—In this section, the terms ‘inves-  
7           tigational drug’, ‘investigational device’, ‘investigational in  
8           vitro clinical test’, ‘treatment investigational new drug ap-  
9           plication’, ‘treatment investigational device exemption’,  
10          and ‘treatment investigational in vitro clinical test exemp-  
11          tion’ shall have the meanings given the terms in regula-  
12          tions prescribed by the Secretary.”.

13          (f) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section  
14          569A(b) of the Federal Food, Drug, and Cosmetic Act (21  
15          U.S.C. 360bbb–8a(b)) is amended—

16                 (1) by striking “subsection” each place it ap-  
17                 pears and inserting “paragraph”; and

18                 (2) by inserting “an in vitro clinical test, as de-  
19                 fined in paragraph (ss) of such section,” before “or  
20                 a biological product”.

21          (g) PATIENT PARTICIPATION IN MEDICAL PRODUCT  
22          DISCUSSION.—The heading of subsection (a) of section  
23          569C of the Federal Food, Drug, and Cosmetic Act (21  
24          U.S.C. 360bbb–8c) is amended by striking “DRUGS AND

1 DEVICES” and inserting “DRUGS, DEVICES, AND IN  
2 VITRO CLINICAL TESTS”.

3 (h) REGULATIONS AND HEARINGS.—Clause (ii) of  
4 section 701(h)(1)(C) of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 371(h)(1)(C)) is amended—

6 (1) by inserting “and in vitro clinical tests”  
7 after “devices”; and

8 (2) by moving the margin of such clause 2 ems  
9 to the left.

10 (i) RECORDS.—Section 703 of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

12 (1) by inserting “in vitro clinical tests,” after  
13 “devices,” each place such term appears; and

14 (2) by inserting “in vitro clinical test,” after  
15 “device,” each place such term appears.

16 (j) FACTORY INSPECTION.—Section 704 of the Fed-  
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other  
18 than subsection (g)) is amended—

19 (1) by striking “drugs or devices” each place it  
20 appears and inserting “drugs, devices, or in vitro  
21 clinical tests”;

22 (2) in subsection (a)(1), in the fourth sentence,  
23 by striking “or chapter IX” and inserting “section  
24 587S, section 587M, section 587N, or chapter IX”;

- 1           (3) after making the amendments in para-
- 2           graphs (1) and (2), by inserting “in vitro clinical
- 3           tests,” after “devices,” each place it appears;
- 4           (4) in subsection (a)(2)(B)—
- 5                 (A) by inserting “or in vitro clinical tests”
- 6                 after “prescribe or use devices”; and
- 7                 (B) by inserting “or in vitro clinical tests”
- 8                 after “process devices”;
- 9           (5) by inserting “in vitro clinical test,” after
- 10           “device,” each place it appears;
- 11           (6) in subsection (e), by inserting “, or section
- 12           587M, 587N, or 587S,” after “section 519 or
- 13           520(g)”;
- 14           (7) in subsection (f)(3)—
- 15                 (A) in subparagraph (A), by striking “or”
- 16                 at the end;
- 17                 (B) in subparagraph (B), by striking the
- 18                 period at the end and inserting “; or”; and
- 19                 (C) after subparagraph (B), by inserting
- 20           the following:
- 21                 “(C) is accredited under section 587Q.”;
- 22           and
- 23           (8) by adding at the end the following:

1           “(i) For purposes of this section, the term ‘establish-  
2 ment’ includes a laboratory performing an in vitro clinical  
3 test.”.

4           (k) PUBLICITY.—Section 705(b) of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended  
6 by inserting “in vitro clinical tests,” after “devices,”.

7           (l) PRESUMPTION.—Section 709 of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by  
9 inserting “in vitro clinical test,” after “device,”.

10          (m) LISTING AND CERTIFICATION OF COLOR ADDI-  
11 TIVES FOR FOODS, DRUGS, AND COSMETICS.—Section  
12 721(a) of the Federal Food, Drug, and Cosmetic Act (21  
13 U.S.C. 379e(a)) is amended—

14           (1) in the matter preceding paragraph (1), by  
15 inserting “or in vitro clinical tests” after “or de-  
16 vices”; and

17           (2) in the flush text following paragraph (2)—

18               (A) by inserting “or an in vitro clinical  
19 test” after “a device”; and

20               (B) by inserting “or in vitro clinical tests”  
21 after “devices”.

22          (n) IMPORTS AND EXPORTS.—Section 801 of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)  
24 is amended—

25           (1) in subsection (a)—

1 (A) by inserting “in vitro clinical tests,”  
2 after “devices,” each place it appears; and

3 (B) by inserting “in the case of an in vitro  
4 clinical test, the test does not conform to the  
5 applicable requirements of section 587K, or”  
6 after “requirements of section 520(f), or”;

7 (2) in subsection (d)(3)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),  
10 by inserting “and no component of an in  
11 vitro clinical test or other article of in vitro  
12 clinical test that requires further proc-  
13 essing,” after “health-related purposes”;

14 (ii) in clause (i), by striking “drug or  
15 device” and inserting “drug, device, or in  
16 vitro clinical test”; and

17 (iii) in clause (i)(I), by inserting “in  
18 vitro clinical test,” after “device,”; and

19 (B) in subparagraph (B), by inserting “in  
20 vitro clinical test,” after “device,”;

21 (3) in subsection (e)(1), by inserting “in vitro  
22 clinical test,” after “device,”; and

23 (4) in subsection (o)—

24 (A) by inserting “or in vitro clinical test”  
25 after “device”; and



1 (B) by inserting “, or under section 587J  
2 of each foreign establishment,” after “section  
3 510(i) of each establishment”.

4 (o) OFFICE OF INTERNATIONAL RELATIONS.—Sec-  
5 tion 803 of the Federal Food, Drug, and Cosmetic Act  
6 (21 U.S.C. 383) is amended—

7 (1) in subsection (b)—

8 (A) in the matter preceding paragraph (1),  
9 by inserting “and in vitro clinical tests” after  
10 “devices”; and

11 (B) in paragraph (1), by striking “, and”  
12 and inserting “and quality requirements estab-  
13 lished under section 587K; and”; and

14 (2) in subsection (c)—

15 (A) in paragraph (2), by inserting “in vitro  
16 clinical tests,” after “devices,”; and

17 (B) in paragraph (4), by inserting “or in  
18 vitro clinical tests” after “devices”.

19 (p) RECOGNITION OF FOREIGN GOVERNMENT IN-  
20 SPECTIONS.—Section 809(a)(1) of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-  
22 ed by inserting “, or of foreign establishments registered  
23 under section 587J,” after “510(h)”.

1 (q) FOOD AND DRUG ADMINISTRATION.—Section  
2 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 393(b)(2)) is amended—

4 (1) in subparagraph (D), by striking “and” at  
5 the end;

6 (2) in subparagraph (E), by striking the semi-  
7 colon at the end and inserting “; and”; and

8 (3) by adding at the end the following:

9 “(F) in vitro clinical tests are analytically  
10 and clinically valid;”.

11 (r) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)  
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 399b(b)) is amended—

14 (1) in paragraph (1), by inserting “in vitro clin-  
15 ical tests,” after “devices,”; and

16 (2) in paragraph (4), by inserting “in vitro clin-  
17 ical test developers,” after “device manufacturers,”.

18 (s) COUNTERMEASURE PROVISIONS OF THE PUBLIC  
19 HEALTH SERVICE ACT.—Title III of the Public Health  
20 Service Act is amended—

21 (1) in section 319F–1(a)(2)(A) (42 U.S.C.  
22 247d–6a(a)(2)(A))—

23 (A) in the matter preceding clause (i)—

24 (i) by striking “or device” and insert-  
25 ing “device”; and

1 (ii) by inserting “or an in vitro clin-  
2 ical tests (as that term is defined in sec-  
3 tion 201(ss) of the Federal Food, Drug,  
4 and Cosmetic Act (21 U.S.C. 321(ss)),”  
5 after “Act (21 U.S.C. 321(h)),”; and

6 (B) in each of clauses (ii) and (iii), by  
7 striking “or device” and inserting “device, or in  
8 vitro clinical test”;

9 (2) in section 319F–2(c)(1)(B) (42 U.S.C.  
10 247d–6b(c)(1)(B))—

11 (A) by striking “or device” and inserting  
12 “device”; and

13 (B) by inserting “, or an in vitro clinical  
14 test (as that term is defined in section 201(ss)  
15 of the Federal Food, Drug, and Cosmetic Act  
16 (21 U.S.C. 321(ss))” after “Act (21 U.S.C.  
17 321(h)),”; and

18 (3) in section 319F–3(i)(7) (42 U.S.C. 247d–  
19 6d(i)(7))—

20 (A) in the matter preceding subparagraph

21 (A)—

22 (i) by striking “or device” and insert-  
23 ing “device”; and

24 (ii) by inserting “or an in vitro clin-  
25 ical tests (as that term is defined in sec-

1                   tion 201(ss) of the Federal Food, Drug,  
2                   and Cosmetic Act (21 U.S.C. 321(ss)),”  
3                   after “Act (21 U.S.C. 321(h))”;

4                   (B) in subparagraph (A)—

5                   (i) by moving the margin of clause  
6                   (iii) 2 ems to the left; and

7                   (ii) in clause (iii), by striking “or de-  
8                   vice” and inserting “device, or in vitro clin-  
9                   ical test”; and

10                  (C) in subparagraph (B)—

11                  (i) in clause (i), by striking “approved  
12                  or cleared” and inserting “approved,  
13                  cleared, or offered under a technology cer-  
14                  tification order”; and

15                  (ii) in clause (ii), by striking “or  
16                  520(g)” and inserting “, 520(g), or 587S”.

17 **SEC. 5. TRANSITION.**

18                  (a) IMPLEMENTATION.—

19                   (1) EFFECTIVE DATE.—

20                   (A) IN GENERAL.—Except as otherwise  
21                   provided in this section, the amendments made  
22                   by this Act shall take effect on October 1, 2028  
23                   (in this section and in subchapter J of chapter  
24                   V of the Federal Food, Drug, and Cosmetic

1 Act, as added by this Act, referred to in this  
2 section as the “effective date of this Act”).

3 (B) EXCEPTIONS.—

4 (i) IN GENERAL.—The Secretary of  
5 Health and Human Services (in this sec-  
6 tion referred to as the “Secretary”) may  
7 take the actions described in paragraph  
8 (2), and may expend such funds as the  
9 Secretary determines necessary to ensure  
10 an orderly transition prior to the effective  
11 date of this Act.

12 (ii) IMPLEMENTATION OF CERTAIN  
13 PROVISIONS.—The Secretary may imple-  
14 ment sections 587J and 587U of the Fed-  
15 eral Food, Drug, and Cosmetic Act (as  
16 added by section 3) beginning on October  
17 1, 2024, and such sections may take effect  
18 not earlier than October 1, 2028, to the  
19 extent and for the purposes indicated in  
20 such sections. In the case of a developer  
21 who, between October 1, 2024, and the ef-  
22 fective date of this Act, registers under  
23 such section 587J with respect to an arti-  
24 cle that is an in vitro clinical test, such de-  
25 veloper shall not be required to register

1 with respect to such article under section  
2 510 of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 360).

4 (2) ACTIONS.—The Secretary—

5 (A) shall—

6 (i) within 1 year of the date of enact-  
7 ment of this Act, hold the public meetings  
8 described in section 587D(i) of the Federal  
9 Food, Drug, and Cosmetic Act (as added  
10 by section 3); and

11 (ii) within 3 years of the date of en-  
12 actment of this Act, promulgate final regu-  
13 lations required under the amendments  
14 made by this Act; and

15 (B) may take additional actions after the  
16 date of enactment that the Secretary deter-  
17 mines necessary to ensure an orderly transition,  
18 including—

19 (i) establishment of mitigating meas-  
20 ures for an in vitro clinical test or category  
21 of in vitro clinical tests, which may not  
22 take effect until after the effective date de-  
23 scribed in paragraph (1)(A); and

24 (ii) establishment of the comprehen-  
25 sive test information system under section

1                   587T of the Federal Food, Drug, and Cos-  
2                   metic Act, as added by section 3.

3                   (3) APPLICABILITY OF GUIDANCE AND REGULA-  
4                   TIONS.—Notwithstanding the date on which guid-  
5                   ance or regulations are issued under paragraph (2)  
6                   and section 587K of the Federal Food, Drug, and  
7                   Cosmetic Act, as added by section 3, no guidance or  
8                   regulations issued pursuant to the amendments  
9                   made by this Act shall be implemented or take effect  
10                  until the effective date of this Act, except as other-  
11                  wise specified in this Act (including the amendments  
12                  made by this Act).

13                  (4) IMPLEMENTATION REQUIREMENTS.—In the  
14                  event that the Secretary fails to promulgate the reg-  
15                  ulations required under section 587B(a)(4),  
16                  587D(j), or 587S(b)(1) of the Federal Food, Drug,  
17                  and Cosmetic Act, as added by section 3, by the  
18                  deadline described in subsection (a)(2)(A)(ii), the  
19                  Secretary shall, within 15 days of such missed dead-  
20                  line—

21                         (A) submit a report to the Committee on  
22                         Health, Education, Labor, and Pensions of the  
23                         Senate and the Committee on Energy and Com-  
24                         merce of the House of Representatives pro-

1           viding information related to the status of such  
2           regulations, including—

3                   (i) a rationale for missing the applica-  
4                   ble deadline described in such subsection;

5                   (ii) a description of actions taken to  
6                   the date of submission of the report to pro-  
7                   mulgate each such regulations;

8                   (iii) the expected timeline for promul-  
9                   gating each such regulations;

10                   (iv) an assessment of the impact of  
11                   the delay in promulgating such regulations  
12                   on developers of in vitro clinical tests, in-  
13                   cluding an economic assessment; and

14                   (v) an assessment of the impact of the  
15                   delay in promulgating such regulations on  
16                   patients; and

17                   (B) open a public docket for purposes of  
18                   soliciting public comments on the impact of the  
19                   delay in promulgating such regulations.

20           (b) APPLICATION OF AUTHORITIES TO IN VITRO  
21           CLINICAL TESTS UNDER REVIEW ON THE EFFECTIVE  
22           DATE OF THIS ACT.—For any in vitro clinical test for  
23           which a submission for approval under section 515 of the  
24           Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e),  
25           clearance under section 510(k) of such Act (21 U.S.C.



1 360(k)), authorization under section 513(f)(2) of such Act  
2 (21 U.S.C. 360c(f)(2)), or licensure under section 351 of  
3 the Public Health Service Act (42 U.S.C. 262) is pending  
4 on the effective date of this Act, including transitional in  
5 vitro clinical tests as described in subsection (c), the Sec-  
6 retary may review and take action on such submission  
7 after the effective date of this Act according to the statu-  
8 tory provision under which such submission was sub-  
9 mitted.

10 (c) APPLICATION OF AUTHORITIES TO TRANSI-  
11 TIONAL IN VITRO CLINICAL TESTS.—

12 (1) DEFINITION.—For purposes of this section,  
13 the term “transitional in vitro clinical test” means  
14 an in vitro clinical test that—

15 (A)(i) is first offered for clinical use during  
16 the period beginning on the date that is 45  
17 days after the date of enactment of this Act  
18 and ending on the effective date of this Act; or

19 (ii) is offered solely for investigational use  
20 during the period beginning on the date of en-  
21 actment of this Act and ending on the effective  
22 date of this Act;

23 (B) is developed by a clinical laboratory  
24 certified by the Secretary under section 353 of  
25 the Public Health Service Act (42 U.S.C. 263a)

1           that meets the requirements for performing  
2           high-complexity testing and performed—

3                   (i) in the same clinical laboratory in  
4                   which the test was developed and for which  
5                   a certification is still in effect under such  
6                   section 353 that meets the requirements to  
7                   perform tests of high complexity;

8                   (ii) by another laboratory for which a  
9                   certificate is in effect under such section  
10                  353 that meets the requirements to per-  
11                  form tests of high complexity, is within the  
12                  same corporate organization, and has com-  
13                  mon ownership by the same parent cor-  
14                  poration as the laboratory in which the  
15                  test was developed; or

16                  (iii) in the case of a test that was de-  
17                  veloped by the Centers for Disease Control  
18                  and Prevention or another laboratory in a  
19                  public health laboratory network coordi-  
20                  nated or managed by the Centers for Dis-  
21                  ease Control and Prevention, by a clinical  
22                  laboratory for which a certificate is in ef-  
23                  fect under such section 353 that meets the  
24                  requirements to perform tests of high com-  
25                  plexity, and that is within a public health

1 laboratory network coordinated or man-  
2 aged by the Centers for Disease Control  
3 and Prevention; and

4 (C) when first offered, is not approved  
5 under section 515 of the Federal Food, Drug,  
6 and Cosmetic Act, cleared under section 510(k)  
7 of such Act, authorized under section 513(f)(2)  
8 of such Act, subject to a humanitarian device  
9 exemption under section 520(m) of such Act  
10 (21 U.S.C. 360j(m)), subject to an exemption  
11 for investigation use under section 520(g) of  
12 such Act (21 U.S.C. 360j(g)), authorized under  
13 section 564 of such Act (21 U.S.C. 360bbb-3),  
14 or licensed under section 351 of the Public  
15 Health Service Act (42 U.S.C. 262).

16 (2) PREMARKET REVIEW OR TECHNOLOGY CER-  
17 TIFICATION.—A transitional in vitro clinical test  
18 that is not exempt from premarket review under sec-  
19 tion 587C of the Federal Food, Drug, and Cosmetic  
20 Act, as added by section 3, may continue to be of-  
21 fered, sold, or distributed, as applicable, without  
22 marketing authorization until completion of the Sec-  
23 retary's review of the premarket application or tech-  
24 nology certification application under section 587B  
25 or 587D, as applicable, if—

1 (A) such in vitro clinical test is a high-risk  
2 test (as defined in section 587 of the Federal  
3 Food, Drug, and Cosmetic Act, as added by  
4 section 3) and the application for such test is  
5 submitted not later than 90 days after the ef-  
6 fective date of this Act; or

7 (B) such in vitro clinical test is a mod-  
8 erate-risk test (as defined in such section 587),  
9 the developer lists the test in accordance with  
10 section 587J within 10 calendar days of the ef-  
11 fective date of this subchapter, and the applica-  
12 tion for such test is submitted not later than 1  
13 year after the effective date of this Act.

14 (3) INVESTIGATIONAL USE REQUEST.—A tran-  
15 sitional in vitro clinical test described in paragraph  
16 (1)(A)(ii) that is used in a significant risk investiga-  
17 tion may continue to be offered for investigational  
18 use until completion of the Secretary's review of an  
19 application under 587S, if such application is sub-  
20 mitted not later than 90 days after the effective date  
21 of this Act.

22 (4) TESTS APPROVED BY NEW YORK STATE.—  
23 Notwithstanding paragraph (2), a transitional in  
24 vitro clinical test that has been approved by the New  
25 York State Department of Health may continue to

1 be offered, sold, or distributed, as applicable, after  
2 the effective date if—

3 (A) starting on the effective date of this  
4 Act, the in vitro clinical test complies with the  
5 requirements of subchapter J of the Federal  
6 Food, Drug, and Cosmetic Act, as added by  
7 this Act, except for section 587B of the Federal  
8 Food, Drug, and Cosmetic Act, as added by  
9 section 3, and design control provisions of sec-  
10 tion 587K of such Act;

11 (B) each test report for the test bears a  
12 statement of adequate prominence that reads as  
13 follows: “This in vitro clinical test was devel-  
14 oped and first introduced prior to the effective  
15 date of the VALID Act of 2023. This test was  
16 approved by the New York State Department of  
17 Health, but the test has not been reviewed by  
18 the Food and Drug Administration.”;

19 (C) a premarket application under section  
20 587B of the Federal Food, Drug, and Cosmetic  
21 Act, as added by section 3, or technology cer-  
22 tification application under section 587D of  
23 such Act, as added by section 3, is submitted  
24 no later than—

1 (i) 5 years after the effective date of  
2 this Act, if the in vitro clinical test is ap-  
3 proved by the New York State Department  
4 of Health as a genetic testing molecular  
5 test, a microbiology molecular test, an on-  
6 cology molecular test, or any other type of  
7 molecular test; or

8 (ii) 2 years after the effective date of  
9 this Act, if the in vitro clinical test is ap-  
10 proved by the New York State Department  
11 of Health as a type of test not described  
12 in clause (i); and

13 (D) a test in compliance with this para-  
14 graph may continue to be offered, sold, or dis-  
15 tributed, as applicable, until the completion of  
16 the Secretary's review of the premarket applica-  
17 tion or technology certification application de-  
18 scribed in subparagraph (C).

19 (d) CONVERSION.—

20 (1) DEEMED PREMARKET APPROVAL.—Begin-  
21 ning on the effective date of this Act—

22 (A) any in vitro clinical test with a pre-  
23 market approval under section 515 of the Fed-  
24 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
25 360e) or a licensure under section 351 of the

1           Public Health Service Act (42 U.S.C. 262) is  
2           deemed to be approved pursuant to an applica-  
3           tion under section 587B(a) of the Federal  
4           Food, Drug, and Cosmetic Act, as added by  
5           this Act; and

6                   (B) any in vitro clinical test (as so defined)  
7           that was cleared under section 510(k) of the  
8           Federal Food, Drug, and Cosmetic Act (21  
9           U.S.C. 360(k)) or authorized under section  
10          513(f)(2) of the Federal Food, Drug, and Cos-  
11          metic Act (21 U.S.C. 360c(f)(2)) is deemed to  
12          be approved pursuant to an application under  
13          section 587B(b) of the Federal Food, Drug,  
14          and Cosmetic Act, as added by this Act.

15           (2) DEEMED INVESTIGATIONAL USE EXEMP-  
16          TION.—Any in vitro clinical test that has an inves-  
17          tigational device exemption in effect under section  
18          520(g) of the Federal Food, Drug, and Cosmetic Act  
19          (21 U.S.C. 360j(g)) is deemed to have an investiga-  
20          tional use exemption in effect under section 587S of  
21          such Act, as added by this Act, beginning on the ef-  
22          fective date of this Act.

23           (3) DEEMED HUMANITARIAN DEVICE EXEMP-  
24          TION.—Any in vitro clinical test that has an ap-  
25          proved humanitarian device exemption under section

1 520(m) of such Act is deemed to have a humani-  
2 tarian test exemption under section 587A(g) of such  
3 Act, as added by this Act, beginning on the effective  
4 date of this Act.

5 (4) DEEMED DESIGNATED BREAKTHROUGH.—  
6 Any in vitro clinical test that has received a break-  
7 through device designation under section  
8 515B(e)(1)(D) of such Act (21 U.S.C. 360e-  
9 3(e)(1)(D)) is deemed to have a breakthrough in  
10 vitro clinical test designation under section 587C of  
11 such Act, as added by this Act, beginning on the ef-  
12 fective date of this Act.

13 (5) DEEMED REQUEST FOR INFORMAL FEED-  
14 BACK.—With regard to any in vitro clinical test that  
15 is the subject of a pre-submission request described  
16 in the guidance, “Requests for Feedback and Meet-  
17 ings for Medical Device Submissions: The Q-Sub-  
18 mission Program”, issued by the Food and Drug  
19 Administration on January 6, 2021, such request is  
20 deemed to constitute a request for informal feedback  
21 under section 587F of the Federal Food, Drug, and  
22 Cosmetic Act, as added by section 3, beginning on  
23 the effective date of this Act.

24 (e) PREVIOUSLY CLASSIFIED DEVICES.—Notwith-  
25 standing section 587 of the Federal Food, Drug, and Cos-



1 metric Act, as added by section 3, for purposes of sub-  
2 chapter J of chapter V of such Act, as added by section  
3 3, the following apply:

4 (1) In the case of an in vitro clinical test type  
5 that has been classified by the Secretary as a class  
6 I device pursuant to section 513 of such Act (21  
7 U.S.C. 360c), such in vitro clinical test shall be low-  
8 risk, unless the in vitro clinical test is a test de-  
9 scribed in the second sentence of section 510(l)(1) of  
10 such Act or the test is redesignated by the Secretary  
11 pursuant to section 587F of such Act.

12 (2) In the case of an in vitro clinical test type  
13 that has been classified by the Secretary as a class  
14 II device pursuant to section 513 of such Act (21  
15 U.S.C. 360c), such in vitro clinical test shall be  
16 moderate-risk, unless inaccurate results from the  
17 test would be immediately life threatening or the test  
18 is redesignated by the Secretary pursuant to section  
19 587F of such Act.

20 (3) In the case of an in vitro clinical test type  
21 that has been classified by the Secretary as a class  
22 III device pursuant to section 513 of such Act (21  
23 U.S.C. 360c) or an in vitro clinical test licensed pur-  
24 suant to section 351 of the Public Health Service  
25 Act (42 U.S.C. 262), such in vitro clinical test shall

1 be high-risk, unless redesignated by the Secretary  
2 pursuant to section 587F of the Federal Food,  
3 Drug, and Cosmetic Act.

4 **SEC. 6. EMERGENCY USE AUTHORIZATION.**

5 (a) IN GENERAL.—Section 564 of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-  
7 ed—

8 (1) by inserting “or developer” after “manufac-  
9 turer”, each place such term appears;

10 (2) in subsection (a)—

11 (A) in paragraphs (1) and (4)(C), by in-  
12 serting “in vitro clinical test,” before “or bio-  
13 logical product” each place such term appears;

14 (B) in paragraph (2)(A), by striking “or  
15 515” and inserting “515, or 587B”; and

16 (C) by adding at the end the following:

17 “(F) The terms ‘develop’ and ‘developer’,  
18 with respect to an in vitro clinical test, have the  
19 meanings given such terms in section 587.”;

20 (3) in subsection (b), by inserting “or devel-  
21 oper” after “manufacturer” each place such term  
22 appears;

23 (4) in subsection (e)—

24 (A) by inserting “or developers” after  
25 “manufacturers” each place such term appears;

1 (B) in paragraph (2)(B)(ii), by inserting  
2 “or develop” after “not manufacture”;

3 (C) in paragraph (3)—

4 (i) in subparagraph (A), by striking  
5 “or 520(f)(1)” and inserting “, 520(f)(1),  
6 or 587V”;

7 (ii) in subparagraph (B), by striking  
8 “and” at the end;

9 (iii) in subparagraph (C), by striking  
10 the period and inserting “ or 587O; and”;  
11 and

12 (iv) by adding at the end the fol-  
13 lowing:

14 “(D) quality requirements (with respect to  
15 in vitro clinical tests) under section 587K.”;  
16 and

17 (D) in paragraph (4)—

18 (i) in subparagraph (A), by striking “;  
19 or” and inserting a semicolon;

20 (ii) in subparagraph (B), by striking  
21 the period and inserting “; or”; and

22 (iii) by adding at the end the fol-  
23 lowing:

1           “(C) with respect to in vitro clinical tests,  
2           requirements applicable to restricted in vitro  
3           clinical tests pursuant to section 587O.”;

4           (5) in subsection (k), by striking “or 520(g)”  
5           and inserting “520(g), or 587S”; and

6           (6) in subsection (m)—

7           (A) in the subsection heading, by striking  
8           “LABORATORY TESTS ASSOCIATED WITH DE-  
9           VICES” inserting “IN VITRO CLINICAL TESTS”  
10          after “DEVICES”; and

11          (B) in paragraph (1)—

12                 (i) by striking “to a device” and in-  
13                 serting “to an in vitro clinical test”; and

14                 (ii) by striking “such device” and in-  
15                 serting “such in vitro clinical test”.

16          (b) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-  
17          tion 564A of the Federal Food, Drug, and Cosmetic Act  
18          (21 U.S.C. 360bbb–3a) is amended—

19                 (1) in subsection (a)—

20                         (A) in paragraph (2), by inserting “in vitro  
21                         clinical test,” after “device,”; and

22                         (B) by adding at the end the following:

23                                 “(3) DEVELOPER.—The term ‘developer’, with  
24                                 respect to an in vitro clinical test, has the meaning  
25                                 given such term in section 587.”;

1 (2) by inserting “or developer” after “manufac-  
2 turer” each place it appears; and

3 (3) in subsection (c)(1)—

4 (A) by inserting “or quality requirements”  
5 after “good manufacturing practice require-  
6 ments”; and

7 (B) by striking “or 520(f)(1)” and insert-  
8 ing “, 520(f)(1), or 587K”.

9 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-  
10 tion 564B(2) of the Federal Food, Drug, and Cosmetic  
11 Act (21 U.S.C. 360bbb–3b(2)) is amended—

12 (1) in subparagraph (A), by striking “or 515”  
13 and inserting “515, or 587B”; and

14 (2) in subparagraph (B), by striking “or 520”  
15 and inserting 520, or 587S.

16 **SEC. 7. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

17 Section 511A of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 360a–2) is amended—

19 (1) in subsection (a)(1)(C)—

20 (A) by striking “clear under section  
21 510(k), classify under section 513(f)(2), or ap-  
22 prove under section 515” and inserting “ap-  
23 prove under section 587B, exempt from pre-  
24 market review under section 587C, or grant a

1 technology certification order under section  
2 587D”; and

3 (B) by striking “testing devices” and in-  
4 serting “in vitro clinical tests”;

5 (2) in subsection (c)(5)—

6 (A) by striking “drug or device” and in-  
7 serting “drug, device, or in vitro clinical test”;

8 and

9 (B) by striking “the drug or the device”  
10 and inserting “the drug, device, or in vitro clin-  
11 ical test”;

12 (3) in subsection (e)—

13 (A) in the heading, by striking “TESTING  
14 DEVICES” and inserting “IN VITRO CLINICAL  
15 TESTS”;

16 (B) in paragraph (1)—

17 (i) by striking “510, 513, and 515,”  
18 and inserting “587B, and 587D”;

19 (ii) by striking “antimicrobial suscep-  
20 tibility testing device” and inserting “anti-  
21 microbial susceptibility in vitro clinical  
22 test”; and

23 (iii) by striking “such device” and in-  
24 serting “such in vitro clinical test”; and

25 (C) in paragraph (2)—

1 (i) in the heading, by striking “TEST-  
2 ING DEVICES” and inserting “IN VITRO  
3 CLINICAL TESTS”;

4 (ii) in subparagraphs (A) and (B)  
5 (other than clause (iii) of such subpara-  
6 graph (B)), by striking “device” each place  
7 it appears and inserting “in vitro clinical  
8 test”;

9 (iii) in subparagraph (B)(iii), by strik-  
10 ing “a device” and inserting “an in vitro  
11 clinical test”; and

12 (iv) by amending subparagraph (C) to  
13 read as follows:

14 “(C) The antimicrobial susceptibility in  
15 vitro clinical test meets all other requirements  
16 to be approved under section 587B, to be ex-  
17 empted from premarket review under section  
18 587C, or to be offered under a technology cer-  
19 tification order under section 587D.”;

20 (4) in subsection (f), by amending paragraph  
21 (1) to read as follows:

22 “(1) The term ‘antimicrobial susceptibility in  
23 vitro clinical test’ means an in vitro clinical test that  
24 utilizes susceptibility test interpretive criteria to de-

1       termine and report the in vitro susceptibility of cer-  
2       tain microorganisms to a drug (or drugs).”; and

3               (5) in subsection (g)(2)—

4                       (A) by amending the matter preceding sub-  
5       paragraph (A) to read as follows:

6               “(2) with respect to approving an application  
7       under section 587B or granting a technology certifi-  
8       cation order under section 587D—”; and

9                       (B) in subparagraph (A)—

10                               (i) by striking “device” and inserting  
11       “in vitro clinical test”; and

12                               (ii) by striking “antimicrobial suscep-  
13       tibility testing device” and inserting “anti-  
14       microbial susceptibility in vitro clinical  
15       test”.

16 **SEC. 8. COMBINATION PRODUCTS.**

17       (a) **IN GENERAL.**—Section 503(g) of the Federal  
18       Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is  
19       amended—

20               (1) in paragraph (1)—

21                       (A) in subparagraph (A), by striking “or  
22       biological product” and inserting “in vitro clin-  
23       ical test (except for a product constituted of a  
24       device and an in vitro clinical test), or biological  
25       product”;



1 (B) in subparagraph (B), by adding at the  
2 end the following: “For purposes of this Act, a  
3 product that constitutes a combination of a de-  
4 vice and an in vitro clinical test is not a com-  
5 bination product within the meaning of this  
6 subsection and an in vitro clinical test that is  
7 offered as a separate product intended to in-  
8 form the use of a drug, biological product, or  
9 device is not a combination product within the  
10 meaning of this subsection.”; and

11 (C) in subparagraph (D)(ii)—

12 (i) by inserting “or in vitro clinical  
13 test” after “device”; and

14 (ii) by inserting “and in vitro clinical  
15 tests” before “shall”;

16 (2) in paragraph (3), by striking “safety and  
17 effectiveness or substantial equivalence” and insert-  
18 ing “safety and effectiveness, substantial equiva-  
19 lence, or analytical validity and clinical validity” be-  
20 fore “for the approved constituent part”;

21 (3) in paragraph (4)—

22 (A) in subparagraph (A), by striking “or  
23 513(f)(2) (submitted in accordance with para-  
24 graph (5))” and inserting “513(f)(2) (sub-

1 mitted in accordance with paragraph (5)),  
2 587B, or 587D”; and

3 (B) in subparagraph (C), by striking “or  
4 515” and inserting “515, or 587B, or that is  
5 under an order under section 587D”;

6 (4) in paragraph (5)(A), by striking “or  
7 510(k)” and inserting “, 510(k), 587B, or 587D”;

8 (5) in paragraph (7), by striking “or substan-  
9 tial equivalence” and inserting “, substantial equiva-  
10 lence, or analytical validity and clinical validity”;

11 (6) in paragraph (8), by adding at the end the  
12 following:

13 “(I) This paragraph shall not apply to a  
14 product constituted of a device and an in vitro  
15 clinical test.”; and

16 (7) in paragraph (9)—

17 (A) in subparagraph (C)(i), by striking “or  
18 520(g)” and inserting “520(g), 587B, or  
19 587D”; and

20 (B) in subparagraph (D), by striking “or  
21 520” and inserting “520, 587B, or 587D”.

22 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of  
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 360bbb–2) is amended by adding at the end the following:

1           “(d) EXEMPTION.—This section shall not apply to a  
2 product constituted of only a device and an in vitro clinical  
3 test.”.

4 **SEC. 9. RESOURCES.**

5           (a) FINDINGS.—Congress finds that the fees author-  
6 ized by this section will be dedicated to meeting the goals  
7 identified in the letters from the Secretary of Health and  
8 Human Services to the Committee on Health, Education,  
9 Labor, and Pensions of the Senate and the Committee on  
10 Energy and Commerce of the House of Representatives,  
11 as set forth in the Congressional Record.

12           (b) ESTABLISHMENT OF USER FEE PROGRAM.—

13                   (1) DEVELOPMENT OF USER FEES FOR IN  
14 VITRO CLINICAL TESTS.—

15                           (A) IN GENERAL.—Beginning not later  
16 than October 1, 2025, the Secretary of Health  
17 and Human Services (in this section referred to  
18 as the “Secretary”) shall initiate the develop-  
19 ment of recommendations in accordance with  
20 this section to present to Congress with respect  
21 to the goals, and plans for meeting the goals,  
22 for the process for the review of in vitro clinical  
23 test submissions and applications under sub-  
24 chapter J of chapter V of the Federal Food,  
25 Drug, and Cosmetic Act, as added by this Act,

1 for the first 4 fiscal years after fiscal year 2028  
2 and for the authorization of the In Vitro Clin-  
3 ical Test User Fee Program for such fiscal  
4 years. In developing such recommendations, the  
5 Secretary shall consult with—

6 (i) the Committee on Health, Edu-  
7 cation, Labor, and Pensions of the Senate;

8 (ii) the Committee on Energy and  
9 Commerce of the House of Representa-  
10 tives;

11 (iii) scientific and academic experts;

12 (iv) health care professionals;

13 (v) representatives of patient and con-  
14 sumer advocacy groups; and

15 (vi) the regulated industry.

16 (B) PRIOR PUBLIC INPUT.—Prior to begin-  
17 ning negotiations with the regulated industry  
18 on the authorization of the In Vitro Clinical  
19 Test User Fee Program, as described in this  
20 section, the Secretary shall—

21 (i) publish a notice in the Federal  
22 Register requesting public input on the au-  
23 thorization of user fees;

24 (ii) hold a public meeting at which the  
25 public may present its views on the author-

1            ization, including specific suggestions for  
2            the recommendations submitted under sub-  
3            paragraph (E);

4            (iii) provide a period of 30 days after  
5            the public meeting to obtain written com-  
6            ments from the public suggesting changes  
7            to the In Vitro Clinical Test User Fee Pro-  
8            gram; and

9            (iv) publish any comments received  
10           under clause (iii) on the website of the  
11           Food and Drug Administration.

12           (C) PERIODIC CONSULTATION.—Not less  
13           frequently than once every month during nego-  
14           tiations with the regulated industry, the Sec-  
15           retary shall hold discussions with representa-  
16           tives of patient and consumer advocacy groups  
17           to continue discussions of the authorization of  
18           the In Vitro Clinical Test User Fee Program  
19           and to solicit suggestions to be included in the  
20           recommendations transmitted to Congress  
21           under subparagraph (F).

22           (D) UPDATES TO CONGRESS.—The Sec-  
23           retary, in consultation with regulated industry,  
24           shall provide regular updates on negotiations on  
25           the reauthorization of the In Vitro Clinical Test

1           User Fee Program to the Committee on Health,  
2           Education, Labor, and Pensions of the Senate  
3           and the Committee on Energy and Commerce  
4           of the House of Representatives.

5           (E) PUBLIC REVIEW OF RECOMMENDA-  
6           TIONS.—After negotiations with the regulated  
7           industry, the Secretary shall—

8                   (i) present the recommendations de-  
9                   veloped under subparagraph (A) to the  
10                  Committee on Health, Education, Labor,  
11                  and Pensions of the Senate and the Com-  
12                  mittee on Energy and Commerce of the  
13                  House of Representatives;

14                   (ii) publish such recommendations in  
15                  the Federal Register;

16                   (iii) provide for a period of 30 days  
17                  for the public to provide written comments  
18                  on such recommendations;

19                   (iv) hold a meeting at which the pub-  
20                  lic may present its views on such rec-  
21                  ommendations; and

22                   (v) after consideration of such public  
23                  views and comments, revise such rec-  
24                  ommendations as necessary.

1 (F) TRANSMITTAL OF RECOMMENDA-  
2 TIONS.—

3 (i) IN GENERAL.—Not later than Jan-  
4 uary 15, 2027, the Secretary shall trans-  
5 mit to Congress the revised recommenda-  
6 tions under subparagraph (A), a summary  
7 of the views and comments received under  
8 such subparagraph, and any changes made  
9 to the recommendations in response to  
10 such views and comments.

11 (ii) RECOMMENDATION REQUIRE-  
12 MENTS.—The recommendations trans-  
13 mitted under this subparagraph shall—

14 (I) include the number of full-  
15 time equivalent employees per fiscal  
16 year that are agreed to be hired to  
17 carry out the goals included in such  
18 recommendations for each year of the  
19 5-year period;

20 (II) provide that the amount of  
21 operating reserve balance in the user  
22 fee program established under this  
23 section is not more than the equiva-  
24 lent of 10 weeks of operating reserve;

1 (III) require the development of  
2 a strategic plan for any surplus within  
3 the operating reserve account above  
4 the 10-week operating reserve within  
5 2 years of the establishment of the  
6 program;

7 (IV) include an operating reserve  
8 adjustment such that, if the Secretary  
9 has an operating reserve balance in  
10 excess of 10 weeks of such operating  
11 reserves, the Secretary shall decrease  
12 such fee revenue and fees to provide  
13 for not more than 10 weeks of such  
14 operating reserves;

15 (V) if an adjustment is made as  
16 described in subclause (IV), provide  
17 the rationale for the amount of the  
18 decrease in fee revenue and fees shall  
19 be contained in the Federal Register;  
20 and

21 (VI) provide that the fees as-  
22 sessed and collected for the full-time  
23 equivalent employees at the Center for  
24 Devices and Radiological Health, with  
25 respect to which the majority of time



1 reporting data indicates are dedicated  
2 to the process for the review of in  
3 vitro clinical test submissions and ap-  
4 plications under paragraph (5), are  
5 not supported by the funds authorized  
6 to be collected and assessed under sec-  
7 tion 738 of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 379j).

9 (G) PUBLICATION OF RECOMMENDA-  
10 TIONS.—The Secretary shall publish on the  
11 website of the Food and Drug Administration  
12 the revised recommendations under subpara-  
13 graph (F), a summary of the recommendations,  
14 views, and comments received under subpara-  
15 graphs (B), (C), and (E), and any changes  
16 made to the recommendations originally pro-  
17 posed by the Secretary in response to such rec-  
18 ommendations, views, and comments.

19 (H) MINUTES OF NEGOTIATION MEET-  
20 INGS.—

21 (i) PUBLIC AVAILABILITY.—The Sec-  
22 retary shall make publicly available, on the  
23 website of the Food and Drug Administra-  
24 tion, minutes of all negotiation meetings  
25 conducted under this subsection between

1 the Food and Drug Administration and the  
2 regulated industry not later than 30 days  
3 after such meeting.

4 (ii) CONTENT.—The minutes de-  
5 scribed under clause (i) shall summarize  
6 any substantive proposal made by any  
7 party to the negotiations, any significant  
8 controversies or differences of opinion dur-  
9 ing the negotiations, and the resolution of  
10 any such controversy or difference of opin-  
11 ion.

12 (2) ESTABLISHMENT OF USER FEE PRO-  
13 GRAM.—Effective on October 1, 2028, provided that  
14 the Secretary transmits the recommendations under  
15 paragraph (1)(F), the Secretary is authorized to col-  
16 lect user fees relating to the review of in vitro clin-  
17 ical test submissions and applications submitted  
18 under subchapter J of chapter V of the Federal  
19 Food, Drug, and Cosmetic Act, as added by this  
20 Act, and any other activities or goals included in rec-  
21 ommendations transmitted to Congress pursuant to  
22 this subsection. Fees under such program shall be  
23 assessed and collected only if the requirements under  
24 paragraph (4) are met.

25 (3) AUDIT.—

1           (A) IN GENERAL.—Beginning 2 years after  
2 first receiving a user fee applicable to submis-  
3 sion of an in vitro clinical test application sub-  
4 mitted under subchapter J of chapter V of the  
5 Federal Food, Drug, and Cosmetic Act, as  
6 added by this Act, the Secretary shall, on a bi-  
7 ennial basis, perform an audit of the costs of  
8 reviewing such applications and any other ac-  
9 tivities under such subchapter J included in  
10 recommendations transmitted to Congress pur-  
11 suant to this subsection. Such an audit shall  
12 compare the costs of reviewing such applica-  
13 tions and other activities under such subchapter  
14 J to the amount of the user fee applicable to  
15 such applications and make any necessary ad-  
16 justments as described in subparagraph (B).

17           (B) ALTERATION OF USER FEE.—The fol-  
18 lowing adjustments shall apply with respect to  
19 audits performed under subparagraph (A):

20           (i) If the audit performed 2 years  
21 after first receiving a user fee applicable to  
22 submission of an in vitro clinical test appli-  
23 cation described under subparagraph (A)  
24 indicates that the user fees collected for  
25 purposes of such subchapter J exceed 33

1 percent of the costs of reviewing such ap-  
2 plications and carrying out activities in-  
3 cluded in recommendations transmitted to  
4 Congress pursuant to this subsection, the  
5 Secretary shall alter the user fees applica-  
6 ble to applications submitted under such  
7 subchapter J such that the user fees do  
8 not exceed such percentage.

9 (ii) If the audit performed 6 years  
10 after first receiving a user fee applicable to  
11 submission of an in vitro clinical test appli-  
12 cation described under subparagraph (A)  
13 indicates that the user fees collected for  
14 purposes of such subchapter J exceed 40  
15 percent of the costs of reviewing such ap-  
16 plications, and carrying out activities in-  
17 cluded in recommendations transmitted to  
18 Congress pursuant to this subsection, the  
19 Secretary shall alter the user fees applica-  
20 ble to applications submitted under such  
21 subchapter J such that the user fees do  
22 not exceed such percentage.

23 (iii) If the audit performed 12 years  
24 after first receiving a user fee applicable to  
25 submission of an in vitro clinical test appli-

1 cation described under subparagraph (A),  
2 and any audit performed after such date,  
3 indicates that the user fees collected for  
4 purposes of such subchapter J exceed 49  
5 percent of the costs of reviewing such ap-  
6 plications, and carrying out activities in-  
7 cluded in recommendations transmitted to  
8 Congress pursuant to this subsection, the  
9 Secretary shall alter the user fees applica-  
10 ble to applications submitted under such  
11 subchapter J such that the user fees do  
12 not exceed such percentage.

13 (C) ACCOUNTING STANDARDS.—The Sec-  
14 retary shall perform an audit under subpara-  
15 graph (A) in conformance with the accounting  
16 principles, standards, and requirements pre-  
17 scribed by the Comptroller General of the  
18 United States under section 3511 of title 31,  
19 United States Code, to ensure the validity of  
20 any potential variability.

21 (D) IMPLEMENTATION REQUIREMENTS.—  
22 In the event that the Secretary fails to promul-  
23 gate the regulations described in sections  
24 587B(a)(4), 587D(j), or 587S(b)(1) of the Fed-  
25 eral Food, Drug, and Cosmetic Act, as added

1 by section 3, by the applicable deadline for each  
2 such regulations as described in section  
3 5(a)(2)(A)(ii), the Secretary shall provide that  
4 the user fees applicable to applications sub-  
5 mitted under subchapter J of chapter V of the  
6 Federal Food, Drug, and Cosmetic Act, as  
7 added by section 3, do not exceed 30 percent of  
8 the costs of reviewing such applications.

9 (4) CONDITIONS.—The user fee program de-  
10 scribed in this subsection shall take effect only if the  
11 Food and Drug Administration issues a regulation  
12 related to the review requirements for in vitro diag-  
13 nostic tests that would be subject to premarket re-  
14 view under section 587B of the Federal Food, Drug,  
15 and Cosmetic Act, as added by section 3, the review  
16 requirements for test categories eligible for tech-  
17 nology certification under section 587D of such Act,  
18 as added by section 3, and the parameters for the  
19 test categories that would be exempt from any re-  
20 view under subchapter J of chapter V of such Act.

21 (5) USER FEE PROGRAM DEFINITIONS AND RE-  
22 SOURCE REQUIREMENTS.—

23 (A) IN GENERAL.—The term “process for  
24 the review of in vitro clinical test submissions  
25 and applications” means the following activities

1 of the Secretary with respect to the review of in  
2 vitro clinical test premarket and technology cer-  
3 tification applications including supplements for  
4 such applications:

5 (i) The activities necessary for the re-  
6 view of premarket applications, premarket  
7 reports, technology certification applica-  
8 tions, and supplements to such applica-  
9 tions.

10 (ii) Actions related to submissions in  
11 connection with in vitro clinical test devel-  
12 opment, the issuance of action letters that  
13 allow the marketing of in vitro clinical  
14 tests or which set forth in detail the spe-  
15 cific deficiencies in such applications, re-  
16 ports, supplements, or submissions and,  
17 where appropriate, the actions necessary to  
18 support the development of in vitro clinical  
19 tests.

20 (iii) The inspection of manufacturing  
21 establishments and other facilities under-  
22 taken as part of the Secretary's review of  
23 pending premarket applications, technology  
24 certifications, and supplements.

1 (iv) Monitoring of research conducted  
2 in connection with the review of such appli-  
3 cations, supplements, and submissions.

4 (v) Review of in vitro clinical test ap-  
5 plications subject to section 351 of the  
6 Public Health Service Act (42 U.S.C. 262)  
7 and activities conducted in anticipation of  
8 the submission of such applications for in-  
9 vestigational use under section 587S of the  
10 Federal Food, Drug, and Cosmetic Act (as  
11 added by section 3).

12 (vi) The development of guidance, pol-  
13 icy documents, or regulations to improve  
14 the process for the review of premarket ap-  
15 plications, technology certification applica-  
16 tions, and supplements.

17 (vii) The development of voluntary  
18 test methods, consensus standards, or  
19 mandatory performance standards in con-  
20 nection with the review of such applica-  
21 tions, supplements, or submissions and re-  
22 lated activities.

23 (viii) The provision of technical assist-  
24 ance to in vitro clinical test developers in  
25 connection with the submission of such ap-



1                    plications, reports, supplements, or submis-  
2                    sions.

3                    (ix) Any activity undertaken in con-  
4                    nection with the initial classification or re-  
5                    classification of an in vitro clinical test in  
6                    connection with any requirement for ap-  
7                    proval or eligibility for an exemption from  
8                    premarket review of an in vitro clinical  
9                    test.

10                  (x) Any activity undertaken in connec-  
11                  tion with making a pathway determination  
12                  of an in vitro clinical test, including the  
13                  identification, establishment, and imple-  
14                  mentation of mitigation measures.

15                  (xi) Evaluation of postmarket studies  
16                  required as a condition of an approval of  
17                  a premarket application of an in vitro clin-  
18                  ical test and ensuring such studies are con-  
19                  ducted as required.

20                  (xii) Any activity undertaken in con-  
21                  nection with ensuring in vitro clinical tests  
22                  offered under an exemption from pre-  
23                  market review pursuant to section 587C or  
24                  587G meet the criteria for such exemption  
25                  and the applicable standard.

1 (xiii) Compiling, developing, and re-  
2 viewing information on in vitro clinical  
3 tests necessary to identify issues with the  
4 ability of in vitro clinical tests to meet the  
5 applicable standard, as applicable.

6 (B) RESOURCE REQUIREMENTS.—Fees col-  
7 lected and assessed under this section shall be  
8 used for the process for the review of in vitro  
9 clinical test applications, as described in sub-  
10 paragraph (A), and shall—

11 (i) be subject to the limitation under  
12 section 738(g)(3) of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C.  
14 379j(g)(3)), in the same manner that fees  
15 collected and assessed under section  
16 737(9)(C) of such Act (21 U.S.C.  
17 379i(9)(C)) are subject to such limitation;

18 (ii) include travel expenses for officers  
19 and employees of the Food and Drug Ad-  
20 ministration only if the Secretary deter-  
21 mines that such travel is directly related to  
22 an activity described in subparagraph (A);  
23 and

24 (iii) not be allocated to purposes de-  
25 scribed under section 722(a) of the Con-

1 consolidated Appropriations Act, 2018 (Public  
2 Law 115–141).

3 (c) REPORTS.—

4 (1) PERFORMANCE REPORT.—

5 (A) IN GENERAL.—

6 (i) GENERAL REQUIREMENTS.—Be-  
7 ginning with fiscal year 2028, for each fis-  
8 cal year for which fees are collected under  
9 this section, the Secretary shall prepare  
10 and submit to the Committee on Health,  
11 Education, Labor, and Pensions of the  
12 Senate and the Committee on Energy and  
13 Commerce of the House of Representatives  
14 annual reports concerning the progress of  
15 the Food and Drug Administration in  
16 achieving the goals identified in the rec-  
17 ommendations transmitted to Congress by  
18 the Secretary pursuant to subsection  
19 (b)(1)(F) during such fiscal year and the  
20 future plans of the Food and Drug Admin-  
21 istration for meeting the goals.

22 (ii) ADDITIONAL INFORMATION.—Be-  
23 ginning with fiscal year 2028, the annual  
24 report under this subparagraph shall in-  
25 clude the progress of the Food and Drug

1 Administration in achieving the goals, and  
2 future plans for meeting the goals, includ-  
3 ing—

4 (I) the number of premarket ap-  
5 plications filed under section 587B of  
6 the Federal Food, Drug, and Cos-  
7 metic Act during the applicable fiscal  
8 year;

9 (II) the number of technology  
10 certification applications submitted  
11 under section 587D of the Federal  
12 Food, Drug, and Cosmetic Act during  
13 the applicable fiscal year for each re-  
14 view division;

15 (III) the number of breakthrough  
16 designations under section 587I of the  
17 Federal Food, Drug, and Cosmetic  
18 Act during the applicable fiscal year;  
19 and

20 (IV) the number of information  
21 requests requested by the Secretary  
22 pursuant to section 587G(d) of such  
23 Act.

24 (iii) REAL-TIME REPORTING.—

1 (I) IN GENERAL.—Not later than  
2 30 calendar days after the end of the  
3 second quarter of fiscal year 2028,  
4 and not later than 30 calendar days  
5 after the end of each quarter of each  
6 fiscal year thereafter, the Secretary  
7 shall post the data described in sub-  
8 clause (II) on the website of the Food  
9 and Drug Administration for such  
10 quarter and on a cumulative basis for  
11 such fiscal year, and may remove du-  
12 plicative data from the annual report  
13 under this subparagraph.

14 (II) DATA.—The Secretary shall  
15 post the following data in accordance  
16 with subclause (I):

17 (aa) The number and titles  
18 of draft and final regulations on  
19 topics related to the process for  
20 the review of in vitro clinical test  
21 submissions and applications,  
22 and whether such regulations  
23 were required by statute or pur-  
24 suant to the recommendations  
25 transmitted to Congress by the

1 Secretary pursuant to subsection  
2 (b)(1)(F).

3 (bb) The number and titles  
4 of draft and final guidance on  
5 topics related to the process for  
6 the review of in vitro clinical test  
7 submissions and applications,  
8 and whether such guidances were  
9 issued as required by statute or  
10 pursuant to the recommendations  
11 transmitted to Congress by the  
12 Secretary pursuant to subsection  
13 (b)(1)(F).

14 (cc) The number and titles  
15 of public meetings held on topics  
16 related to the process for the re-  
17 view of in vitro clinical tests, and  
18 if such meetings were required by  
19 statute or pursuant to the rec-  
20 ommendations transmitted to  
21 Congress by the Secretary pursu-  
22 ant to subsection (b)(1)(F).

23 (iv) RATIONALE FOR IVCT USER FEE  
24 PROGRAM CHANGES.—Beginning with fis-  
25 cal year 2028, the Secretary shall include

1 in the annual performance report under  
2 paragraph (1)—

3 (I) data, analysis, and discussion  
4 of the changes in the number of indi-  
5 viduals hired as agreed upon in the  
6 recommendations transmitted to Con-  
7 gress by the Secretary pursuant to  
8 subsection (b)(1)(F) and the number  
9 of remaining vacancies, the number of  
10 full-time equivalents funded by fees  
11 collected pursuant to this section, and  
12 the number of full-time equivalents  
13 funded by budget authority at the  
14 Food and Drug Administration by  
15 each division within the Center for  
16 Devices and Radiological Health, the  
17 Center for Biologics Evaluation and  
18 Research, the Office of Regulatory Af-  
19 fairs, and the Office of the Commis-  
20 sioner;

21 (II) data, analysis, and discus-  
22 sion of the changes in the fee revenue  
23 amounts and costs for the process for  
24 the review of in vitro clinical test sub-

1 missions and applications, including  
2 identifying—  
3 (aa) drivers of such changes;  
4 and  
5 (bb) changes in the average  
6 total cost per full-time equivalent  
7 in the in vitro clinical test review  
8 program;  
9 (III) for each of the Center for  
10 Devices and Radiological Health, the  
11 Center for Biologics Evaluation and  
12 Research, the Office of Regulatory Af-  
13 fairs, and the Office of the Commis-  
14 sioner, the number of employees for  
15 whom time reporting is required and  
16 the number of employees for whom  
17 time reporting is not required; and  
18 (IV) data, analysis, and discus-  
19 sion of the changes in the average  
20 full-time equivalent hours required to  
21 complete review of each type of in  
22 vitro clinical test application.  
23 (v) ANALYSIS.—For each fiscal year,  
24 the Secretary shall include in the report



1 under clause (i) an analysis of the fol-  
2 lowing:

3 (I) The difference between the  
4 aggregate number of premarket appli-  
5 cations filed under section 587B or  
6 section 587D of the Federal Food,  
7 Drug, and Cosmetic Act and the ag-  
8 gregate number of major deficiency  
9 letters, not approvable letters, and de-  
10 nials for such applications issued by  
11 the agency, accounting for—

12 (aa) the number of applica-  
13 tions filed under each of sections  
14 587B and 587D of the Federal  
15 Food, Drug, and Cosmetic Act  
16 during one fiscal year for which a  
17 decision is not scheduled to be  
18 made until the following fiscal  
19 year; and

20 (bb) the aggregate number  
21 of applications under each of sec-  
22 tions 587B and 587D of the  
23 Federal Food, Drug, and Cos-  
24 metic Act for each fiscal year  
25 that did not meet the goals as

1 identified by the recommenda-  
2 tions transmitted to Congress by  
3 the Secretary pursuant to sub-  
4 section (b)(1)(F).

5 (II) Relevant data to determine  
6 whether the Center for Devices and  
7 Radiological Health has met perform-  
8 ance enhancement goals identified by  
9 the recommendations transmitted to  
10 Congress by the Secretary pursuant to  
11 subsection (b)(1)(F).

12 (III) The most common causes  
13 and trends for external or other cir-  
14 cumstances affecting the ability of the  
15 Food and Drug Administration to  
16 meet review time and performance en-  
17 hancement goals identified by the rec-  
18 ommendations transmitted to Con-  
19 gress by the Secretary pursuant to  
20 subsection (b)(1)(F).

21 (B) PUBLICATION.—With regard to infor-  
22 mation to be reported by the Food and Drug  
23 Administration to industry on a quarterly and  
24 annual basis pursuant to recommendations  
25 transmitted to Congress by the Secretary pur-

1           suant to subsection (b)(1)(F), the Secretary  
2           shall make such information publicly available  
3           on the website of the Food and Drug Adminis-  
4           tration not later than 60 days after the end of  
5           each quarter or 120 days after the end of each  
6           fiscal year, respectively, to which such informa-  
7           tion applies.

8           (C) UPDATES.—The Secretary shall in-  
9           clude in each report under subparagraph (A)  
10          information on all previous cohorts for which  
11          the Secretary has not given a complete response  
12          on all in vitro clinical test premarket applica-  
13          tions and technology certification orders and  
14          supplements, premarket, and technology certifi-  
15          cation notifications in the cohort.

16          (2) CORRECTIVE ACTION REPORT.—Beginning  
17          with fiscal year 2029, for each fiscal year for which  
18          fees are collected under this section, the Secretary  
19          shall prepare and submit a corrective action report  
20          to the Committee on Health, Education, Labor, and  
21          Pensions and the Committee on Appropriations of  
22          the Senate and the Committee on Energy and Com-  
23          merce and the Committee on Appropriations of the  
24          House of Representatives. The report shall include  
25          the following information, as applicable:

1           (A) GOALS MET.—For each fiscal year, if  
2           the Secretary determines, based on the analysis  
3           under paragraph (1)(A)(v), that each of the  
4           goals identified by the recommendations trans-  
5           mitted to Congress by the Secretary pursuant  
6           to subsection (b)(1)(F) for the applicable fiscal  
7           year have been met, the corrective action report  
8           shall include recommendations on ways in which  
9           the Secretary can improve and streamline the in  
10          vitro clinical test premarket application and  
11          technology certification review process.

12          (B) GOALS MISSED.—For each of the goals  
13          identified by the letters described in rec-  
14          ommendations transmitted to Congress by the  
15          Secretary pursuant to subsection (b)(1)(F) for  
16          the applicable fiscal year that the Secretary de-  
17          termines to not have been met, the corrective  
18          action report shall include—

19                 (i) a justification for such determina-  
20                 tion;

21                 (ii) a description of the types of cir-  
22                 cumstances, in the aggregate, under which  
23                 applications or reports submitted under  
24                 sections 587B and 587D of the Federal  
25                 Food, Drug, and Cosmetic Act missed the

1 review goal times but were approved dur-  
2 ing the first cycle review, as applicable;

3 (iii) a summary and any trends with  
4 regard to the circumstances for which a re-  
5 view goal was missed; and

6 (iv) the performance enhancement  
7 goals that were not achieved during the  
8 previous fiscal year and a description of ef-  
9 forts the Food and Drug Administration  
10 has put in place for the fiscal year in  
11 which the report is submitted to improve  
12 the ability of such agency to meet each  
13 such goal for the such fiscal year.

14 (3) FISCAL REPORT.—

15 (A) IN GENERAL.—For fiscal years 2029  
16 and annually thereafter, not later than 120  
17 days after the end of each fiscal year during  
18 which fees are collected under this section, the  
19 Secretary shall prepare and submit to the Com-  
20 mittee on Health, Education, Labor, and Pen-  
21 sions of the Senate and the Committee on En-  
22 ergy and Commerce of the House of Represent-  
23 atives, a report on the implementation of the  
24 authority for such fees during such fiscal year  
25 and the use, by the Food and Drug Administra-

1           tion, of the fees collected during such fiscal  
2           year for which the report is made.

3           (B) CONTENTS.—Such report shall include  
4           expenditures delineated by budget authority and  
5           user fee dollars related to administrative ex-  
6           penses and information technology infrastruc-  
7           ture contracts and expenditures.

8           (C) OPERATING RESERVE.—Such report  
9           shall provide the amount of operating reserves  
10          of carryover user fees available each year, and  
11          any planned allocations or obligations of such  
12          balance of operating reserves for the program.

13          (4) PUBLIC AVAILABILITY.—The Secretary  
14          shall make the reports required under paragraphs  
15          (1) through (3) available to the public on the website  
16          of the Food and Drug Administration.

17          (5) ENHANCED COMMUNICATION.—

18                 (A) COMMUNICATIONS WITH CONGRESS.—  
19                 Each fiscal year, as applicable and requested,  
20                 representatives from the Centers with expertise  
21                 in the review of in vitro clinical tests shall meet  
22                 with representatives from the Committee on  
23                 Health, Education, Labor, and Pensions of the  
24                 Senate and the Committee on Energy and Com-  
25                 merce of the House of Representatives to report

1 on the contents described in the reports under  
2 this section.

3 (B) PARTICIPATION IN CONGRESSIONAL  
4 HEARING.—Each fiscal year, as applicable and  
5 requested, representatives from the Food and  
6 Drug Administration shall participate in a pub-  
7 lic hearing before the Committee on Health,  
8 Education, Labor, and Pensions of the Senate  
9 and the Committee on Energy and Commerce  
10 of the House of Representatives, to report on  
11 the contents described in the reports under this  
12 section. Such hearing shall occur not later than  
13 120 days after the end of each fiscal year for  
14 which fees are collected under this section.

15 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

16 For purposes of funding implementation of this Act  
17 (including the amendments made by this Act), including  
18 undertaking activities for the development of regulations  
19 and guidances, hiring of necessary staff, and the develop-  
20 ment of technology systems to implement this Act (includ-  
21 ing the amendments made by this Act) in a timely, effec-  
22 tive, and efficient manner, there is authorized to be appro-  
23 priated \$480,000,000, to remain available through the end  
24 of fiscal year 2028.

1 **SEC. 11. GUIDANCE ON DIAGNOSTIC INNOVATION.**

2 Not later than January 1, 2025, the Secretary shall  
3 issue guidance to assist developers of in vitro clinical tests  
4 intended to identify or diagnose rare diseases and in vitro  
5 clinical tests intended to address an unmet medical need.  
6 Such guidance shall include considerations for addressing  
7 barriers to developing sufficient data to demonstrate clin-  
8 ical validity for such tests, such as challenges associated  
9 with data collection and obstacles to the timely generation  
10 of evidence.

11 **SEC. 12. GAO REPORT ON UNIQUE CONSIDERATIONS.**

12 Not later than 3 years after the date of enactment  
13 of this Act, the Comptroller General of the United States  
14 shall submit to the Committee on Health, Education,  
15 Labor, and Pensions of the Senate and the Committee on  
16 Energy and Commerce of the House of Representatives  
17 a report—

18 (1) evaluating the unique considerations for  
19 hospital-based laboratories, laboratories serving aca-  
20 demic medical centers, and other health care practi-  
21 tioners, as appropriate, in implementing this Act, in-  
22 cluding the amendments made by this Act; and

23 (2) including recommendations based on the  
24 findings of the report.



1 **SEC. 13. ASSESSMENTS.**

2 Section 1834A(g) of the Social Security Act (42  
3 U.S.C. 1395m–1(g)) is amended by adding at the end the  
4 following new paragraph:

5 “(3) DETERMINATIONS WITH RESPECT TO IN  
6 VITRO CLINICAL TESTS.—On or after the date that  
7 is 45 days after the date of enactment of the  
8 VALID Act of 2023, for purposes of determining  
9 whether an in vitro clinical test (as defined in sec-  
10 tion 201(ss) of the Federal Food, Drug, and Cos-  
11 metic Act) is reasonable and necessary for the diag-  
12 nosis or treatment of illness or injury (under section  
13 1862(a)(1)(A)), any assessment of the analytical va-  
14 lidity or clinical validity of such test shall apply the  
15 definitions given such terms in subchapter J of  
16 chapter V of the Federal Food, Drug, and Cosmetic  
17 Act.”.

18 **SEC. 14. SEVERABILITY.**

19 If any provision of this Act is declared unconstitu-  
20 tional, or the applicability of this Act to any person or  
21 circumstance is held invalid, the constitutionality of the  
22 remainder of this Act and the applicability thereof to other  
23 persons and circumstances shall not be affected.