

117TH CONGRESS  
1ST SESSION

# S. 2209

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical tests, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

JUNE 24, 2021

Mr. BURR (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Verifying Accurate Leading-edge IVCT Development Act  
6 of 2021” or the “VALID Act of 2021”.

7 (b) TABLE OF CONTENTS.—The table of contents of  
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Definitions.

Sec. 3. Regulation of in vitro clinical tests.

“SUBCHAPTER J—IN VITRO CLINICAL TESTS

- “Sec. 587. Definitions.
- “Sec. 587A. Applicability.
- “Sec. 587B. Premarket review.
- “Sec. 587C. Breakthrough in vitro clinical tests.
- “Sec. 587D. Technology certification.
- “Sec. 587E. Mitigating measures.
- “Sec. 587F. Regulatory pathway redesignation.
- “Sec. 587G. Advisory committees.
- “Sec. 587H. Request for informal feedback.
- “Sec. 587I. Registration and listing.
- “Sec. 587J. Test design and quality requirements.
- “Sec. 587K. Labeling requirements.
- “Sec. 587L. Adverse event reporting.
- “Sec. 587M. Corrections and removals.
- “Sec. 587N. Restricted in vitro clinical tests.
- “Sec. 587O. Appeals.
- “Sec. 587P. Accredited persons.
- “Sec. 587Q. Recognized standards.
- “Sec. 587R. Investigational use.
- “Sec. 587S. Collaborative communities for in vitro clinical tests.
- “Sec. 587T. Comprehensive test information system.
- “Sec. 587U. Preemption.
- “Sec. 587V. Adulteration.
- “Sec. 587W. Misbranding.
- “Sec. 587X. Postmarket surveillance.
- “Sec. 587Y. Electronic format for submissions.
- “Sec. 587Z. Postmarket remedies.

Sec. 4. Enforcement and other provisions.

Sec. 5. Transition.

Sec. 6. Emergency use authorization.

Sec. 7. Antimicrobial susceptibility tests.

Sec. 8. Combination products.

Sec. 9. Resources.

**1 SEC. 2. DEFINITIONS.**

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

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

5 “(ss)(1) The term ‘in vitro clinical test’—

6 “(A) means a test intended by its developer (as  
7 defined in section 587) to be used in the collection,  
8 preparation, analysis, or in vitro clinical examination

1 of specimens taken or derived from the human body  
2 for the purpose of—

3 “(i) identifying or diagnosing a disease or  
4 condition;

5 “(ii) providing information for diagnosing,  
6 screening, measuring, detecting, predicting,  
7 prognosing, analyzing, or monitoring a disease  
8 or condition, including by making a determina-  
9 tion of an individual’s state of health; or

10 “(iii) selecting, monitoring, or informing  
11 therapy or treatment for a disease or condition;  
12 and

13 “(B) may include—

14 “(i) a test protocol or laboratory test pro-  
15 tocol;

16 “(ii) an instrument (as defined in section  
17 587(11));

18 “(iii) a specimen receptacle;

19 “(iv) software, excluding software that is  
20 excluded by section 520(o) from the definition  
21 of a device under section 201(h), and excluding  
22 modifications that are exempt in accordance  
23 with section 587A(l)(2)(A); and

24 “(v) subject to subparagraph (2), a compo-  
25 nent or part of a test, a test protocol, an instru-

1           ment, an article, or software described in any of  
2           clauses (A) through (D) of such subparagraph,  
3           whether alone or in combination, including re-  
4           agents, calibrators, and controls.

5           “(2) Notwithstanding subparagraph (1)(v), an article  
6           intended to be used as a component or part of an in vitro  
7           clinical test described in subparagraph (1) is excluded  
8           from the definition in subparagraph (1) if the article con-  
9           sists of any of the following:

10           “(A) Blood, blood components, or human cells  
11           or tissues, from the time of acquisition, donation, or  
12           recovery of such article, including determination of  
13           donor eligibility, as applicable, until such time as the  
14           article is released as a component or part of an in  
15           vitro clinical test by the establishment that collected  
16           such article.

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

21           “(C) General purpose laboratory equipment, in-  
22           cluding certain pre-analytical equipment, as deter-  
23           mined by the Secretary.

1           “(D) An article used solely for personal protec-  
2           tion during the administering, conducting, or other-  
3           wise performing of test activities.”;

4           (2) by adding at the end of section 201(g) the  
5           following:

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

8           (3) in section 201(h), by striking “section  
9           520(o)” and inserting “section 520(o) or an in vitro  
10          clinical test”.

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

14           (1) by striking “(1) The term ‘biological prod-  
15           uct’ means” and inserting “(1)(A) The term ‘biologi-  
16           cal product’ means”; and

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

18           “(B) The term ‘biological product’ does not in-  
19           clude an in vitro clinical test as defined in section  
20           201(ss) of the Federal Food, Drug, and Cosmetic  
21           Act.”.

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

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

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

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

7 (2) by adding at the end of chapter V the fol-  
8 lowing:

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

10 **“SEC. 587. DEFINITIONS.**

11 “In this subchapter:

12 “(1) ANALYTICAL VALIDITY.—

13 “(A) The term ‘analytical validity’ means,  
14 with respect to an in vitro clinical test, the abil-  
15 ity of the in vitro clinical test, to—

16 “(i) sufficiently identify, measure, de-  
17 tect, calculate, or analyze one or more  
18 analytes, biomarkers, substances, or other  
19 targets intended to be identified, measured,  
20 detected, calculated, or analyzed by the  
21 test; or

22 “(ii) as applicable, assist in such iden-  
23 tification, measurement, detection, calcula-  
24 tion, or analysis.

25 “(B) For an article for taking or deriving  
26 specimens from the human body described in

1 section 201(ss)(1)(B)(iii), the term ‘analytical  
2 validity’ means that such article performs as in-  
3 tended and will support the analytical validity  
4 of an in vitro clinical test with which it is used.

5 “(2) APPLICABLE STANDARD.—The term ‘ap-  
6 plicable standard’, with respect to an in vitro clinical  
7 test, means a reasonable assurance of analytical and  
8 clinical validity, except that such term—

9 “(A) with respect to test instruments,  
10 means a reasonable assurance of analytical va-  
11 lidity; and

12 “(B) with respect to articles for taking or  
13 deriving specimens from the human body for  
14 purposes described in clause (i) or (ii) of section  
15 201(ss)(1)(A) means a reasonable assurance of  
16 analytical validity and, where applicable, safety.

17 “(3) CLINICAL USE.—The term ‘clinical use’  
18 means the operation, application, or functioning of  
19 an in vitro clinical test in connection with human  
20 specimens, including patient, consumer, and donor  
21 specimens, for the purpose for which it is intended  
22 as described in section 201(ss)(1)(A).

23 “(4) CLINICAL VALIDITY.—The term ‘clinical  
24 validity’ means the ability of an in vitro clinical test

1 to achieve the purpose for which it is intended as de-  
2 scribed in section 201(ss)(1)(A).

3 “(5) CROSS-REFERENCED TEST.—The term  
4 ‘cross-referenced test’ means an in vitro clinical test  
5 that references in its labeling the name or intended  
6 use of another medical product that is not an in  
7 vitro clinical test.

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

10 “(A) designing, validating, producing,  
11 manufacturing, remanufacturing, propagating,  
12 or assembling an in vitro clinical test;

13 “(B) importing an in vitro clinical test;

14 “(C) modifying an in vitro clinical test ini-  
15 tially developed by a different person in a man-  
16 ner that—

17 “(i) changes any of the listing ele-  
18 ments that define indications for use speci-  
19 fied in paragraph (10), performance  
20 claims, or, as applicable, the safety of such  
21 in vitro clinical test; or

22 “(ii) affects the analytical or clinical  
23 validity of the in vitro clinical test as in-  
24 tended by the developer; or



1           “(D) adopting, using, or disseminating for  
2           use as an in vitro clinical test an article not  
3           previously intended for clinical use.

4           “(7) DEVELOPER.—The term ‘developer’ means  
5           a person who engages in an activity described in  
6           paragraph (6) for clinical use.

7           “(8) FIRST-OF-A-KIND.—The term ‘first-of-a-  
8           kind’ means, with respect to an in vitro clinical test,  
9           a test that has an intended use and a combination  
10          of the elements specified in paragraph (10) that dif-  
11          fer from the intended use and such elements of  
12          other in vitro clinical tests that already are legally  
13          available in the United States.

14          “(9) HIGH-RISK.—

15                 “(A) IN GENERAL.—Subject to subpara-  
16                 graph (B), the term ‘high-risk’, with respect to  
17                 an in vitro clinical test or category of in vitro  
18                 clinical tests—

19                         “(i) means that, when used as in-  
20                         tended by the developer, an undetected in-  
21                         accurate result from such test or cat-  
22                         egory—

23                                 “(I) presents unreasonable risk  
24                                 for serious or irreversible harm or  
25                                 death to a patient or patients, or

1 would otherwise cause serious harm to  
2 the public health; or

3 “(II) is potentially likely to result  
4 in the absence, significant delay, or  
5 discontinuation of life-supporting or  
6 life-sustaining medical treatment; and

7 “(ii) shall account for the degree to  
8 which the technology for the intended use  
9 of an in vitro clinical test or tests is well-  
10 characterized and the criteria for perform-  
11 ance of the test or tests are well-estab-  
12 lished for the intended use, the clinical cir-  
13 cumstances under which the in vitro clin-  
14 ical test is used, and the availability of  
15 other tests (such as confirmatory or ad-  
16 junctive tests).

17 “(B) EXCEPTION.—The term ‘high-risk’  
18 does not include an in vitro clinical test de-  
19 scribed in subparagraph (A) if—

20 “(i) mitigating measures are estab-  
21 lished to prevent, detect, or otherwise miti-  
22 gate the risk of inaccurate results as de-  
23 scribed in subparagraph (A), or

24 “(ii) an exemption from the definition  
25 of such term applies under section 587A.

1           “(10) INDICATIONS FOR USE.—The term ‘indi-  
2           cations for use’ means one or more in vitro clinical  
3           tests that have all of the following notification ele-  
4           ments in common:

5                   “(A) Substance or substances measured by  
6                   the in vitro clinical test, such as an analyte,  
7                   protein, or pathogen.

8                   “(B) Test method.

9                   “(C) Test purpose or purposes, as de-  
10                  scribed in section 201(ss)(1)(A).

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

14                  “(E) Context of use, such as in a clinical  
15                  laboratory, in a health care facility, prescription  
16                  home use, over-the-counter use, or direct-to-  
17                  consumer testing.

18           “(11) INSTRUMENT.—The term ‘instrument’  
19           means an in vitro clinical test that is hardware in-  
20           tended by the hardware’s developer to be used with  
21           one or more in vitro clinical tests to generate a clin-  
22           ical test result, including software used to effectuate  
23           the hardware’s functionality.

24           “(12) INSTRUMENT FAMILY.—The term ‘instru-  
25           ment family’ means more than one instrument for

1 which the developer demonstrates and documents,  
2 with respect to all such instruments, that all—

3 “(A) have the same basic architecture, de-  
4 sign, and performance characteristics, such as  
5 tolerance limits and signal range;

6 “(B) have the same intended use or uses  
7 and function;

8 “(C) share the same measurement prin-  
9 ciples, detection methods, and reaction condi-  
10 tions; and

11 “(D) produce the same or similar analyt-  
12 ical results from samples of the same specimen  
13 type or types.

14 “(13) LABORATORY OPERATIONS.—The term  
15 ‘laboratory operations’—

16 “(A) means the conduct of a laboratory ex-  
17 amination or other laboratory procedure on ma-  
18 terials derived from the human body, including  
19 the conduct of an in vitro clinical test and asso-  
20 ciated activities within or under the oversight of  
21 a laboratory and not related to the design 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) conducting standard operating  
5                   procedures; and

6                   “(iii) preparing reagents or other test  
7                   materials that do not meet the definition of  
8                   a in vitro clinical test for clinical use under  
9                   section 201(ss).

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 by the developer—

16                  “(A) would cause minimal or no harm, or  
17                  minimal or no disability, or immediately revers-  
18                  ible harm, or would lead to only a remote risk  
19                  of adverse patient impact or adverse public  
20                  health impact, taking into account the degree to  
21                  which the technology for the intended use of an  
22                  in vitro clinical test or category of tests is well-  
23                  characterized and the criteria for performance  
24                  of the test or category of tests are well-estab-  
25                  lished for the intended use, the clinical cir-

1           cumstances under which the in vitro clinical  
2           test or category of tests is used, and the avail-  
3           ability of other tests (such as confirmatory or  
4           adjunctive tests); or

5           “(B) would cause a serious adverse health  
6           consequence, harm that is reversible, a delay in  
7           necessary treatment that is not life-supporting  
8           or life-sustaining, or would lead to a serious  
9           risk of adverse patient experience or adverse  
10          public health impact, but applied mitigating  
11          measures have the capacity to ensure the test  
12          meets the standard described in subparagraph  
13          (A).

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

16                 “(A) means controls, standards, or require-  
17                 ments that the Secretary determines, based on  
18                 available evidence—

19                         “(i) are necessary for an in vitro clin-  
20                         ical test, or a category of in vitro clinical  
21                         tests, to meet the applicable standard; or

22                         “(ii) to mitigate the risk of harm en-  
23                         suing from an inaccurate result such that  
24                         a test or category of tests subject to such  
25                         mitigating measures does not meet the def-

1           initiation of high risk, or such that a test or  
2           category of tests subject to such mitigating  
3           measures is low risk; and

4           “(B) includes, as appropriate, applicable  
5           requirements regarding labeling, conformance  
6           to performance standards or guidance, perform-  
7           ance testing, submission of clinical data, adver-  
8           tising, website posting of information, clinical  
9           studies, postmarket surveillance, user com-  
10          prehension studies, training, and availability of  
11          confirmatory laboratory or clinical findings.

12          “(16) SPECIMEN RECEPTACLE.—The term  
13          ‘specimen receptacle’ means an in vitro clinical test  
14          specifically intended for the holding, storing, or  
15          transporting of specimens derived from the human  
16          body or for in vitro examination for purposes de-  
17          scribed in clause (i) or (ii) of section 201(ss)(1)(A).

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

19                 “(A) means a developer’s grouping of in  
20                 vitro clinical tests that do not significantly dif-  
21                 fer in control mechanisms, energy sources, or  
22                 operating principals and for which design, de-  
23                 velopment, and manufacturing, including ana-  
24                 lytical and clinical validation as applicable, of

1 the tests would be addressed in a similar man-  
2 ner or through similar procedures; and

3 “(B) may include clot detection, colorimetric (non-immunoassay), electrochemical  
4 (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry  
5 (non-immunoassay), immunoassay, mass spectrometry or chromatography (such as HPLC),  
6 microbial culture, next generation sequencing (also known as ‘NGS’), nephelometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, single-based technology, spectroscopy, and any other  
7 technology, as the Secretary determines appropriate.  
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16 “(18) TEST.—The term ‘test’, unless otherwise  
17 provided, means an in vitro clinical test.

18 “(19) VALID SCIENTIFIC EVIDENCE.—The term  
19 ‘valid scientific evidence’—

20 “(A) means, with respect to an in vitro  
21 clinical test, evidence—

22 “(i) that has been generated and evaluated by persons qualified by training or  
23 experience to do so, using procedures gen-  
24



1 erally accepted by other persons so quali-  
2 fied; and

3 “(ii) from which it can be fairly and  
4 responsibly concluded by qualified experts  
5 whether the applicable standard has been  
6 met by the in vitro clinical test for its in-  
7 tended use; and

8 “(B) may include evidence described in  
9 subparagraph (A) consisting of—

- 10 “(i) peer-reviewed literature;  
11 “(ii) clinical guidelines;  
12 “(iii) reports of significant human ex-  
13 perience with an in vitro clinical test;  
14 “(iv) bench studies;  
15 “(v) case studies or histories;  
16 “(vi) clinical data;  
17 “(vii) consensus standards;  
18 “(viii) reference standards;  
19 “(ix) data registries;  
20 “(x) postmarket data;  
21 “(xi) real world data;  
22 “(xii) clinical trials; and  
23 “(xiii) data collected in countries  
24 other than the United States if such data  
25 are demonstrated to be adequate for the

1           purpose of making a regulatory determina-  
2           tion under the applicable standard in the  
3           United States.

4           “(20) WELL-CHARACTERIZED.—The term ‘well-  
5           characterized’, with respect to an in vitro clinical  
6           test, means well-established and well-recognized by  
7           the scientific or clinical community, if adequately  
8           evidenced by one or more of the following:

9                   “(A) Peer-reviewed literature.

10                   “(B) Practice guidelines.

11                   “(C) Consensus standards.

12                   “(D) Recognized standards of care.

13                   “(E) Technology in use for many years.

14                   “(F) Scientific publication by multiple  
15           sites.

16                   “(G) Adoption by the scientific or clinical  
17           community.

18                   “(H) Real world data.

19   **“SEC. 587A. APPLICABILITY.**

20           “(a) IN GENERAL.—

21                   “(1) APPLICABILITY OF THIS SUBCHAPTER.—

22                           “(A) IN GENERAL.—An in vitro clinical  
23           test shall be subject to the requirements of this  
24           subchapter, except as otherwise provided this  
25           subchapter.

1           “(B) INTERSTATE COMMERCE.—Any in  
2           vitro clinical test that is offered for clinical use  
3           in the United States is deemed to be introduced  
4           into interstate commerce for purposes of enforcing  
5           the requirements of this Act.

6           “(C) NON-APPLICABLE REQUIREMENT.—  
7           Subject to any exemption or exclusion in this  
8           section, an in vitro clinical test shall not be sub-  
9           ject to any provision or requirement of this Act  
10          other than this subchapter unless such other  
11          provision or requirement—

12                   “(i) applies expressly to in vitro clin-  
13                   ical tests; or

14                   “(ii) describes the authority of the  
15                   Secretary when regulating such in vitro  
16                   clinical tests or subset of in vitro clinical  
17                   tests, with respect to—

18                           “(I) all articles regulated by the  
19                           Secretary pursuant to this Act; or

20                           “(II) a subset of such articles  
21                           that includes in vitro clinical tests.

22           “(2) LABORATORIES AND BLOOD AND TISSUE  
23           ESTABLISHMENTS.—

24                   “(A) RELATION TO LABORATORY CERTIFI-  
25                   CATION PURSUANT TO SECTION 353 OF THE

1 PHSA.—Nothing in this subchapter shall be  
2 construed to modify the authority of the Sec-  
3 retary with respect to laboratories or clinical  
4 laboratories under section 353 of the Public  
5 Health Service Act.

6 “(B) AVOIDING DUPLICATION.—In imple-  
7 menting this subchapter, the Secretary shall  
8 avoid issuing or enforcing regulations that are  
9 duplicative of regulations under section 353.

10 “(C) BLOOD AND TISSUE.—Nothing in  
11 this subchapter shall be construed to modify the  
12 authority of the Secretary with respect to lab-  
13 oratories, establishments, or other facilities to  
14 the extent they are engaged in the propagation,  
15 manufacture, or preparation, including filling,  
16 testing, labeling, packaging, and storage, of  
17 blood, blood components, human cells, tissues,  
18 or tissue products under this Act or section 351  
19 or 361 of the Public Health Service Act.

20 “(3) PRACTICE OF MEDICINE.—

21 “(A) IN GENERAL.—Nothing in this sub-  
22 chapter shall be construed to limit or interfere  
23 with the authority of a health care practitioner  
24 to prescribe or administer any legally marketed  
25 in vitro clinical test for any condition or disease

1 within a health care practitioner-patient rela-  
2 tionship pursuant to applicable Federal or State  
3 law.

4 “(B) RULES OF CONSTRUCTION.—

5 “(i) SALE, DISTRIBUTION, LABEL-  
6 ING.—Nothing in this paragraph shall be  
7 construed to limit the authority of the Sec-  
8 retary to establish or enforce restrictions  
9 on the sale, distribution, or labeling of an  
10 in vitro clinical test under this Act.

11 “(ii) PROMOTION OF UNAPPROVED  
12 USES.—Nothing in this paragraph shall be  
13 construed to alter any prohibition on the  
14 promotion of unapproved uses of legally  
15 marketed in vitro clinical tests.

16 “(4) SPECIAL RULE.—

17 “(A) PREMARKET REVIEW APPLICABLE.—  
18 Notwithstanding the exemptions from pre-  
19 market review under section 587B set forth in  
20 subsections (b), (c), (d), (e), (f), (g), (h), (j),  
21 and (k) of such section, an in vitro clinical test  
22 (including any article for taking or deriving  
23 specimens) shall be subject to the requirements  
24 of section 587B if the Secretary determines, in  
25 accordance with subparagraph (B), that—

1           “(i)(I) there is insufficient valid sci-  
2           entific evidence to support the analytical  
3           validity or the clinical validity of such in  
4           vitro clinical test; and

5           “(II) such in vitro clinical test is  
6           being offered by its developer with materi-  
7           ally deceptive or fraudulent analytical or  
8           clinical claims;

9           “(ii) it is reasonably possible that  
10          such in vitro clinical test will cause serious  
11          adverse health consequences; or

12          “(iii) in the case of specimen recep-  
13          tacles, there is sufficient valid scientific  
14          evidence indicating that a specimen recep-  
15          tacle did not perform as intended, will not  
16          support the analytical validity of tests with  
17          which it is used, or as applicable, is not  
18          safe for use.

19          “(B) PROCESS.—

20          “(i) REQUEST FOR INFORMATION.—If  
21          the Secretary has valid scientific evidence  
22          indicating that the criteria listed in sub-  
23          paragraph (A) apply to an in vitro clinical  
24          test, the Secretary may request that the  
25          developer of the test submit information—

1                   “(I) pertaining to such criteria;  
2                   and

3                   “(II) establishing the basis for  
4                   any claimed exemption from pre-  
5                   market review.

6                   “(ii) DEADLINE FOR SUBMITTING IN-  
7                   FORMATION.—The developer of an in vitro  
8                   clinical test shall submit the information  
9                   requested pursuant to clause (i) within 30  
10                  days of receipt of such request.

11                  “(iii) REVIEW DEADLINE.—Upon re-  
12                  ceiving a submission under clause (ii), the  
13                  Secretary shall—

14                         “(I) review the submitted infor-  
15                         mation within 60 calendar days of  
16                         such receipt; and

17                         “(II) determine whether the cri-  
18                         teria listed in subparagraph (A) apply  
19                         to the in vitro clinical test.

20                         “(iv) PREMARKET REVIEW RE-  
21                         QUIRED.—

22                                 “(I) IN GENERAL.—If the Sec-  
23                                 retary finds that the criteria listed in  
24                                 subparagraph (A) apply to the in vitro  
25                                 clinical test, the developer shall—

1           “(aa) promptly, and not  
2 later than 90 days after the date  
3 of receipt of such information,  
4 submit an application for pre-  
5 market review of the test under  
6 section 587B; or

7           “(bb) cease to market the  
8 test.

9           “(II) EXTENSION.—The Sec-  
10 retary may grant an extension to a  
11 developer of the 90-day time period  
12 under subclause (I)(aa), as appro-  
13 priate.

14           “(v) CONTINUED MARKETING.—Dur-  
15 ing the period beginning on the date of a  
16 request for information under clause (ii)  
17 and ending on the date of the disposition  
18 of an application for premarket review of  
19 the in vitro clinical test under section  
20 587B, the developer of the test may con-  
21 tinue to market the test for clinical use,  
22 unless the Secretary issues an order to the  
23 developer under clause (vi) to immediately  
24 cease distribution of the test.



1                   “(vi) ORDER TO CEASE DISTRIBUTION.—  
2

3                   “(I) IN GENERAL.—If the devel-  
4                   oper of an in vitro clinical test fails to  
5                   submit an application for premarket  
6                   review of the test by the deadline ap-  
7                   plicable under clause (iv), or the Sec-  
8                   retary finds that the criteria listed in  
9                   subparagraph (A) apply to an in vitro  
10                  clinical test and that it is in the best  
11                  interest of the public health, the Sec-  
12                  retary may issue an order, within 10  
13                  calendar days of the applicable dead-  
14                  line or finding by the Secretary, re-  
15                  quiring the developer of such in vitro  
16                  clinical test, and any other appro-  
17                  priate person (including a distributor  
18                  or retailer of the in vitro clinical test)  
19                  to immediately—

20                  “(aa) cease distribution of  
21                  the test pending approval of an  
22                  application for premarket review  
23                  of the test under section 587B;  
24                  and

1                   “(bb) notify health profes-  
2                   sionals and other user facilities of  
3                   the order to cease distribution  
4                   and advise health care profes-  
5                   sionals to cease use of such in  
6                   vitro clinical test.

7                   “(II) HEARING AND REVIEW.—

8                   An order under subclause (I) shall  
9                   provide the person subject to the  
10                  order with an opportunity for an in-  
11                  formal hearing, to be held not later  
12                  than 10 days after the date of the  
13                  issuance of the order, on the actions  
14                  required by the order and on whether  
15                  the order should be amended to re-  
16                  quire a recall of such in vitro clinical  
17                  test. If, after providing an opportunity  
18                  for such a hearing, the Secretary de-  
19                  termines that inadequate grounds  
20                  exist to support the actions required  
21                  by the order, the Secretary shall ter-  
22                  minate the order within 30 days of  
23                  the hearing. Upon terminating an  
24                  order, the Secretary shall provide

1                   written notice of such termination to  
2                   the developer.

3                   “(vii) AMENDMENT TO REQUIRE RE-  
4                   CALL.—If the Secretary determines that  
5                   an order issued under clause (vi) should be  
6                   amended to include a recall of the in vitro  
7                   clinical test with respect to which the order  
8                   was issued, the Secretary shall amend the  
9                   order to require a recall. In such amended  
10                  order, the Secretary shall specify a time-  
11                  frame in which the in vitro clinical test re-  
12                  call will occur and shall require periodic re-  
13                  ports to the Secretary describing the  
14                  progress of the recall. Upon termination of  
15                  the recall, the Secretary shall provide writ-  
16                  ten notice of such termination to the devel-  
17                  oper.

18                  “(viii) EFFECT OF TEST APPROVAL.—  
19                  Any order issued under this paragraph  
20                  with respect to an in vitro clinical test  
21                  shall cease to be in effect if such test is  
22                  granted approval under section 587B, pro-  
23                  vided that the in vitro clinical test is devel-  
24                  oped and offered for clinical use in accord-  
25                  ance with such approval.

1 “(5) EMERGENCY USE.—

2 “(A) IN GENERAL.—In the case of a deter-  
3 mination under section 319(a) of the Public  
4 Health Service Act or a declaration under sec-  
5 tion 564(b) of this Act, an in vitro clinical test  
6 is exempt from the requirements of this sub-  
7 chapter and may be lawfully marketed in ac-  
8 cordance with subparagraph (B).

9 “(B) CRITERIA.—An in vitro clinical test  
10 is exempt from the requirements of this sub-  
11 chapter and may be lawfully marketed in ac-  
12 cordance with the exemption described in sub-  
13 paragraph (A) if—

14 “(i) such test—

15 “(I) is submitted for emergency  
16 use authorization under section  
17 564(b); or

18 “(II) is developed and used in  
19 laboratories for which a certificate is  
20 in effect under section 353 of the  
21 Public Health Service Act to conduct  
22 high-complexity testing and the devel-  
23 oper; and

24 “(ii) the developer—

1                   “(I) validates such in vitro clin-  
2                   ical test prior to use;

3                   “(II) notifies the Secretary of the  
4                   assay validation; and

5                   “(III) submits an emergency use  
6                   authorization application under sec-  
7                   tion 564 within 15 calendar days of  
8                   marketing the test.

9                   “(C) DISPOSITION OF PRODUCT.—With re-  
10                  spect to a previously unapproved in vitro clin-  
11                  ical test or an in vitro clinical test with an un-  
12                  approved use, for which an emergency use au-  
13                  thorization under section 564(b) ceases to be  
14                  effective, the Secretary shall consult with the  
15                  manufacturer of such product with respect to  
16                  the appropriate disposition of the product.

17                  “(D) STREAMLINING OF APPLICATION RE-  
18                  VIEW.—A developer may include any data or in-  
19                  formation already submitted to the Secretary  
20                  within the emergency use authorization as a  
21                  part of a premarket application under section  
22                  587B or a technology certification application  
23                  under section 587D.

24                  “(6) EFFECT ON OTHER LAWS.—Any in vitro  
25                  clinical test that is lawfully marketed under this Act,

1 including tests that are approved under section  
2 587B, cleared pursuant to an active technology cer-  
3 tification order under section 587D, or exempt from  
4 premarket review under an exemption in this sec-  
5 tion, shall be eligible for introduction into interstate  
6 commerce except as otherwise provided in this sub-  
7 chapter.

8 “(b) COMPONENTS AND PARTS.—

9 “(1) EXEMPTION.—

10 “(A) IN GENERAL.—Subject to subpara-  
11 graph (B), a component, part, or raw material  
12 described in section 201(ss)(1)(B)(v) is exempt  
13 from the requirements of this subchapter if it  
14 is—

15 “(i) intended for further development  
16 as described in paragraph (2); or

17 “(ii) otherwise to be regulated based  
18 on its risk when used as intended by the  
19 developer, notwithstanding its subsequent  
20 use by a developer as a component, part,  
21 or raw material of another in vitro clinical  
22 test.

23 “(B) INAPPLICABILITY TO OTHER  
24 TESTS.—Notwithstanding subparagraph (A), an  
25 in vitro clinical test that is described in section

1           201(ss)(1)(B) and that uses a component or  
2           part described in such subparagraph shall be  
3           subject to the requirements of this subchapter,  
4           unless the test is otherwise exempt under this  
5           section.

6           “(2) FURTHER DEVELOPMENT.—A component,  
7           part, or raw material (as described in paragraph  
8           (1)(A)) is intended for further development (for pur-  
9           poses of such paragraph) if—

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

12                   “(B) in the case of such a test that is in-  
13                   troduced or delivered for introduction into  
14                   interstate commerce after the date of enactment  
15                   of the Verifying Accurate Leading-edge IVCT  
16                   Development Act of 2021, the labeling of such  
17                   test bears the following statement: ‘This prod-  
18                   uct is intended solely for further development of  
19                   an in vitro clinical test and is exempt from  
20                   FDA regulation. This product must be evalu-  
21                   ated by the in vitro clinical test developer if it  
22                   is used with or in the development of an in vitro  
23                   clinical test.’.

24           “(c) GRANDFATHERED TESTS.—

1           “(1) EXEMPTION.—An in vitro clinical test that  
2           meets the criteria set forth in paragraph (2) is ex-  
3           empt from the requirements of this subchapter, ex-  
4           cept as provided under subsection (a)(4), the reg-  
5           istration and listing requirements under section  
6           587I, and the adverse reporting requirements under  
7           section 587L, and may be lawfully marketed subject  
8           to the other applicable requirements of this Act, if—

9           “(A) each test report template for the test  
10           bears a statement of adequate prominence that  
11           reads as follows: ‘This in vitro clinical test was  
12           developed and first introduced prior to the date  
13           of enactment of the Verifying Accurate Lead-  
14           ing-edge IVCT Development Act of 2021 and  
15           has not been reviewed by the Food and Drug  
16           Administration.’; and

17           “(B) the developer of the test—

18           “(i) maintains documentation dem-  
19           onstrating that the test meets and con-  
20           tinues to meet the criteria set forth in  
21           paragraph (2); and

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



1           “(2) CRITERIA FOR EXEMPTION.—An in vitro  
2 clinical test is exempt as specified in paragraph (1)  
3 if the test—

4           “(A)(i) was first offered for clinical use by  
5 such laboratory before the date of enactment of  
6 the Verifying Accurate Leading-edge IVCT De-  
7 velopment Act of 2021;

8           “(ii) was developed by a clinical laboratory  
9 for which a certificate was in effect under sec-  
10 tion 353 of the Public Health Service Act that  
11 meets the requirements under such section 353  
12 for performing high-complexity testing; and

13           “(iii) is performed—

14           “(I) in the same clinical laboratory in  
15 which it was developed;

16           “(II) by another clinical laboratory for  
17 which a certificate is in effect under sec-  
18 tion 353 within the same corporate organi-  
19 zation and having common ownership by  
20 the same parent corporation; or

21           “(III) by a laboratory within a public  
22 health laboratory network coordinated or  
23 managed by the Centers for Disease Con-  
24 trol and Prevention;

1           “(B) does not have in effect an approval  
2           under section 515, a clearance under section  
3           510(k), an authorization under section  
4           513(f)(2), or an exemption under section  
5           520(m); and

6           “(C) is not modified on or after the date  
7           of enactment of the Verifying Accurate Lead-  
8           ing-edge IVCT Development Act of 2021 by its  
9           initial developer (or another person) in a man-  
10          ner such that the test is a new in vitro clinical  
11          test under subsection (l).

12          “(3) MODIFICATIONS.—In the case of a modi-  
13          fication to an in vitro clinical test that is exempt as  
14          specified in paragraph (1) or such modification is  
15          otherwise not subject to premarket review pursuant  
16          to section 587A(l), the test continues to qualify for  
17          such exemption if the person modifying such test—

18               “(A) documents each such modification  
19               and maintains a summary of the basis for such  
20               determination; and

21               “(B) provides such documentation and  
22               summary to the Secretary upon request or in-  
23               spection.

24          “(d) TESTS EXEMPT FROM SECTION 510(k).—

1           “(1) EXEMPTION.—An in vitro clinical test is  
2 exempt from premarket review under section 587B  
3 and may be lawfully marketed subject to the other  
4 applicable requirements of this Act, if the in vitro  
5 clinical test—

6           “(A)(i) was offered for clinical use prior to  
7 the date of enactment of the Verifying Accurate  
8 Leading-edge IVCT Development Act of 2021;  
9 and

10           “(ii) immediately prior to such date of en-  
11 actment was exempt pursuant to subsection (l)  
12 or (m)(2) of section 510 from the requirements  
13 for submission of a report under section 510(k);  
14 or

15           “(B)(i) was not offered for clinical use  
16 prior to such date of enactment;

17           “(ii) is not a test platform; and

18           “(iii) falls within a category of tests that  
19 was exempt from the requirements for submis-  
20 sion of a report under section 510(k) as of such  
21 date of enactment (including class II devices  
22 and excluding class I devices described in sec-  
23 tion 510(l)).

24           “(2) EFFECT ON SPECIAL CONTROLS.—For any  
25 in vitro clinical test, or category of in vitro clinical

1 tests, that is exempt from premarket review based  
2 on the criteria in paragraph (2), any special control  
3 that applied to a device within a predecessor cat-  
4 egory immediately prior to the date of enactment of  
5 Verifying Accurate Leading-edge IVCT Development  
6 Act of 2021 shall be deemed a mitigating measure  
7 applicable under section 587E to an in vitro clinical  
8 test within the successor category, except to the ex-  
9 tent such mitigating measure is withdrawn or  
10 changed in accordance with section 587E.

11 “(3) NEAR-PATIENT TESTING.—Not later than  
12 1 year after the date of enactment of the Verifying  
13 Accurate Leading-edge IVCT Development Act of  
14 2021, the Secretary shall issue draft guidance indi-  
15 cating categories of tests that shall be exempt from  
16 premarket review under section 587B when offered  
17 for near-patient testing (point of care), which were  
18 not exempt from submission of a report under sec-  
19 tion 510(k) pursuant to subsection (l) or (m)(2) of  
20 section 510 and regulations imposing limitations on  
21 exemption for in vitro devices intended for near-pa-  
22 tient testing (point of care).

23 “(e) LOW-RISK TESTS.—

24 “(1) EXEMPTION.—An in vitro clinical test is  
25 exempt from premarket review under section 587B

1 and may be lawfully marketed subject to the other  
2 applicable requirements of this Act, including section  
3 587I(b)(6), if such test meets the definition of low-  
4 risk under section 587.

5 “(2) LIST OF LOW-RISK TESTS.—

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

13 “(B) INCLUSION.—The list under subpara-  
14 graph (A) shall consist of—

15 “(i) all in vitro clinical tests and cat-  
16 egories of in vitro clinical tests that are ex-  
17 empt from premarket review pursuant to  
18 subsection (d)(1) or (d)(3); and

19 “(ii) all in vitro clinical tests and cat-  
20 egories of in vitro clinical tests that are  
21 designated by the Secretary pursuant to  
22 subparagraph (C) as low-risk for purposes  
23 of this subsection.

24 “(C) DESIGNATION OF TESTS AND CAT-  
25 EGORIES.—Without regard to subchapter II of

1 chapter 5 of title 5, United States Code, the  
2 Secretary may designate, in addition to the  
3 tests and categories described in subparagraph  
4 (B)(i), additional in vitro clinical tests, and cat-  
5 egories of in vitro clinical tests, as low-risk in  
6 vitro clinical tests for purposes of the exemption  
7 under this subsection. The Secretary may make  
8 such a designation on the Secretary's own ini-  
9 tiative or in response to a request by any per-  
10 son. In making such a designation for a test or  
11 category of tests, the Secretary shall consider—

12 “(i) whether the test, or category of  
13 tests, is low-risk; and

14 “(ii) such other factors as the Sec-  
15 retary determines to be relevant to the pro-  
16 tection of the public health.

17 “(f) MANUAL TESTS.—

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

1           “(A) is designed, manufactured, and used  
2 within a single clinical laboratory for which a  
3 certificate is in effect under section 353 of the  
4 Public Health Service Act that meets the re-  
5 quirements under section 353 for performing  
6 high-complexity testing;

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

12           “(C) is not intended for testing donors, do-  
13 nations, and recipients of blood, blood compo-  
14 nents, human cells, tissues, cellular-based prod-  
15 ucts, or tissue-based products.

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

20           “(A) no component or part of such test, in-  
21 cluding any reagent, is introduced into inter-  
22 state commerce under the exemption under sub-  
23 section (b)(1) (relating to components or parts  
24 intended for further development), and any ar-  
25 ticle for taking or deriving specimens from the

1 human body used in conjunction with the test  
2 remains subject to the requirements of this sub-  
3 chapter; or

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

7 “(g) HUMANITARIAN TEST EXEMPTION.—

8 “(1) IN GENERAL.—An in vitro clinical test is  
9 exempt from premarket review under section 587B  
10 and may be lawfully marketed subject to the other  
11 applicable requirements of this Act, if—

12 “(A) such in vitro clinical test is intended  
13 for use for a disease or condition for which no  
14 more than 10,000 (or such other number deter-  
15 mined by the Secretary) individuals would be  
16 subject to negative or positive diagnosis by such  
17 test in the United States per year; and

18 “(B) the developer of the test—

19 “(i) maintains documentation (which  
20 may include literature citations in special-  
21 ized medical journals, textbooks, special-  
22 ized medical society proceedings, govern-  
23 mental statistics publications, or, if no  
24 such studies or literature citations exist,  
25 credible conclusions from appropriate re-



1 search or surveys) demonstrating that such  
2 test meets and continues to meet the cri-  
3 teria described in this paragraph; and

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

6 “(2) CROSS-REFERENCED TESTS.—In order to  
7 be eligible for an exemption under this subsection,  
8 the developer of a cross-referenced test shall submit  
9 a request under section 587H for informal feedback.

10 “(h) CUSTOM TESTS AND LOW-VOLUME TESTS.—An  
11 in vitro clinical test is exempt from premarket review  
12 under section 587B, the quality requirements under sec-  
13 tion 587J, and the notification requirements under section  
14 587I, and may be lawfully marketed subject to the other  
15 applicable requirements of this Act, if—

16 “(1) such in vitro clinical test—

17 “(A) is a low-volume test performed in a  
18 laboratory in which it was developed or devel-  
19 oped in a laboratory within the same corporate  
20 organization with the laboratory in which such  
21 test is performed and is administered to no  
22 more than 5 patients per year, unless otherwise  
23 determined by the Secretary; or

24 “(B) is a custom test developed or modi-  
25 fied to diagnose a unique pathology or physical

1 condition of a specific patient for which no  
2 other in vitro clinical test is commercially avail-  
3 able in the United States, and is—

4 “(i) not intended for use with respect  
5 to other patients; and

6 “(ii) after the development of the cus-  
7 tom test, not included in any test menu,  
8 template test report, or other promotional  
9 materials, and not otherwise advertised;  
10 and

11 “(2) the developer of the test—

12 “(A) maintains documentation dem-  
13 onstrating that such test meets and continues  
14 to meet the applicable criteria described in  
15 paragraph (1);

16 “(B) makes such documentation, such as a  
17 prescription order requesting the custom test  
18 for an individual patient, available to the Sec-  
19 retary upon request; and

20 “(C) informs the Secretary, on an annual  
21 basis, in a manner prescribed by the Secretary  
22 by guidance, that such test was introduced into  
23 interstate commerce.

24 “(i) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

1           “(1) IN GENERAL.—The provisions of this sub-  
2 chapter shall not apply to a test intended by the de-  
3 veloper to be used solely for public health surveil-  
4 lance activities, including the collection and testing  
5 of information or biospecimens, conducted, sup-  
6 ported, requested, ordered, required, or authorized  
7 by a public health authority.

8           “(2) LIMITATION.—The public health surveil-  
9 lance activities described in paragraph (1)—

10           “(A) are limited to activities necessary to  
11 allow a public health authority to identify, mon-  
12 itor, assess, or investigate potential public  
13 health signals, onsets of disease outbreaks, or  
14 conditions of public health importance (includ-  
15 ing trends, risk factors, patterns in diseases,  
16 and increases in injuries from using consumer  
17 products); and

18           “(B) include activities associated with pro-  
19 viding timely situational awareness and priority  
20 setting during the course of a threat to the pub-  
21 lic health (including natural or man-made dis-  
22 asters and deliberate attacks on the United  
23 States).

24           “(3) EXCLUSION.—An in vitro clinical test is  
25 not excluded from the provisions of this subchapter

1 if such test is intended for use in making clinical de-  
2 cisions for individual patients.

3 “(j) LAW ENFORCEMENT OR EMPLOYER TESTING.—

4 An in vitro clinical test that is intended solely for use in  
5 forensic analysis, law enforcement activity, or employment  
6 purposes is exempt from the requirements of this Act. An  
7 in vitro clinical test that is intended for use in making  
8 clinical decisions for individual patients, or whose individ-  
9 ually identifiable results may be reported back to an indi-  
10 vidual patient or the patient’s health care provider, even  
11 if also intended for law enforcement or employment testing  
12 purposes, is not intended solely for use in law enforcement  
13 or employment testing for purposes of this subsection.

14 “(k) IN VITRO CLINICAL TESTS UNDER A TECH-

15 NOLOGY CERTIFICATION ORDER.—An in vitro clinical test  
16 that is within the scope of a technology certification order,  
17 as described in section 587D(a), is exempt from premarket  
18 review under section 587B.

19 “(l) MODIFIED TESTS.—

20 “(1) IN GENERAL.—An in vitro clinical test  
21 that is modified, by the initial developer of the test  
22 or a different person, is a new in vitro clinical test  
23 subject to the requirements of this subchapter if the  
24 modification—

1           “(A) affects the analytical or clinical valid-  
2           ity of such test;

3           “(B) causes the test to no longer comply  
4           with applicable mitigating measures under sec-  
5           tion 587E or restrictions under section 587N;  
6           or

7           “(C) as applicable, affects the safety of an  
8           article for taking or deriving specimens from  
9           the human body for a purpose described in sec-  
10          tion 201(ss)(1).

11          “(2) EXEMPTIONS.—Notwithstanding para-  
12          graph (1), an in vitro clinical test that is modified  
13          by the initial developer of the test or a different per-  
14          son is not a new in vitro clinical test if the modifica-  
15          tion—

16               “(A) is a software update that does not  
17               have an adverse effect on the analytical or clin-  
18               ical validity or result in an increased risk to pa-  
19               tients and consumers;

20               “(B) is made pursuant to methods or cri-  
21               teria included in the change protocol premarket  
22               submission, amendment, or supplement ap-  
23               proved by the Secretary for the in vitro clinical  
24               test being modified;

1           “(C) is a labeling change that is appro-  
2           priate to address patient or user harm; or

3           “(D) is a specimen-related modification  
4           that—

5                   “(i) is made to extend specimen sta-  
6                   bility; or

7                   “(ii) aligns with the data and infor-  
8                   mation submitted in an approved applica-  
9                   tion for premarket review under section  
10                  587B or a technology certification order  
11                  issued under section 587D.

12           “(3) DOCUMENTATION.—When a person modi-  
13           fies an in vitro clinical test that was developed by  
14           another person, such modified test is exempt from  
15           the requirements of this subchapter provided that  
16           such person—

17                   “(A) documents the modification that was  
18                   made and the basis for determining that the  
19                   modification, considering the changes individ-  
20                   ually and collectively, was not a type of modi-  
21                   fication described in paragraph (1); and

22                   “(B) provides such documentation to the  
23           Secretary upon request or inspection.

1       “(m) INVESTIGATIONAL USE.—An in vitro clinical  
2 test for investigational use is exempt from the require-  
3 ments of this Act, except as provided in section 587R.

4       “(n) TRANSFER OR SALE OF IN VITRO CLINICAL  
5 TESTS.—

6               “(1) TRANSFER AND ASSUMPTION OF REGU-  
7 LATORY OBLIGATIONS.—If ownership of an in vitro  
8 clinical test is sold or transferred in such manner  
9 that the developer transfers the regulatory submis-  
10 sions and obligations applicable under this sub-  
11 chapter with respect to the test, the transferee or  
12 purchaser becomes the developer of the test and  
13 shall have all regulatory obligations applicable to  
14 such a test under this subchapter. The transferee or  
15 purchaser shall update the registration and listing  
16 information under section 587I for the in vitro clin-  
17 ical test.

18               “(2) TRANSFER OR SALE OF PREMARKET AP-  
19 PROVAL.—

20                       “(A) NOTICE REQUIRED.—If a developer  
21 of an in vitro clinical test transfers or sells the  
22 approval of the in vitro clinical test, the trans-  
23 feror or seller shall—

24                               “(i) submit a notice of the transfer or  
25 sale to the Secretary and update the reg-

1           istration and listing information under sec-  
2           tion 587I for the in vitro clinical test; and

3           “(ii) submit a supplemental applica-  
4           tion if required under section 587B(h).

5           “(B) EFFECTIVE DATE OF APPROVAL  
6           TRANSFER.—A transfer or sale described in  
7           subparagraph (A) shall become effective upon  
8           completion of a transfer or sale described in  
9           paragraph (1) or the approval of a supple-  
10          mental application under section 587B(h) if re-  
11          quired, whichever is later. The transferee or  
12          purchaser shall update the registration and list-  
13          ing information under section 587I for the in  
14          vitro clinical test within 15 calendar days of the  
15          effective date of the transfer or sale.

16          “(3) TRANSFER OR SALE OF TECHNOLOGY CER-  
17          TIFICATION.—

18                 “(A) REQUIREMENTS FOR TRANSFER OR  
19                 SALE OF TECHNOLOGY CERTIFICATION.—An  
20                 unexpired technology certification can be trans-  
21                 ferred or sold if the transferee or purchaser—

22                         “(i) is an eligible person under section  
23                         587D(b)(1); and

24                         “(ii) maintains, upon such transfer or  
25                         sale, the site, test design and quality re-



1            requirements, processes and procedures  
2            under the scope of technology certification,  
3            and scope of the technology certification  
4            identified in the applicable technology cer-  
5            tification order.

6            “(B) NOTICE REQUIRED.—If a developer  
7            of an in vitro clinical test transfers or sells a  
8            technology certification order that has not ex-  
9            pired, the transferor or seller shall submit a no-  
10           notice of the transfer or sale to the Secretary and  
11           shall update the registration and listing infor-  
12           mation under section 587I for all in vitro clin-  
13           ical tests covered by the technology certifi-  
14           cation.

15           “(C) EFFECTIVE DATE OF TECHNOLOGY  
16           CERTIFICATION TRANSFER.—The transfer of a  
17           technology certification shall become effective  
18           upon completion of a transfer or sale described  
19           in subparagraph (A). The transferee or pur-  
20           chaser shall update the registration and listing  
21           information under section 587I for the in vitro  
22           clinical test within 30 calendar days of the ef-  
23           fective date of the technology certification  
24           transfer.

1           “(D) NEW TECHNOLOGY CERTIFICATION  
2           REQUIRED.—If the requirements of subpara-  
3           graph (A)(ii) are not met, the technology cer-  
4           tification order may not be transferred and the  
5           transferee or purchaser of an in vitro clinical  
6           test is required to submit an application for  
7           technology certification and obtain a technology  
8           certification order prior to offering the test for  
9           clinical use.

10          “(o) GENERAL LABORATORY EQUIPMENT.—Any in-  
11          strument that does not produce an analytical result, and  
12          that functions as a component of pre-analytical procedures  
13          related to in vitro clinical tests, is not subject to the re-  
14          quirements of this subchapter, provided that—

15                 “(1) the instrument is operating in a clinical  
16          laboratory that is certified under section 353 of the  
17          Public Health Service Act; and

18                 “(2) the instrument can be serviced by the  
19          manufacturer of such instrument or, if that manu-  
20          facturer is no longer in business, a third party with  
21          the ability to service such instrument.

22          “(p) INSTRUMENT FAMILIES.—In the case of an in-  
23          strument family, premarket approval under section  
24          587B(d) of one version of the in vitro clinical test is re-  
25          quired, and previous and updated versions of the same test

1 within such instrument family shall be deemed to be sub-  
2 ject to the approval pursuant to that section, unless the  
3 Secretary determines otherwise, as set forth in guidance.

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

11 “(r) REGULATIONS.—The Secretary may issue regu-  
12 lations to implement this subchapter.

13 **“SEC. 587B. PREMARKET REVIEW.**

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

17 “(1) an approval of an application filed pursu-  
18 ant to subsection (c) or (d) is effective with respect  
19 to test; or

20 “(2) the test is exempt under section 587A  
21 from premarket review under this section.

22 “(b) TRANSPARENCY AND PREDICTABILITY.—

23 “(1) PRE-SUBMISSION MEETING OR REQUEST  
24 FOR INFORMAL FEEDBACK.—Pursuant to section  
25 587H, prior to filing an application under subsection

1 (c) or (d), any person may request a meeting or  
2 written correspondence with the Secretary to discuss  
3 the eligibility of an in vitro clinical test for pre-  
4 market review or other information related to the fil-  
5 ing of an application. The Secretary shall respond to  
6 such request within 45 calendar days.

7 “(2) STREAMLINING OF APPLICATIONS.—

8 “(A) PREMARKET APPLICATION AND  
9 TECHNOLOGY CERTIFICATION.—If a person  
10 files a premarket application under this section  
11 and provides any additional documentation re-  
12 quired under section 587D, the in vitro clinical  
13 test that is the subject of the application may  
14 be utilized as the representative test reviewed  
15 by the Secretary to provide an approval for  
16 both a premarket application under this section  
17 and a technology certification order under sec-  
18 tion 587D.

19 “(B) REPRESENTATIVE ASSAYS FOR PRE-  
20 MARKET APPROVAL.—With respect to a tech-  
21 nology certification application filed under sec-  
22 tion 587D, the representative test, as described  
23 in subparagraph (A), used to issue a technology  
24 certification order under section 587D shall be

1           deemed a test with premarket approval under  
2           this section.

3           “(c) APPLICATION.—

4           “(1) FILING.—Any person may file with the  
5           Secretary an application for premarket approval of  
6           an in vitro clinical test.

7           “(2) APPLICATION CONTENT.—An application  
8           submitted under paragraph (1) with respect to an in  
9           vitro clinical test shall include the following, in such  
10          format as the Secretary specifies:

11           “(A) General information regarding the in  
12          vitro clinical test, including—

13           “(i) the name and address of the ap-  
14          plicant;

15           “(ii) the table of contents for the ap-  
16          plication and the identification of the infor-  
17          mation the applicant claims as trade secret  
18          or confidential commercial or financial in-  
19          formation;

20           “(iii) a description of the test’s in-  
21          tended use;

22           “(iv) an explanation regarding test  
23          function and any significant performance  
24          characteristics; and

1           “(v) an explanation of how the devel-  
2           opment and validation activities support  
3           the test meeting the applicable standard.

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

7                   “(i) a brief description of any existing  
8                   alternative practices or procedures for di-  
9                   agnosing the disease or condition for which  
10                  the in vitro clinical test is intended, as ap-  
11                  plicable;

12                   “(ii) a brief description of the foreign  
13                   and domestic marketing history of the test,  
14                   if any, including a list of all countries in  
15                   which the test has been marketed and a  
16                   list of all countries in which the test has  
17                   been withdrawn from marketing for any  
18                   reason related to the applicable standard  
19                   of the in vitro clinical test, if known by the  
20                   applicant;

21                   “(iii) a summary of the any studies  
22                   submitted for such test, including a de-  
23                   scription of the objective of the study, a  
24                   description of the experimental design of  
25                   the study, a brief description of how the

1 data were collected and analyzed, a brief  
2 description of the results of the technical  
3 data submitted, and a brief description of  
4 any nonclinical or clinical studies;

5 “(iv) a risk assessment of the test;  
6 and

7 “(v) conclusions drawn from any stud-  
8 ies described in clause (iii), including a dis-  
9 cussion demonstrating that the data and  
10 information in the application constitute  
11 valid scientific evidence and meet the appli-  
12 cable standard under section 587(2), an  
13 explanation of how the development and  
14 validation activities, as applicable, support  
15 that the test meets the applicable standard  
16 under section 587(2), and a discussion of  
17 any adverse effects of the test on health  
18 and proposals to mitigate those risks, if  
19 any.

20 “(C) The signature of the person filing the  
21 premarket application or an authorized rep-  
22 resentative.

23 “(D) A bibliography of all published re-  
24 ports reasonably known to the applicant related  
25 to such test and a discussion of data and infor-

1           mation relevant to the evaluation of the applica-  
2           ble standard that may be met by such test.

3           “(E) A statement that the applicant be-  
4           lieves to the best of the applicant’s knowledge  
5           that all data and information submitted to the  
6           Secretary are truthful and accurate and that no  
7           material fact has been omitted in the applica-  
8           tion.

9           “(F) Except as provided under subsection  
10          (d), applicable information regarding the meth-  
11          ods used in, or the facilities or controls used  
12          for, the development of the test to demonstrate  
13          compliance with the applicable quality require-  
14          ments under section 587J.

15          “(G) Information demonstrating compli-  
16          ance with any relevant—

17                 “(i) mitigating measures under sec-  
18                 tion 587E; and

19                 “(ii) standards established or recog-  
20                 nized under section 514 prior to the date  
21                 of enactment of the Verifying Accurate  
22                 Leading-edge IVCT Development Act of  
23                 2021, or, after applicable standards are es-  
24                 tablished or recognized under section  
25                 587Q, with such standards.



1           “(H) Valid scientific evidence to support  
2 analytical and clinical validity of the test, which  
3 shall include—

4                   “(i) summary information for all sup-  
5 porting validation studies performed;

6                   “(ii) raw data, such as tabulations of  
7 data and results as required under section  
8 814.20(b)(6)(ii) of title 21, Code of Fed-  
9 eral Regulations (or any successor regula-  
10 tions);

11                   “(iii) for nonclinical laboratory studies  
12 involving the test, a statement that studies  
13 were conducted in compliance with applica-  
14 ble good laboratory practices; and

15                   “(iv) for investigations involving  
16 human subjects, statements that any clin-  
17 ical investigation involving human subjects  
18 was conducted in compliance with applica-  
19 ble—

20                           “(I) institutional review board  
21 regulations;

22                           “(II) informed consent regula-  
23 tions; and

24                           “(III) investigational use require-  
25 ments in section 587R.

1           “(I) To the extent the application seeks  
2 authorization to make modifications to the test  
3 within the scope of the approval, a change pro-  
4 tocol that includes validation procedures and  
5 acceptance criteria for anticipated modifications  
6 that could be made to the test within the scope  
7 of the approval.

8           “(J) Proposed labeling, in accordance with  
9 the requirements of section 587K.

10           “(K) Such other data or information as  
11 the Secretary may require in accordance with  
12 the least burdensome requirements of sub-  
13 section (j).

14           “(3) GUIDANCE FOR PREMARKET AND SPECIAL  
15 PREMARKET APPLICATIONS.—In accordance with  
16 section 5 of the Verifying Accurate Leading-edge  
17 IVCT Development Act of 2021, the Secretary shall  
18 issue draft guidance detailing the information to be  
19 provided in a premarket application and special pre-  
20 market application under this section. The Secretary  
21 shall issue final guidance not later than 90 calendar  
22 days after the close of the comment period for such  
23 guidance.

24           “(4) REFUSE TO FILE A PREMARKET OR SPE-  
25 CIAL PREMARKET APPLICATION.—If, after receipt of

1 an application under this section, the Secretary re-  
2 fuses to file such application, the Secretary shall  
3 provide to the developer, within 60 calendar days of  
4 receipt of such application, a description of the rea-  
5 son for such refusal, and identify the information re-  
6 quired, if any, to allow for the filing of the applica-  
7 tion.

8 “(5) SUBSTANTIVE REVIEW FOR DEFICIENT AP-  
9 PPLICATION.—If, after receipt of an application under  
10 this section, the Secretary determines that any por-  
11 tion of such application is deficient, the Secretary  
12 shall provide to the applicant, within 75 calendar  
13 days of receipt of such application, a description of  
14 such deficiencies and identify the information re-  
15 quired to correct such deficiencies.

16 “(d) SPECIAL PREMARKET REVIEW.—

17 “(1) IN GENERAL.—Any person may file with  
18 the Secretary an application for special premarket  
19 approval for—

20 “(A) an instrument;

21 “(B) a specimen receptacle;

22 “(C) an in vitro clinical test eligible for a  
23 technology certification order under section  
24 587D; or

1           “(D) a first-of-a-kind test (unless it is a  
2           high-risk test), a direct-to-consumer test, or  
3           cross-referenced test that does not have miti-  
4           gating measures.

5           “(2) APPLICATION CONTENT.—An application  
6           under paragraph (1) shall include—

7           “(A) the information required for applica-  
8           tions submitted under subsection (c)(2), except  
9           that applications under paragraph (1) need not  
10          include—

11           “(i) quality requirement information;

12           or

13           “(ii) raw data unless explicitly re-  
14          quested by the Secretary;

15          “(B) in the case of a specimen receptacle,  
16          safety information; and

17          “(C) data, as applicable, to support soft-  
18          ware validation, electromagnetic compatibility,  
19          and electrical safety, and information dem-  
20          onstrating compliance with maintaining quality  
21          systems documentation.

22          “(3) 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       587P need not occur unless requested by the Sec-  
2       retary.

3       “(e) INSTRUMENT FAMILY.—When an in vitro clin-  
4       ical test has been approved, or is otherwise legally mar-  
5       keted, for use on a specific approved or legally marketed  
6       instrument within an instrument family, a submission  
7       under this section shall not be required for that in vitro  
8       clinical test in order for it to be used on a new instrument  
9       within that instrument’s family.

10       “(f) AMENDMENTS TO AN APPLICATION.—

11               “(1) IN GENERAL.—An applicant may amend  
12       an original or supplemental application under sub-  
13       section (c) or (d).

14               “(2) REQUIRED AMENDMENT OR SUPPLE-  
15       MENT.—An applicant shall amend or supplement an  
16       application submitted under subsection (c) or (d) if  
17       the applicant becomes aware of information that—

18                       “(A) could reasonably affect an evaluation  
19       of whether the applicable standard has been  
20       met; or

21                       “(B) could reasonably affect the statement  
22       of contraindications, warnings, precautions, and  
23       adverse reactions in the proposed labeling.

24               “(3) REQUEST FOR AMENDMENT OR SUPPLE-  
25       MENT.—The Secretary may request that an appli-

1 cant amend or supplement an application under sub-  
2 section (c) or (d) with any information necessary for  
3 review under this section.

4 “(g) ACTION ON AN APPLICATION FOR PREMARKET  
5 APPROVAL.—

6 “(1) REVIEW.—

7 “(A) DISPOSITION.—As promptly as pos-  
8 sible, but not later than 90 calendar days after  
9 an application under subsection (c) is accepted  
10 for submission (unless the Secretary determines  
11 that an extension is necessary to review one or  
12 more major amendments to the application), or  
13 not later than 60 calendar days after an appli-  
14 cation under subsection (d) is accepted for sub-  
15 mission, the Secretary, after considering any  
16 applicable report and recommendations pursu-  
17 ant to advisory committees under section 587G,  
18 or prior to the establishment of such advisory  
19 committees, any recommendations by a classi-  
20 fication panel under section 513, shall issue an  
21 order approving the application, unless the Sec-  
22 retary finds that the grounds for approval in  
23 paragraph (2) are not met.

24 “(B) RELIANCE ON PROPOSED LABEL-  
25 ING.—In determining whether to approve or

1 deny an application under paragraph (1), the  
2 Secretary shall rely on the intended use in-  
3 cluded in the proposed labeling, provided that  
4 such labeling is not false or misleading based on  
5 a fair evaluation of all material facts.

6 “(2) APPROVAL OF AN APPLICATION.—

7 “(A) IN GENERAL.—The Secretary shall  
8 approve an application submitted under sub-  
9 section (c) with respect to an in vitro clinical  
10 test if the Secretary finds that there is a rea-  
11 sonable assurance that the applicable standard  
12 is met, and—

13 “(i) except as provided under sub-  
14 section (d), the applicant is in compliance  
15 with applicable quality requirements in sec-  
16 tion 587J or as otherwise specified in a  
17 condition of approval, or maintains the  
18 documentation required to be in compli-  
19 ance with such requirements if the appli-  
20 cant is not required to submit such docu-  
21 mentation as a part of the application  
22 under this section;

23 “(ii) the application does not contain  
24 a false statement of material fact;

1           “(iii) based on a fair evaluation of all  
2 material facts, the proposed labeling is  
3 truthful and non-misleading and complies  
4 with the requirements of section 587K;

5           “(iv) except as provided under sub-  
6 section (d), the applicant permits, if re-  
7 quested, authorized employees of the Food  
8 and Drug Administration and persons ac-  
9 credited under section 587P an oppor-  
10 tunity—

11           “(I) to inspect at a reasonable  
12 time and in a reasonable manner the  
13 facilities and all pertinent equipment,  
14 finished and unfinished materials,  
15 containers, and labeling therein, in-  
16 cluding all things (including records,  
17 files, papers, and controls) bearing on  
18 whether an in vitro clinical test is  
19 adulterated, misbranded, or otherwise  
20 in violation of this Act; and

21           “(II) to view and to copy and  
22 verify all records pertinent to the ap-  
23 plication and the in vitro clinical test;

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



1 587Q and any applicable mitigating meas-  
2 ures under section 587E; and

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 requirements of this section.

8 “(B) CONDITIONS OF APPROVAL.—An  
9 order approving an application pursuant to this  
10 paragraph may require conditions of approval  
11 for the in vitro clinical test, including conform-  
12 ance with performance standards under section  
13 587Q and restrictions under section 587N.

14 “(C) FIRST-OF-A-KIND TEST.—For a first-  
15 of-a-kind in vitro clinical test, an order approv-  
16 ing an application pursuant to this paragraph—

17 “(i) may impose requirements for  
18 tests with the same indications for use, in-  
19 cluding conformance with performance  
20 standards under section 587Q and miti-  
21 gating measures under section 587E, and  
22 comply with restrictions under section  
23 587N; and

24 “(ii) shall indicate whether subsequent  
25 in vitro clinical tests with the same in-

1           tended use may meet an exemption set  
2           forth in section 587A.

3           “(D) PUBLICATION.—The Secretary shall  
4           publish each order approving an application  
5           pursuant to this paragraph on the public  
6           website of the Food and Drug Administration  
7           and make publicly available a summary of the  
8           data used to grant the approval, except to the  
9           extent the Secretary determines that such  
10          order—

11                   “(i) contains commercially confidential  
12                   or trade secret information; or

13                   “(ii) relates to national security or  
14                   countermeasures is restricted from disclo-  
15                   sure pursuant to statutory provisions other  
16                   than this section.

17          “(3) REVIEW OF DENIALS.—An applicant  
18          whose application submitted under subsection (c) or  
19          (d) has been denied approval may, by petition filed  
20          not more than 60 calendar days after the date on  
21          which the applicant receives notice of such denial,  
22          obtain review of the denial in accordance with sec-  
23          tion 587O.

24          “(h) SUPPLEMENTS TO AN APPLICATION.—

1           “(1) RISK ANALYSIS.—Prior to implementing  
2 any modification to an in vitro clinical test, the hold-  
3 er of the application approved under subsection (c)  
4 or (d) for such test shall perform risk analyses in  
5 accordance with section 587J, unless such modifica-  
6 tion is included in the change protocol submitted by  
7 the applicant and approved under this section or ex-  
8 empt under section 587A(l).

9           “(2) SUPPLEMENT REQUIREMENT.—

10           “(A) IN GENERAL.—Except as provided in  
11 subparagraph (B), or otherwise specified by the  
12 Secretary, the holder of the application ap-  
13 proved under subsection (g) for an in vitro clin-  
14 ical test shall submit to the Secretary and re-  
15 ceive approval of a supplement before imple-  
16 menting a modification to the test, unless such  
17 modification is exempt under section 587A(l).

18           “(B) ADJUSTMENTS TO CHANGE PRO-  
19 TOCOL.—A person may submit under this para-  
20 graph a supplemental application adjusting the  
21 change protocol of the test at any time after the  
22 initial filing of an application under subsection  
23 (c) or (d).

24           “(C) EXCEPTIONS.—Subject to subpara-  
25 graphs (D) and (E), and so long as the holder

1 of an approved application submitted under  
2 subsection (c) or (d) for an in vitro clinical test  
3 does not add a manufacturing site, or change  
4 activities at an existing manufacturing site,  
5 with respect to the test, the holder may, with-  
6 out prior approval of a supplement, implement  
7 the following modifications to the test:

8 “(i) Modifications included in and im-  
9 plemented in accordance with an approved  
10 change protocol under subsection (c)(2)(I).

11 “(ii) Modifications that do not  
12 change—

13 “(I) the analytical or clinical va-  
14 lidity of the test;

15 “(II) the intended use of the test  
16 unless provided under an approved  
17 change protocol under subsection  
18 (c)(2)(I); or

19 “(III) the safety of the specimen  
20 receptacles.

21 “(iii) Labeling changes to appro-  
22 priately address a safety concern.

23 “(iv) Modifications that are exempt  
24 under section 587A(l).

1           “(D) REPORTING FOR CHANGE PROTOCOL  
2           MODIFICATIONS.—As a component of the report  
3           required under subsection (k), the holder of an  
4           application approved under subsection (g) for  
5           an in vitro clinical test shall—

6                   “(i) report any modification to the  
7                   test described in clause (i) or (ii) of sub-  
8                   paragraph (C) in the next annual report  
9                   for the test under subsection (k) following  
10                  the date on which the test, with such modi-  
11                  fication, is introduced into interstate com-  
12                  merce; and

13                   “(ii) include in such report—

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

16                           “(II) as applicable, a summary of  
17                           the analytical validity and clinical va-  
18                           lidity of the test, as modified, and any  
19                           changes to acceptance criteria.

20           “(E) REPORTING FOR OTHER CATEGORY  
21           OF EXCEPTIONS.—The holder of the application  
22           approved under subsection (e) or (d) for an in  
23           vitro clinical test shall—

24                   “(i) report to the Secretary any modi-  
25                   fication to the test described in clause (iii)

1 of subparagraph (C) not more than 60  
2 days after the date on which the test, with  
3 the modification, is introduced into inter-  
4 state commerce; and

5 “(ii) include in the report—

6 “(I) a summary of the relevant  
7 change or changes;

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

10 “(III) a description of how the  
11 change or changes were evaluated.

12 “(F) REQUEST FOR SUPPLEMENT.—Upon  
13 review of the information received under sub-  
14 paragraph (D) and a finding that the relevant  
15 modification is inconsistent with the standard  
16 specified under subparagraph (C), the Secretary  
17 may require a supplement under subparagraph  
18 (A). If the Secretary determines that a supple-  
19 ment under subparagraph (A) is required, the  
20 Secretary shall notify the applicant of such de-  
21 termination. Such notification shall include a  
22 justification for the submission of a supplement.  
23 Prior to the submission of a supplement under  
24 this subparagraph, the applicant may request a  
25 meeting or written correspondence to gain agen-

1           cy feedback as to the necessity of such supple-  
2           mental filing. The Secretary shall respond to  
3           such meeting request within 30 calendar days  
4           of receipt.

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

8                   “(A) for modifications other than manufac-  
9                   turing site changes—

10                           “(i) a description of the modification;

11                           “(ii) data to demonstrate that the ap-  
12                           plicable standard is met;

13                           “(iii) acceptance criteria; and

14                           “(iv) any revised labeling; and

15                   “(B) for manufacturing site changes—

16                           “(i) the information listed in subpara-  
17                           graph (A); and

18                           “(ii) information regarding the meth-  
19                           ods used in, or the facilities or controls  
20                           used for, the development of the test to  
21                           demonstrate compliance with the applicable  
22                           quality requirements under section 587J.

23           “(4) ADDITIONAL DATA.—The Secretary may  
24           require, when necessary, data to evaluate a modifica-  
25           tion to an in vitro clinical test that is in addition to

1 the data otherwise required under the preceding  
2 paragraphs if the data request is in accordance with  
3 the least burdensome requirements under subsection  
4 (j).

5 “(5) CONDITIONS OF APPROVAL.—In an order  
6 approving a supplement under this subsection, the  
7 Secretary may require conditions of approval for the  
8 in vitro clinical test, including compliance with re-  
9 strictions under section 587N and conformance to  
10 performance standards under section 587Q.

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

13 “(A) the data demonstrate that the modi-  
14 fied in vitro clinical test meets the applicable  
15 standard; and

16 “(B) the holder of the application approved  
17 under subsection (g) for the test has dem-  
18 onstrated compliance with applicable quality  
19 and inspection requirements, as applicable and  
20 appropriate.

21 “(7) PUBLICATION.—The Secretary shall pub-  
22 lish on the public website of the Food and Drug Ad-  
23 ministration notice of any order approving a supple-  
24 ment under this subsection, except that such publi-  
25 cation shall exclude—



1           “(A) commercial confidential or trade se-  
2           cret information; and

3           “(B) any other information that the Sec-  
4           retary determines to relate to national security  
5           or countermeasures or to be restricted from dis-  
6           closure pursuant to another provision of law.

7           “(8) REVIEW OF DENIAL.—An applicant whose  
8           supplement under this subsection has been denied  
9           approval may, by petition filed on or before the 60th  
10          calendar day after the date upon which the applicant  
11          receives notice of such denial, obtain review of the  
12          denial in accordance with section 5870.

13          “(i) WITHDRAWAL AND TEMPORARY SUSPENSION OF  
14          APPROVAL.—

15                 “(1) ORDER WITHDRAWING APPROVAL.—

16                 “(A) IN GENERAL.—The Secretary may,  
17                 within 10 calendar days of providing due notice  
18                 and an opportunity for an informal hearing to  
19                 the holder of an approved application for an in  
20                 vitro clinical test under this section, issue an  
21                 order withdrawing approval of the application if  
22                 the Secretary finds that—

23                         “(i) the grounds for approval under  
24                         subsection (g) are no longer met; or

1           “(ii) there is a reasonable likelihood  
2           that the test would cause death or serious  
3           adverse health consequences, including by  
4           causing the absence, delay, or discontinu-  
5           ation of life-saving or life sustaining med-  
6           ical treatment.

7           “(B) CONTENT.—An order under subpara-  
8           graph (A) withdrawing approval of an applica-  
9           tion shall state each ground for withdrawal and  
10          shall notify the holder of such application 60  
11          calendar days prior to issuing such order.

12          “(C) PUBLICATION.—The Secretary shall  
13          publish any order under subparagraph (A) on  
14          the public website of the Food and Drug Ad-  
15          ministration, except that such publication shall  
16          exclude—

17                  “(i) commercial confidential or trade  
18                  secret information; and

19                  “(ii) any other information that the  
20                  Secretary determines to relate to national  
21                  security or countermeasures or to be re-  
22                  stricted from disclosure pursuant to an-  
23                  other provision of law.

24          “(2) ORDER OF TEMPORARY SUSPENSION.—If,  
25          after providing due notice and an opportunity for an

1 informal hearing to the holder of an approved appli-  
2 cation for an in vitro clinical test under this section,  
3 the Secretary determines there is a reasonable likeli-  
4 hood that the in vitro clinical test would cause death  
5 or serious adverse health consequences, including by  
6 causing the absence, delay, or discontinuation of life-  
7 saving or life-sustaining medical treatment, the Sec-  
8 retary shall by order temporarily suspend the ap-  
9 proval of the application. If the Secretary issues  
10 such an order, the Secretary shall proceed expedi-  
11 tiously under paragraph (1) to withdraw approval of  
12 such application.

13 “(j) LEAST BURDENSOME REQUIREMENTS.—

14 “(1) IN GENERAL.—In carrying out this sub-  
15 chapter, the Secretary shall consider the least bur-  
16 densome means necessary to provide a reasonable  
17 assurance of analytical and clinical validity, or appli-  
18 cable standard, and other regulatory requirements,  
19 as determined by the Secretary.

20 “(2) NECESSARY DEFINED.—For purposes of  
21 paragraph (1) and paragraph (3), the term ‘nec-  
22 essary’ means the minimum required information  
23 that would support a determination by the Secretary  
24 that the application provides a reasonable assurance  
25 of analytical and clinical validity, or other applicable

1 standard or regulatory requirement, as determined  
2 by the Secretary.

3 “(3) CONSIDERATION OF ROLE OF  
4 POSTMARKET INFORMATION.—For purposes of this  
5 subsection, the Secretary shall consider the role of  
6 postmarket information in determining the least bur-  
7 densome appropriate means necessary to dem-  
8 onstrate that the applicable standard and other reg-  
9 ulatory requirements have been met.

10 “(k) ANNUAL REPORT.—

11 “(1) IN GENERAL.—Unless the Secretary speci-  
12 fies otherwise, the holder of an approved application  
13 under this section shall submit an annual report  
14 each year at a time designated by the Secretary in  
15 the approval order. Such report shall—

16 “(A) identify all modifications required to  
17 be reported that an approved application holder  
18 has made to any test that is covered by the ap-  
19 proval order, including any modification that  
20 requires a supplement under subsection (h)(2);  
21 and

22 “(B) include any other information re-  
23 quired by the Secretary.

24 “(2) EXCEPTION.—The annual reporting re-  
25 quirement in paragraph (1) shall not apply to in

1 vitro clinical tests that are deemed to have a pre-  
2 market approval based on a prior approval under  
3 section 515(c), clearance under section 510(k), or  
4 authorization under section 513(f) of this Act, or  
5 that are grandfathered under 587A(c).

6 “(l) SERVICE OF ORDERS.—Orders of the Secretary  
7 under this section with respect to applications under sub-  
8 section (c) or (d) or supplements under subsection (h)  
9 shall be served—

10 “(1) in person by any officer or employee of the  
11 Department of Health and Human Services des-  
12 ignated by the Secretary; or

13 “(2) by mailing the order by registered mail or  
14 certified mail or electronic equivalent addressed to  
15 the applicant at the last known address in the  
16 records of the Secretary.

17 **“SEC. 587C. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

18 “(a) IN GENERAL.—The purpose of this section is  
19 to encourage the Secretary to apply efficient and flexible  
20 approaches to expedite the development of, and prioritize  
21 the review of, in vitro clinical tests that represent break-  
22 through technologies, and to provide the Secretary with  
23 sufficient authority to do so.

24 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary  
25 shall establish a program to expedite the development of,

1 and provide for the priority review of, in vitro clinical  
2 tests.

3 “(c) ELIGIBILITY.—The program developed under  
4 subsection (b) shall be available for any in vitro clinical  
5 test that—

6 “(1) provides or enables more effective treat-  
7 ment or diagnosis of life-threatening or irreversibly  
8 debilitating human disease or conditions compared  
9 to existing approved or precertified alternatives; and

10 “(2) is a test—

11 “(A) that represents a breakthrough tech-  
12 nology;

13 “(B) for which no approved or precertified  
14 alternative exists;

15 “(C) that offers a clinically meaningful ad-  
16 vantage over existing approved or precertified  
17 alternatives, including the potential, compared  
18 to existing approved or precertified alternatives,  
19 to reduce or eliminate the need for hospitaliza-  
20 tion, improve patient quality of life, facilitate  
21 patients’ ability to manage their own care (such  
22 as through self-directed personal assistance), or  
23 establish long-term clinical efficiencies; or

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

1 “(d) DESIGNATION.—

2 “(1) REQUEST.—To receive breakthrough ap-  
3 proval under this section, an applicant may request  
4 that the Secretary designate the in vitro clinical test  
5 for expedited development and priority review. Any  
6 such request for designation may be made at any  
7 time prior to the submission of an application under  
8 section 587B, and shall include information dem-  
9 onstrating that the test is eligible for designation  
10 under subsection (c).

11 “(2) DETERMINATION.—Not later than 60 cal-  
12 endar days after the receipt of a request under para-  
13 graph (1), the Secretary shall determine whether the  
14 in vitro clinical test that is the subject of the request  
15 meets the criteria described in subsection (c). If the  
16 Secretary determines that the test meets the criteria,  
17 the Secretary shall designate the test for expedited  
18 development and priority review.

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

23 “(4) WITHDRAWAL.—

24 “(A) IN GENERAL.—The designation of an  
25 in vitro clinical test under this subsection is

1           deemed to be withdrawn, and such in vitro clin-  
2           ical test shall no longer be eligible for designa-  
3           tion under this section, if an application for ap-  
4           proval under section 587B is denied. Such test  
5           shall be eligible for designation upon a new re-  
6           quest for such designation.

7           “(B) EXCEPTION.—The Secretary may not  
8           withdraw a designation granted under this sub-  
9           section based on the subsequent approval or  
10          technology certification of another test that—

11                           “(i) is designated under this section;

12                           or

13                           “(ii) was given priority review under  
14                           section 515B.

15          “(e) ACTIONS.—For purposes of expediting the devel-  
16          opment and review of in vitro clinical tests under this sec-  
17          tion, the Secretary may take the actions and additional  
18          actions set forth in paragraphs (1) and (2), respectively,  
19          of section 515B(e) when reviewing such tests. Any ref-  
20          erence or authorization in section 515B(e) with respect  
21          to a device shall be deemed a reference or authorization  
22          with respect to an in vitro clinical test for purposes of this  
23          section.

24          “(f) GUIDANCE.—



1           “(1) IN GENERAL.—Not later than one year  
2 after the date of enactment of the Verifying Accu-  
3 rate Leading-edge IVCT Development Act of 2021,  
4 the Secretary shall issue draft guidance on the im-  
5 plementation of this section. Such guidance shall—

6                   “(A) set forth the process by which a per-  
7 son may seek a designation under subsection  
8 (d);

9                   “(B) provide a template for request under  
10 subsection (d);

11                   “(C) identify the criteria the Secretary will  
12 use in evaluating a request for designation; and

13                   “(D) identify the criteria and processes the  
14 Secretary will use to assign a team of staff, in-  
15 cluding team leaders, to review in vitro clinical  
16 tests designated for expedited development and  
17 priority review, including any training required  
18 for such personnel to ensure effective and effi-  
19 cient review.

20           “(2) PROCESS.—Prior to finalizing the guid-  
21 ance under paragraph (1), the Secretary shall seek  
22 public comment on the draft guidance. The Sec-  
23 retary shall issue final guidance one year after the  
24 close of the comment period for the draft guidance.

1       “(g) ANNUAL REPORT.—Unless otherwise specified  
2 by the Secretary, the requirements under section 587B(k)  
3 apply to in vitro clinical tests designated under this sec-  
4 tion.

5       “(h) SERVICE OF ORDERS.—Orders of the Secretary  
6 under this section shall be served—

7               “(1) in person by any officer or employee of the  
8 Department of Health and Human Services des-  
9 ignated by the Secretary; or

10              “(2) by mailing the order by registered mail or  
11 certified mail or electronic equivalent addressed to  
12 the applicant at his last known address in the  
13 records of the Secretary.

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

15       “(a) IN GENERAL.—

16              “(1) ELIGIBILITY.—Any eligible person may  
17 seek a technology certification order in accordance  
18 with this section.

19              “(2) EXCEPTION.—An in vitro clinical test is  
20 exempt from premarket review under section 587B  
21 and may be introduced into interstate commerce if  
22 the developer is eligible under this section and the  
23 in vitro clinical test—

24                      “(A) is an eligible in vitro clinical test  
25                      under subsection (b)(2); and

1           “(B) falls within the scope of a technology  
2           certification order issued under this section that  
3           is in effect.

4           “(b) ELIGIBILITY.—

5           “(1) ELIGIBLE PERSON.—In this section, the  
6           term ‘eligible person’ means an in vitro clinical test  
7           developer unless, at the time such person seeks or  
8           would seek technology certification order, the per-  
9           son—

10           “(A) has been found to have committed a  
11           significant violation of section 353 of the Public  
12           Health Service Act, unless—

13           “(i) such violation occurred more than  
14           5 years prior to the date on which such  
15           technology certification order is or would  
16           be sought; or

17           “(ii) such violation has been resolved;

18           “(B) fails to maintain required certifi-  
19           cations under section 353 of the Public Health  
20           Service Act, as applicable; or

21           “(C) has been found to have submitted in-  
22           formation to the Secretary that—

23           “(i) makes false or misleading state-  
24           ments about a technology certification

1 order previously issued or an application  
2 approved under section 587B; or

3 “(ii) violates any requirement of this  
4 subchapter, where such violation exposes  
5 individuals to serious risk of illness, injury,  
6 or death.

7 “(2) TECHNOLOGY CERTIFICATION ELIGIBILITY  
8 LIMITATIONS.—An in vitro clinical test is not eligible  
9 under subsection (a)(2) for exemption from pre-  
10 market review under section 587B, if—

11 “(A) such test is—

12 “(i) a component or part of an in  
13 vitro clinical test as described in section  
14 201(ss)(1)(B)(v);

15 “(ii) an instrument under section  
16 201(ss)(1)(B)(ii);

17 “(iii) a specimen receptacle under sec-  
18 tion 201(ss)(1)(B)(iii);

19 “(iv) an in vitro clinical test, including  
20 reagents used in such tests, intended for  
21 use for testing donors, donations, and re-  
22 cipients of blood, blood components,  
23 human cells, tissues, cellular-based prod-  
24 ucts, or tissue-based products; or

1                   “(v) a high-risk in vitro clinical test  
2                   without mitigating measures under section  
3                   587E, which may include first-of-a-kind in  
4                   vitro clinical tests, home use in vitro clin-  
5                   ical tests, cross-referenced in vitro clinical  
6                   tests, and direct-to-consumer in vitro clin-  
7                   ical tests.

8                   “(c) PUBLIC MEETING AND INPUT.—

9                   “(1) PUBLIC DOCKET.—Not later than 30 days  
10                  after the date of enactment of the Verifying Accu-  
11                  rate Leading-edge IVCT Development Act of 2021,  
12                  the Secretary shall establish a public docket to re-  
13                  ceive comments concerning recommendations for im-  
14                  plementation of this section, including criteria and  
15                  procedures for subsections (e) through (j). The pub-  
16                  lic docket shall remain open for the duration of time  
17                  that this section remains in effect.

18                  “(2) PUBLIC MEETING.—Not later than 180  
19                  days after the date of enactment of the Verifying  
20                  Accurate Leading-edge IVCT Development Act of  
21                  2021, the Secretary shall convene a public meeting  
22                  to which stakeholders from organizations rep-  
23                  resenting patients and consumers, academia, and the  
24                  in vitro clinical test industry are invited in order to  
25                  discuss the technology certification process including

1 application requirements, inspections, alignment  
2 with third-party accreditors, and the definition of  
3 ‘technology’ under section 587(17).

4 “(d) REGULATIONS.—The Secretary shall issue regu-  
5 lations on technology certification including describing cri-  
6 teria or procedures relating to technology certification  
7 under this section, which shall be subject to public com-  
8 ment for a minimum of 60 days from issuance prior to  
9 finalizing such regulations after considering the comments  
10 received. The regulation shall include an outline of the ap-  
11 plication and recertification process, opportunities to meet  
12 with officials of the Food and Drug Administration and  
13 plans to streamline inspections.

14 “(e) APPLICATION FOR TECHNOLOGY CERTIFI-  
15 CATION.—

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

20 “(2) CONTENT OF APPLICATION.—An applica-  
21 tion for technology certification shall contain—

22 “(A) a statement identifying the scope of  
23 the proposed technology certification, which  
24 shall be no broader than a single technology in-  
25 tended to be offered under the application;

1           “(B) information describing that the per-  
2           son seeking a technology certification order is  
3           an eligible person under subsection (b)(1);

4           “(C) information describing that the meth-  
5           ods used in, and the facilities and controls used  
6           for, the development of eligible in vitro clinical  
7           tests covered by the scope of the technology cer-  
8           tification conform to the applicable quality re-  
9           quirements of section 587J;

10          “(D) procedures for analytical validation,  
11          including all procedures for validation,  
12          verification, and acceptance criteria, and an ex-  
13          planation as to how such procedures, when  
14          used, provide a reasonable assurance of analyt-  
15          ical validity of eligible in vitro clinical tests  
16          within the proposed scope of the technology cer-  
17          tification order;

18          “(E) procedures for clinical validation, in-  
19          cluding all procedures for validation,  
20          verification, and acceptance criteria, and an ex-  
21          planation as to how such procedures, when  
22          used, provide a reasonable assurance of clinical  
23          validity of eligible in vitro clinical tests within  
24          the proposed scope of the technology certifi-  
25          cation order;

1           “(F) a submission under section 587I(b)  
2 for each in vitro clinical test that the developer  
3 intends to introduce into interstate commerce  
4 upon receiving a technology certification order;

5           “(G) 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 filing of the application  
11 under this section to serve as the rep-  
12 resentative test and validate and run with-  
13 in the developer’s stated scope;

14               “(ii) the information specified in sub-  
15 section (c) or (d) of section 587B, as appli-  
16 cable, for the representative in vitro clin-  
17 ical test or tests, including information and  
18 data required pursuant to subsection  
19 (c)(2)(H) of section 587B, unless the Sec-  
20 retary determines that such information is  
21 not necessary;

22               “(iii) an explanation of the choice of  
23 the representative in vitro clinical test or  
24 tests for the technology certification appli-  
25 cation and how such test adequately dem-



1           onstrates the range of procedures that the  
2           developer includes in the application under  
3           subparagraphs (C), (D), (E), and (F); and

4           “(iv) a brief explanation of the ways  
5           in which the procedures included in the ap-  
6           plication under subparagraphs (C), (D),  
7           (E), and (F) have been applied to the rep-  
8           resentative in vitro clinical test or tests;

9           “(H) such other information as the Sec-  
10          retary may determine necessary; and

11          “(I) a statement that the applicant believes  
12          to the best of the applicant’s knowledge that all  
13          data and information submitted to the Sec-  
14          retary are truthful and accurate and that no  
15          material fact has been omitted.

16          “(3) REFERENCE TO APPROVED PREMARKET  
17          APPLICATION UNDER SECTION 587B.—With respect  
18          to the content requirements in the technology certifi-  
19          cation application described in paragraph (2), a de-  
20          veloper may incorporate by reference any content of  
21          an application previously submitted by the developer  
22          and approved under section 587B.

23          “(f) ACTION ON AN APPLICATION FOR TECHNOLOGY  
24          CERTIFICATION.—

25          “(1) SECRETARY RESPONSE.—

1           “(A) IN GENERAL.—As promptly as prac-  
2           ticable, and no later than 90 days after receipt  
3           of an application under subsection (c), the Sec-  
4           retary shall—

5                   “(i) issue a technology certification  
6                   order granting the application, which shall  
7                   specify the scope of the technology certifi-  
8                   cation, if the Secretary finds that all of the  
9                   grounds in paragraph (3) are met; or

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

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

20           “(2) DEFICIENT APPLICATIONS.—

21                   “(A) If, after receipt of an application  
22                   under this section, the Secretary determines  
23                   that any portion of such application is deficient,  
24                   the Secretary, not later than 60 days after re-  
25                   ceipt of such application, shall provide to the

1 applicant a description of such deficiencies and  
2 identify the information required to correct  
3 such deficiencies.

4 “(B) When responding to the deficiency  
5 letter, the applicant 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 grant a technology certification  
11 order under this section if, on the basis of the infor-  
12 mation submitted to the Secretary as part of the ap-  
13 plication and any other information with respect to  
14 such applicant, the Secretary finds that—

15 “(A) in accordance with subsection  
16 (e)(2)(D), there is a showing of reasonable as-  
17 surance of analytical validity for all eligible in  
18 vitro clinical tests within the proposed scope of  
19 the technology certification, as evidenced by the  
20 procedures for analytical validation;

21 “(B) in accordance with subsection  
22 (e)(2)(E), there is a showing of reasonable as-  
23 surance of clinical validity for eligible in vitro  
24 clinical tests within the proposed scope of the  
25 technology certification, as evidenced by the

1 clinical program, including procedures for clin-  
2 ical validation;

3 “(C) the methods used in, or the facilities  
4 or controls used for, the development of eligible  
5 in vitro clinical tests covered by the proposed  
6 scope of the technology certification conform to  
7 the applicable requirements of section 587J;

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

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

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

16 “(i) meet the applicable standard for  
17 such order; and

18 “(ii) reasonably represent the range of  
19 procedures for analytical validation and  
20 clinical validation included in the applica-  
21 tion, as applicable; and

22 “(G) the applicant permits authorized em-  
23 ployees of the Food and Drug Administration  
24 or persons accredited under this Act an oppor-  
25 tunity to inspect at a reasonable time and in a

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

12 “(4) EFFECT OF TECHNOLOGY CERTIFICATION  
13 ORDER.—An in vitro clinical test or tests within the  
14 scope of a granted technology certification order are  
15 cleared to be introduced into interstate commerce.

16 “(5) REVIEW OF DENIALS.—If the Secretary  
17 denies an application for technology certification, in-  
18 cluding an application for renewal under subsection  
19 (g), the Secretary will provide a summary of defi-  
20 ciencies on which the Secretary based its denial. An  
21 applicant whose application has been denied may, by  
22 petition filed on or before the date that is 30 cal-  
23 endar days after the date upon which such applicant  
24 receives notice of such denial, obtain review thereof  
25 in accordance with section 5870.

1 “(g) DURATION; SUBSEQUENT SUBMISSIONS.—

2 “(1) ORDER DURATION.—A technology certifi-  
3 cation order shall remain in effect until the earlier  
4 of—

5 “(A) the expiration of such technology cer-  
6 tification order under paragraph (2); or

7 “(B) the withdrawal of such technology  
8 certification order under subsection (j).

9 “(2) EXPIRATION.—

10 “(A) An initial technology certification  
11 order issued under subsection (f)(3) shall expire  
12 4 years after the date that such order is issued,  
13 except that if an application for renewal under  
14 paragraph (3) has been received not later than  
15 30 days prior to the expiration of such order  
16 under this paragraph, such order shall expire  
17 on the date on which the Secretary has granted  
18 or denied the application for renewal. Any such  
19 subsequent renewal of a technology certification  
20 shall expire on such date specified by the Sec-  
21 retary that is not later than 4 years after the  
22 date that such technology certification order is  
23 issued.

24 “(B) In the event of expiration of tech-  
25 nology certification order, the clearance of tests

1 introduced into interstate commerce under such  
2 order prior to its expiration pursuant to sub-  
3 section (f)(3) remain in effect.

4 “(3) RENEWAL.—

5 “(A) IN GENERAL.—Any person previously  
6 granted a technology certification order in ef-  
7 fect may seek renewal of such order provided  
8 that—

9 “(i) such person is an eligible person  
10 under subsection (b)(1);

11 “(ii) the previously granted technology  
12 certification order—

13 “(I) is not on temporary hold  
14 under subsection (i); and

15 “(II) was not withdrawn under  
16 subsection (j); and

17 “(iii) none of the information specified  
18 in subsection (e)(2) has substantially  
19 changed, except as described in supple-  
20 ments to orders granted under paragraph  
21 (4).

22 “(B) CONTENT.—An application for re-  
23 newal under this paragraph shall include infor-  
24 mation concerning one or more representative  
25 in vitro clinical tests in accordance with sub-

1 section (e)(2)(G), except that such representa-  
2 tive test or tests shall be different from the rep-  
3 resentative test or tests relied upon as the rep-  
4 resentative assay in any prior technology certifi-  
5 cation, if applicable.

6 “(C) PROCESS.—The Secretary’s action on  
7 an application for renewal of technology certifi-  
8 cation under this paragraph shall be conducted,  
9 to the extent practicable, in coordination with  
10 inspections conducted under section 353 of the  
11 Public Health Service Act, if applicable, and  
12 any order resulting from such renewal applica-  
13 tion shall be treated as a technology certifi-  
14 cation order for purposes of this subchapter.

15 “(4) SUPPLEMENTS AND REPORTS.—

16 “(A) SUPPLEMENTS.—Except as provided  
17 in subparagraph (B), any person with a tech-  
18 nology certification order in effect may seek a  
19 supplement to such order upon a change or  
20 changes to the information provided in the ap-  
21 plication for technology certification under sub-  
22 paragraphs (C), (D), and (E) of subsection  
23 (e)(2), provided that—

24 “(i) such person is an eligible person  
25 under subsection (b)(1); and



1           “(ii) such change does not expand the  
2           scope of the technology certification, unless  
3           the Secretary determines that such expan-  
4           sion is appropriate.

5           A supplement to an order may contain only in-  
6           formation relevant to the change or changes.  
7           The Secretary’s action on a supplement shall be  
8           in accordance with subsection (f), and any  
9           order resulting from such supplement shall be  
10          treated as an amendment to a technology cer-  
11          tification order that is in effect.

12          “(B) REPORTS.—

13           “(i) IN GENERAL.—If a change is  
14           made to an in vitro clinical test or tests  
15           that is beyond the scope of a technology  
16           certification order but is made in order to  
17           address a potential risk to public health by  
18           adding a new specification or test method,  
19           the person may immediately implement  
20           such change or changes and shall report  
21           such changes or changes to the Secretary  
22           within 30 days.

23           “(ii) CONTENT.—Any report to the  
24           Secretary under this subparagraph shall  
25           include—

1                   “(I) a summary of the relevant  
2                   change or changes;

3                   “(II) the rationale for imple-  
4                   menting such change or changes;

5                   “(III) a description of how the  
6                   change or changes were evaluated;  
7                   and

8                   “(IV) data indicating analytical  
9                   and clinical validity.

10                  “(iii) SUPPLEMENTAL REPORTS.—  
11                  Upon review of such report and a finding  
12                  that the relevant change or changes are in-  
13                  consistent with the standard specified  
14                  under this subparagraph, the Secretary  
15                  may require a supplement under subpara-  
16                  graph (A).

17                  “(h) MAINTENANCE REQUIREMENTS.—For the dura-  
18                  tion of a technology certification order, a holder of a tech-  
19                  nology certification order shall—

20                         “(1) use the procedures included in the relevant  
21                         application, supplement, or report under subsections  
22                         (b) and (e);

23                         “(2) ensure compliance with any applicable  
24                         mitigating measures;

1           “(3) maintain, and provide to the Secretary  
2 upon request, records related to any in vitro clinical  
3 test offered under the technology certification order,  
4 where those records are necessary to demonstrate  
5 compliance with applicable provisions of this sub-  
6 chapter; and

7           “(4) comply with the listing requirements under  
8 section 587I for each in vitro clinical test offered  
9 under the technology certification order.

10       “(i) TEMPORARY HOLD.—

11           “(1) IN GENERAL.—Upon one or more findings  
12 under paragraph (4) and after promptly notifying  
13 the developer of such findings, the Secretary may  
14 issue a temporary hold prohibiting any holder of a  
15 technology certification order from introducing into  
16 interstate commerce an in vitro clinical test that was  
17 not previously the subject of a notification under  
18 section 587I. The temporary hold must identify the  
19 grounds for the temporary hold under paragraph (4)  
20 and the rationale for such finding, and may only re-  
21 main in place until the Secretary responds to a writ-  
22 ten request under paragraph (3).

23           “(2) NOTIFICATION TO THE DEVELOPER.—The  
24 Secretary shall not place a temporary hold under  
25 this subsection unless the Secretary has promptly

1 notified the developer of such hold and provided 30  
2 calendar days for the developer to come into compli-  
3 ance with or resolve the findings under paragraph  
4 (4).

5 “(3) WRITTEN REQUESTS.—Any written re-  
6 quest to the Secretary from the holder of a tech-  
7 nology certification order that a temporary hold  
8 under paragraph (1) be removed shall receive a deci-  
9 sion, in writing and specifying the reasons therefore,  
10 within 90 days after receipt of such request. Any  
11 such request shall include information to support the  
12 removal of the temporary hold.

13 “(4) GROUNDS FOR TEMPORARY HOLD.—A  
14 temporary hold under this subsection may be  
15 instated upon a finding or findings that the holder  
16 of a technology certification order—

17 “(A) is not in compliance with any mainte-  
18 nance requirements under subsection (h);

19 “(B) labels or advertises one or more in  
20 vitro clinical tests with false or misleading  
21 claims; or

22 “(C) is no longer an eligible person under  
23 subsection (b)(1).

24 “(j) WITHDRAWAL.—The Secretary may, after due  
25 notice and opportunity for informal hearing, issue an

1 order withdrawing a technology certification order if the  
2 Secretary finds that—

3 “(1) the application, supplement, or report  
4 under subsection (e) or (g) contains materially false  
5 or misleading information or fails to reveal a mate-  
6 rial fact;

7 “(2) such holder fails to correct materially false  
8 or misleading labeling or advertising upon the re-  
9 quest of the Secretary;

10 “(3) in connection with a technology certifi-  
11 cation, the holder provides materially false or mis-  
12 leading information to the Secretary; or

13 “(4) the holder of such technology certification  
14 order fails to correct the grounds for temporary hold  
15 within a timeframe specified in the temporary hold  
16 order.

17 “(k) REPORTS TO CONGRESS.—

18 “(1) IN GENERAL.—Not later than one year  
19 after date of enactment of the Verifying Accurate  
20 Leading-edge IVCT Development Act of 2021, and  
21 annually thereafter for the next 4 years, the Sec-  
22 retary shall submit to the Committee on Energy and  
23 Commerce of the House of Representatives and the  
24 Committee on Health, Education, Labor, and Pen-  
25 sions of the Senate, and make publicly available, in-

1 cluding through posting on the website of the Food  
2 and Drug Administration, a report containing the  
3 information described in paragraph (2).

4 “(2) CONTENT.—

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

7 “(i) the total number of applications  
8 for technology certifications filed, granted,  
9 withdrawn and denied;

10 “(ii) the total number of technology  
11 certification orders put on temporary hold  
12 under subsection (i) and the number of  
13 technology certification orders withdrawn  
14 under subsection (j);

15 “(iii) the types of technologies for  
16 which technology certification orders were  
17 granted;

18 “(iv) the total number of developers,  
19 including laboratories, with technology cer-  
20 tification orders in effect; and

21 “(v) the total number of approved  
22 tests under section 587B that were reclas-  
23 sified and granted a technology certifi-  
24 cation order under this section.

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

5           “(C) PERFORMANCE REPORTS.—The re-  
6 ports required under this section may be issued  
7 with performance reports as required under sec-  
8 tion 9 of the Verifying Accurate Leading-edge  
9 IVCT Development Act of 2021.

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

11       “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

12           “(1) ESTABLISHING, CHANGING, OR WITH-  
13 DRAWING.—

14           “(A) ESTABLISHMENT.—If the Secretary  
15 requires the establishment of mitigating meas-  
16 ures pursuant to clause (i) or (ii) of section  
17 587(15)(A) for any in vitro clinical test, the  
18 Secretary may require such mitigating meas-  
19 ures for any other in vitro clinical test with the  
20 same indications for use.

21           “(B) PROCESS.—Notwithstanding sub-  
22 chapter II of chapter 5 of title 5, United States  
23 Code, the Secretary may—

24           “(i) establish, change, or withdraw  
25 mitigating measures by—

1           “(I) publishing a proposed ad-  
2           ministrative order in the Federal Reg-  
3           ister;

4           “(II) providing an opportunity  
5           for public comment for a period of not  
6           less than 30 calendar days; and

7           “(III) after consideration of any  
8           comments submitted, publishing a  
9           final administrative order in the Fed-  
10          eral Register; and

11          “(ii) may establish mitigating meas-  
12          ures with respect to a category in a pre-  
13          market approval order or technology cer-  
14          tification order.

15          “(2) IN VITRO CLINICAL TESTS PREVIOUSLY  
16          APPROVED, CLEARED, OR EXEMPTED AS DEVICES.—

17          “(A) IN GENERAL.—Any special controls  
18          or restrictions applicable to an in vitro clinical  
19          test with the same indications for use pursuant  
20          to section 587(10) based on prior regulation as  
21          a device approved under section 515, cleared or  
22          exempt under section 510(k), or classified  
23          under section 513(f)(2), including any such spe-  
24          cial controls or restrictions established during  
25          the period beginning on the date of enactment



1 of the Verifying Accurate Leading-edge IVCT  
2 Development Act of 2021 and ending on the ef-  
3 fective date of such Act (as described in section  
4 5(b) of such Act)—

5 “(i) shall continue to apply to such  
6 approved, cleared, or exempted in vitro  
7 clinical test after such effective date; and

8 “(ii) are deemed to be mitigating  
9 measures as of the effective date of such  
10 approval, clearance, or exemption.

11 “(B) CHANGES.—The Secretary may es-  
12 tablish, change, or withdraw mitigating meas-  
13 ures for such a test or indications for use the  
14 procedures under paragraph (1).

15 “(b) DOCUMENTATION.—

16 “(1) TESTS SUBJECT TO PREMARKET RE-  
17 VIEW.—The developer of an in vitro clinical test sub-  
18 ject to premarket review under section 587B and to  
19 which mitigating measures apply shall—

20 “(A) in accordance with section  
21 587B(c)(2)(G)(i), submit documentation to the  
22 Secretary as part of the application for the test  
23 under subsection (c) or (d) of section 587B  
24 demonstrating that such mitigating measures  
25 have been met;

1           “(B) if such application is approved, main-  
2           tain documentation demonstrating that such  
3           mitigating measures continue to be met fol-  
4           lowing a test modification by the developer; and

5           “(C) after responding to any informal com-  
6           munications from the Secretary, make such  
7           documentation available to the Secretary upon  
8           request or inspection.

9           “(2) OTHER TESTS.—The developer of an in  
10          vitro clinical test that is marketed within the scope  
11          of a technology certification order or other exemp-  
12          tion from premarket review under section 587B and  
13          to which mitigating measures apply shall—

14           “(A) maintain documentation in accord-  
15           ance with the applicable quality requirements  
16           under section 587J demonstrating that such  
17           mitigating measures continue to be met fol-  
18           lowing a test modification by the developer;

19           “(B) after responding to any informal  
20           communications from the Secretary, make such  
21           documentation available to the Secretary upon  
22           request or inspection; and

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

1       “(c) MITIGATING MEASURES FOR CROSS-REF-  
2       ERENCED TESTS.—Not later than 1 year after the imple-  
3       mentation of the Verifying Accurate Leading-edge IVCT  
4       Development Act of 2021, the Secretary shall issue miti-  
5       gating measures for cross-referenced tests.

6       **“SEC. 587F. REGULATORY PATHWAY REDESIGNATION.**

7       “(a) TECHNOLOGY CERTIFICATION AND EXEMPTION  
8       DETERMINATIONS.—

9               “(1) IN GENERAL.—Based on new information,  
10       including the establishment of mitigating measures  
11       under section 587E, and after considering available  
12       evidence respecting tests with the same indications  
13       for use pursuant to section 587(10), the Secretary  
14       may, upon the initiative of the Secretary or upon pe-  
15       tition of an interested person—

16               “(A) revoke any exemption or requirement  
17       in effect under this subchapter with respect to  
18       such indications for use; or

19               “(B) determine that such indications for  
20       use are eligible for technology certification in  
21       accordance with section 587D(b)(2).

22       “(2) PROCESS.—Any action under paragraph  
23       (1) shall be made by publication of a notice of such  
24       proposed action on the website of the Food and  
25       Drug Administration, the consideration of comments

1 to a public docket on such proposal, and publication  
2 of a final action on such website within 60 calendar  
3 days of the close of the comment period posted to  
4 such public docket, notwithstanding subchapter II of  
5 chapter 5 of title 5, United States Code.

6 “(b) REVOCATION.—The Secretary may revoke any  
7 exemption with respect to such test or indications for use  
8 pursuant to section 587(10), if—

9 “(1) new clinical information indicates that the  
10 exemption of an in vitro clinical test or tests from  
11 premarket review under section 587B or exemption  
12 under section 587A has a reasonable probability of  
13 severe adverse health consequences, including the  
14 absence, delay, or discontinuation of appropriate  
15 medical treatment.

16 “(2) PROCESS.—Any action under this sub-  
17 section shall be made by publication of a notice of  
18 such proposed action in the Federal Register, con-  
19 sideration of comments to a public docket on such  
20 proposal, and publication of a final notice in the  
21 Federal Register, notwithstanding subchapter II of  
22 chapter 5 of title 5, United States Code.

23 **“SEC. 587G. ADVISORY COMMITTEES.**

24 “(a) IN GENERAL.—The Secretary may establish ad-  
25 visory committees or use advisory committee panels of ex-

1   perts established before the date of enactment of this sec-  
2   tion for the purposes of providing expert scientific advice  
3   and making recommendations related to—

4           “(1) the approval of an application for an in  
5   vitro clinical test submitted under this subchapter,  
6   including for evaluating, as applicable, the analytical  
7   validity, clinical validity, and safety of in vitro clin-  
8   ical tests;

9           “(2) the potential effectiveness of mitigating  
10   measures for a determination on the applicable regu-  
11   latory pathway under section 587F or risk evalua-  
12   tion for an in vitro clinical test or tests;

13           “(3) quality requirements under section 587J  
14   or applying such requirements to in vitro clinical  
15   tests developed or imported by developers; or

16           “(4) such other purposes as the Secretary de-  
17   termines appropriate.

18   “(b) APPOINTMENTS.—

19           “(1) VOTING MEMBERS.—The Secretary shall  
20   appoint to each committee established under sub-  
21   section (a), as voting members, individuals who are  
22   qualified by training and experience to evaluate in  
23   vitro clinical tests referred to the committee for the  
24   purposes specified in subsection (a), including indi-  
25   viduals with, to the extent feasible, scientific exper-

1       tise in the development, manufacture, or utilization  
2       of such in vitro clinical tests, laboratory operations,  
3       and the use of in vitro clinical tests. The Secretary  
4       shall designate one member of each committee to  
5       serve as chair.

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

10               “(A) a representative of consumer inter-  
11       ests; and

12               “(B) a representative of interests of in  
13       vitro clinical test developers not directly af-  
14       fected by the matter to be brought before the  
15       committee.

16               “(3) LIMITATION.—No individual who is in the  
17       regular full-time employee of the United States and  
18       engaged in the administration of this Act may be a  
19       member of any advisory committee established under  
20       subsection (a).

21               “(4) EDUCATION AND TRAINING.—The Sec-  
22       retary shall, as appropriate, provide education and  
23       training to each new committee member before such  
24       member participates in a committee’s activities, in-  
25       cluding education regarding requirements under this

1 Act and related regulations of the Secretary, and the  
2 administrative processes and procedures related to  
3 committee meetings.

4 “(5) MEETINGS.—The Secretary shall ensure  
5 that scientific advisory committees meet regularly  
6 and at appropriate intervals so that any matter to  
7 be reviewed by such a committee can be presented  
8 to the committee not more than 60 calendar days  
9 after the matter is ready for such review. Meetings  
10 of the committee may be held using electronic com-  
11 munication to convene the meetings.

12 “(6) COMPENSATION.—Members of an advisory  
13 committee established under subsection (a), while at-  
14 tending meetings or conferences or otherwise en-  
15 gaged in the business of the advisory committee—

16 “(A) shall be entitled to receive compensa-  
17 tion at rates to be fixed by the Secretary, but  
18 not to exceed the daily equivalent of the rate in  
19 effect for positions classified above level GS-15  
20 of the General Schedule; and

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

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

4 **“SEC. 587H. REQUEST FOR INFORMAL FEEDBACK.**

5 “Before submitting a premarket application or tech-  
6 nology certification application for an in vitro clinical  
7 test—

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

13 “(A) the submission process and the type  
14 and amount of evidence expected to dem-  
15 onstrate the applicable standard;

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

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

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

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



1           “(B) within 15 calendar days after such  
2           meeting or conference, provide to the developer  
3           a written record or response describing the  
4           issues discussed and conclusions reached in the  
5           meeting or conference.

6 **“SEC. 587I. REGISTRATION AND LISTING.**

7           “(a) REGISTRATION OF ESTABLISHMENTS FOR IN  
8 VITRO CLINICAL TESTS.—

9           “(1) IN GENERAL.—Each person described in  
10          subsection (b)(1), or an accredited person under sec-  
11          tion 587P, acting on behalf of such a person, shall—

12                 “(A) during the period beginning on Octo-  
13                 ber 1 and ending on December 31 of each year,  
14                 register with the Secretary the name of such  
15                 person, places of business of such person, all es-  
16                 tablishments engaged in the activities specified  
17                 under this paragraph, the establishment reg-  
18                 istration number of each such establishment,  
19                 and a point of contact for each such establish-  
20                 ment, including an electronic point of contact;  
21                 and

22                 “(B) submit an initial registration con-  
23                 taining the information required under subpara-  
24                 graph (A) not later than—

1           “(i) the date of implementation of this  
2           section if such establishment is engaged in  
3           any activity described in subsection (b)(1)  
4           on the date of enactment of this section,  
5           unless the Secretary establishes by guid-  
6           ance a date later than such implementation  
7           date for all or a category of such establish-  
8           ments; or

9           “(ii) 30 days prior to engaging in any  
10          activity described in subsection (b)(1) after  
11          enactment of this section, if such establish-  
12          ment is not engaged in any activity de-  
13          scribed in this paragraph on the date of  
14          enactment of this section.

15           “(2) REGISTRATION NUMBERS.—The Secretary  
16          may assign a registration number to any person or  
17          an establishment registration number to any estab-  
18          lishment registered in accordance with this section.  
19          Registration information shall be made publicly  
20          available by publication on the website maintained  
21          by the Food and Drug Administration, in accord-  
22          ance with subsection (d).

23           “(3) INSPECTION.—Each person or establish-  
24          ment that is required to be registered with the Sec-

1       retary under this section shall be subject to inspec-  
2       tion pursuant to section 704.

3       “(b) LISTING INFORMATION FOR IN VITRO CLINICAL  
4 TESTS.—

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

6               “(A) is a developer, a contract manufac-  
7               turer (including contract packaging), contract  
8               sterilizer, repackager, relabeler, or distributor of  
9               an in vitro clinical test; and

10               “(B) introduces or proposes to begin the  
11               introduction or delivery for introduction into  
12               interstate commerce through an exemption  
13               under section 587A(f)(2)(b) or 587A(g) or  
14               through the filing of an application under sec-  
15               tion 587B or 587D,

16       shall submit a listing to the Secretary containing the  
17       information described in paragraph (2) in accord-  
18       ance with the applicable schedule described under  
19       subsection (c). Such listing shall be prepared in such  
20       form and manner as the Secretary may specify in  
21       guidance. Listing information shall be submitted  
22       through the comprehensive test information system  
23       in accordance with section 587T, as appropriate.

24           “(2) SUBMISSIONS.—Each developer submitting  
25       a listing under paragraph (1) shall electronically

1 submit to the comprehensive test information system  
2 under section 587T the following information for  
3 each in vitro clinical test for which such person is  
4 a developer in the form and manner prescribed by  
5 the Secretary:

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

8 “(B) Contact information for the official  
9 correspondent for the listing.

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

13 “(D) CLIA certificate number for any lab-  
14 oratory certified by the Secretary under section  
15 353 of the Public Health Service Act that  
16 meets the requirements for performing high-  
17 complexity testing that is the developer of the  
18 in vitro clinical test, and CLIA certificate num-  
19 ber for any laboratory under common ownership  
20 that is performing the test developed by such  
21 test developer.

22 “(E) Whether the in vitro clinical test is,  
23 as applicable, offered as a test approved under  
24 section 587B, offered under a technology cer-  
25 tification o, or offered as an in vitro clinical test

1 under section 587Arder issued under section  
2 587D.

3 “(F) Indications for use information under  
4 section 587(10).

5 “(G) Brief narrative description of the in  
6 vitro clinical test.

7 “(H) A brief summary of the analytical  
8 and clinical performance of the in vitro clinical  
9 test, and as applicable, the lot release criteria.

10 “(I) A brief description of conformance  
11 with any applicable mitigating measures, re-  
12 strictions, and standards.

13 “(J) Representative labeling for the in  
14 vitro clinical test, as appropriate.

15 “(K) A statement that the information  
16 submitted is truthful and accurate.

17 “(3) TEST LISTING NUMBER.—The Secretary  
18 may assign a test listing number to each in vitro  
19 clinical test that is the subject of a listing under this  
20 section. The process for assigning test listing num-  
21 bers may be established through guidance, and may  
22 include the recognition of standards, formats, or  
23 conventions developed by a third-party organization.

24 “(4) ABBREVIATED LISTING.—A person who is  
25 not a developer but is otherwise required to register

1       pursuant to subsection (a) shall submit an abbrevi-  
2       viated listing to the Secretary containing the infor-  
3       mation described in subparagraphs (A) through (C)  
4       of paragraph (2), and the name of the developer.  
5       The information shall be submitted in accordance  
6       with the applicable schedule described under sub-  
7       section (c). Such abbreviated listing shall be pre-  
8       pared in such form and manner as the Secretary  
9       may specify in guidance. Listing information shall be  
10      submitted to the comprehensive test information sys-  
11      tem in accordance with section 587T, as appro-  
12      priate.

13           “(5) GRANDFATHERED TESTS.—A developer of  
14      an in vitro clinical test developer offering a test that  
15      is grandfathered under section 587A(c) shall submit  
16      listing information required under subparagraphs  
17      (A) through (K) of paragraph (2).

18           “(6) LOW-RISK TESTS.—A developer of a low  
19      risk in vitro clinical test shall notify and submit list-  
20      ing information to the Secretary within one year of  
21      offering such test for clinical use.

22           “(7) EXEMPT TESTS.—A developer of an in  
23      vitro clinical test who introduces or proposes to  
24      begin the introduction or delivery for introduction  
25      into interstate commerce pursuant to an exemption

1 under section 587A may submit listing information  
2 under this subsection.

3 “(c) TIMELINES FOR SUBMISSION.—

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

7 “(A) For an in vitro clinical test that was  
8 listed as a device under section 510(j) prior to  
9 the date of enactment of this section, a person  
10 shall maintain a device listing under section  
11 510 until such time as the system for submit-  
12 ting the notification information required under  
13 subsection (b) becomes available and thereafter  
14 shall submit the notification information no  
15 later than 1 year after the system for submit-  
16 ting the notification under this section becomes  
17 available.

18 “(B) For an in vitro clinical test that is  
19 subject to the grandfathering provisions of sec-  
20 tion 587A(c), a person shall submit the listing  
21 information required under subsection (b)(5) no  
22 later than 1 year after the system for submit-  
23 ting the notification under this section becomes  
24 available.

1           “(C) For an in vitro clinical test that is  
2 not described in subparagraph (A) or (B), a  
3 person shall submit the required notification in-  
4 formation prior to offering, introducing, or mar-  
5 keting the in vitro clinical test as follows:

6           “(i) For an in vitro clinical test that  
7 is not exempt from premarket approval  
8 under section 587B, a person shall submit  
9 the required listing information no later  
10 than 30 business days after the date of ap-  
11 proval of the premarket approval applica-  
12 tion.

13           “(ii) For a developer who has received  
14 a technology certification order under sec-  
15 tion 587D, a person shall submit the re-  
16 quired listing information at least 30 busi-  
17 ness days after receiving such technology  
18 certification order.

19           “(2) UPDATES.—

20           “(A) UPDATES AFTER CHANGES.—Each  
21 developer required to submit listing information  
22 under this section shall update such informa-  
23 tion within 10 business days of any change that  
24 causes any previously notified information to be  
25 inaccurate or incomplete.



1           “(B) ANNUAL UPDATES.—Each developer  
2           required to submit listing information under  
3           this section shall update its information annu-  
4           ally during the period beginning on October 1  
5           and ending on December 31 of each year as a  
6           component of the annual report submitted  
7           under sections 587B and 587D.

8           “(d) PUBLIC AVAILABILITY OF NOTIFICATION IN-  
9           FORMATION.—

10           “(1) IN GENERAL.—Notification information  
11           submitted pursuant to this section shall be made  
12           publicly available on the website of the Food and  
13           Drug Administration in accordance with paragraph  
14           (3).

15           “(2) CONFIDENTIALITY.—Notification informa-  
16           tion for an in vitro clinical test that is subject to  
17           premarket approval or technical certification shall  
18           remain confidential until such date as the in vitro  
19           clinical test receives the applicable premarket ap-  
20           proval or the developer receives a technology certifi-  
21           cation order.

22           “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY  
23           REQUIREMENTS.—The registration and listing infor-  
24           mation requirements described in subsections (a)

1 and (b) shall not apply to the extent the Secretary  
2 determines that such information relates to—

3 “(A) trade secret or commercial confiden-  
4 tial information; or

5 “(B) national security or countermeasures  
6 or is restricted from disclosure pursuant to an-  
7 other provision of law.

8 “(e) SUBMISSION OF INFORMATION BY ACCREDITED  
9 PERSONS.—If agreed upon by the developer, the informa-  
10 tion required under this section may be submitted by an  
11 accredited person under section 587P.

12 **“SEC. 587J. TEST DESIGN AND QUALITY REQUIREMENTS.**

13 “(a) APPLICABILITY.—

14 “(1) IN GENERAL.—Each developer and each  
15 other person required to register under section  
16 587I(b)(1) shall establish and maintain quality re-  
17 quirements in accordance with the applicable re-  
18 quirements set forth in subsection (b), except as pro-  
19 vided in section 587A.

20 “(2) CERTIFIED LABORATORY REQUIRE-  
21 MENTS.—A developer that operates a clinical labora-  
22 tory certified by the Secretary under section 353 of  
23 the Public Health Service Act that—

24 “(A) meets the requirements for per-  
25 forming high-complexity testing;

1           “(B)(i) develops an vitro clinical test or in-  
2           dications for use; or

3           “(ii) modifies another developer’s in vitro  
4           clinical test in that certified laboratory in a  
5           manner described in section 587(6)(C); and

6           “(C) develops an in vitro clinical test or in-  
7           dications for use that are for use only within  
8           that certified laboratory or within another cer-  
9           tified laboratory with common ownership,  
10          shall establish and maintain quality requirements  
11          that comply with the requirements set forth in sub-  
12          section (b)(2).

13           “(3) APPLICABILITY FOR CERTAIN IN VITRO  
14          CLINICAL TESTS.—The applicable requirements set  
15          forth in subsection (b)(1) shall apply to any instru-  
16          ment, specimen receptacle, or component or part  
17          that is developed for use by a clinical laboratory to  
18          which paragraph (2) applies.

19           “(4) REGULATIONS.—In promulgating regula-  
20          tions under this section, the Secretary shall consider  
21          whether and to what extent international harmoni-  
22          zation is appropriate.

23          “(b) QUALITY REQUIREMENTS.—

24           “(1) QUALITY REQUIREMENTS FOR LABORA-  
25          TORIES WITHOUT CLIA CERTIFICATION TO CONDUCT

1 HIGH-COMPLEXITY TESTS.—The quality require-  
2 ments applicable under this section shall—

3 “(A) avoid duplication of regulations under  
4 section 353 of the Public Health Service Act;

5 “(B) apply only to the development, valida-  
6 tion, production, preparation, propagation, or  
7 assembly related to the design and associated  
8 manufacture and distribution of an in vitro clin-  
9 ical test offered under this subchapter;

10 “(C) not apply with respect to laboratory  
11 operations; and

12 “(D) shall include the following, subject to  
13 paragraphs (2) and (3)—

14 “(i) management responsibility;

15 “(ii) quality audits;

16 “(iii) personnel;

17 “(iv) design controls;

18 “(v) document controls;

19 “(vi) purchasing controls;

20 “(vii) identification and traceability;

21 “(viii) production and process con-  
22 trols;

23 “(ix) acceptance activities;

24 “(x) nonconforming product;

25 “(xi) corrective and preventive action;

- 1 “(xii) labeling and packaging controls;  
2 “(xiii) handling, storage, distribution,  
3 and installation;  
4 “(xiv) records;  
5 “(xv) servicing; and  
6 “(xvi) statistical techniques.

7 “(2) QUALITY REQUIREMENTS FOR LABORA-  
8 TORIES CERTIFIED TO CONDUCT HIGH-COMPLEXITY  
9 TESTS.—Quality requirements applicable to the in  
10 vitro clinical tests and developers described in sub-  
11 section (a)(2) shall—

12 “(A) avoid duplication of regulations under  
13 section 353 of the Public Health Service Act;  
14 and

15 “(B) consist of, as directed related to the  
16 design and development—

- 17 “(i) design controls;  
18 “(ii) purchasing controls;  
19 “(iii) acceptance activities;  
20 “(iv) corrective and preventative ac-  
21 tion; and  
22 “(v) records.

23 “(3) QUALITY REQUIREMENTS FOR CERTAIN  
24 LABORATORIES DISTRIBUTING IN VITRO CLINICAL

1 TESTS OR TEST PROTOCOLS WITHIN ORGANIZATIONS  
2 OR PUBLIC HEALTH NETWORKS.—

3 “(A) IN GENERAL.—Quality requirements  
4 applicable to the developer who is distributing  
5 in vitro clinical test distributed as described in  
6 subparagraph (B) shall consist of the following:

7 “(i) The requirements in paragraph  
8 (2).

9 “(ii) The labeling requirements in  
10 paragraph (1)(C)(xii).

11 “(iii) The requirement to maintain  
12 records of the laboratories to which the in  
13 vitro clinical test or test protocol is distrib-  
14 uted.

15 “(B) DISTRIBUTING LABORATORY.—Sub-  
16 paragraph (A) shall apply to developers that  
17 meet the following conditions:

18 “(i) The laboratory distributing the  
19 test protocol is certified by the Secretary  
20 under section 353 of the Public Health  
21 Service Act and meets the requirements for  
22 performing high-complexity testing.

23 “(ii) The laboratory develops its own  
24 in vitro clinical test or modifies another de-

1            developer’s in vitro clinical test in a manner  
2            described in section 587(6)(C).

3            “(iii) The laboratory distributes the in  
4            vitro clinical test or test protocol for such  
5            test only to another laboratory that—

6                            “(I) is certified by the Secretary  
7                            under section 353 of the Public  
8                            Health Service Act and meets the re-  
9                            quirements for performing high-com-  
10                            plexity testing;

11                            “(II) is within the same cor-  
12                            porate organization and having com-  
13                            mon ownership by the same parent  
14                            corporation; or as applicable, is a lab-  
15                            oratory within a public health labora-  
16                            tory network coordinated or managed  
17                            by the Centers for Disease Control  
18                            and Prevention; and

19                            “(III) implements the test pro-  
20                            tocol without further modification.

21            “(c) REGULATIONS.—In implementing quality re-  
22            quirements for test developers under this section, the Sec-  
23            retary shall—

24                            “(1) for purposes of facilitating international  
25            harmonization, consider whether the developer par-

1        participates in an audit program in which the United  
2        States participates or the United States recognizes  
3        or conforms with standards recognized by the Sec-  
4        retary; and

5            “(2) ensure a least burdensome approach de-  
6        scribed in section 587B(j) by leveraging, to the ex-  
7        tent applicable, the quality assurance requirements  
8        applicable to developers certified by the Secretary  
9        under section 353 of the Public Health Service Act.

10    **“SEC. 587K. LABELING REQUIREMENTS.**

11        “(a) IN GENERAL.—An in vitro clinical test shall  
12        bear or be accompanied by labeling, and a label as applica-  
13        ble, that meet the requirements set forth in subsections  
14        (b) and (c), unless such test is exempt as specified in sub-  
15        section (d) or (e).

16        “(b) LABELS.—

17            “(1) IN GENERAL.—The label of an in vitro  
18        clinical test shall meet the requirements set forth in  
19        paragraph (2), except this requirement shall not  
20        apply to an in vitro clinical test that—

21            “(A) consists solely of a test protocol; or

22            “(B) is developed, manufactured, and used  
23        solely within a single laboratory certified by the  
24        Secretary under section 353 of the Public



1 Health Service Act that meets the requirements  
2 for performing high-complexity testing.

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

7 “(c) LABELING.—

8 “(1) IN GENERAL.—Labeling accompanying an  
9 in vitro clinical test, including labeling in the form  
10 of a package insert, standalone laboratory reference  
11 document, or other similar document except the la-  
12 beling specified in paragraph (2), shall include ade-  
13 quate directions for use and shall meet the require-  
14 ments set forth in regulations promulgated under  
15 this section, except as provided in subsection (d) or  
16 (e).

17 “(2) CONTENT.—

18 “(A) IN GENERAL.—Labeling accom-  
19 panying an in vitro clinical test that is in the  
20 form of a test report template or ordering infor-  
21 mation shall include—

22 “(i) the test listing number that was  
23 provided to the developer at the time of  
24 listing;

1           “(ii) instructions for how and where  
2           to report an adverse event under section  
3           587L;

4           “(iii) instructions for how and where  
5           to access the performance summary data  
6           displayed in the listing database for the  
7           test;

8           “(iv) the intended use of the in vitro  
9           clinical test; and

10          “(v) any warnings, contraindications,  
11          or limitations.

12          “(B) PUBLIC AVAILABILITY OF INFORMA-  
13          TION.—The Secretary shall make all of the in-  
14          formation described in subparagraph (A) with  
15          respect to each in vitro clinical test available to  
16          the public, as applicable, in accordance with  
17          section 587T, except to the extent that the Sec-  
18          retary determines that such information is—

19               “(i) trade secret or commercial con-  
20               fidential information; or

21               “(ii) national security or counter-  
22               measures or is restricted from disclosure  
23               pursuant to another provision of law.

24          “(3) ADDITIONAL REQUIREMENTS.—Labeling  
25          for an in vitro clinical test used for

1 immunohematology testing shall meet the applicable  
2 requirements set forth in part 660 of title 21, Code  
3 of Federal Regulations (or any successor regula-  
4 tions), related to the labeling of blood grouping re-  
5 agents, reagent red blood cells, and anti-human  
6 globulin.

7 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-  
8 MENTS.—

9 “(1) IN GENERAL.—

10 “(A) IN GENERAL.—With respect to an in  
11 vitro clinical test that meets the criteria of sub-  
12 paragraph (B), the ‘state in one place’ regula-  
13 tions under section 809.10(b) of title 21 of the  
14 Code of Federal Regulations (or any successor  
15 regulations) may be satisfied by the laboratory  
16 posting such information on its website or in  
17 multiple documents, if such documents are  
18 maintained and accessible in one place.

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

22 “(i) designed and manufactured by a  
23 laboratory certified by the Secretary under  
24 section 353 of the Public Health Service

1 Act that meets the requirements for per-  
2 forming high-complexity testing; and

3 “(ii) performed in the same laboratory  
4 in which it was developed or by another  
5 such laboratory certified by the Secretary  
6 under section 353 of the Public Health  
7 Service Act that meets the requirements  
8 for performing high complexity testing and  
9 is under common ownership with the lab-  
10 oratory that designed and manufactured  
11 the test.

12 “(2) TEST INSTRUMENT LABELING.—The label-  
13 ing for an instrument is not required to bear the in-  
14 formation indicated in paragraphs (3), (4), (5), (7),  
15 (8), (9), (10), (11), (12), and (13) of section  
16 809.10(b) of title 21 of the Code of Federal Regula-  
17 tions (or any successor regulations).

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

24 “(4) LAB RESEARCH OR INVESTIGATIONAL  
25 USE.—A shipment or other delivery of an in vitro

1 clinical test for research or investigational use pur-  
2 suant to section 587A(m) shall be exempt from the  
3 labeling requirements of subsections (b) and (c)(1)  
4 and from any standard promulgated through regula-  
5 tions, except as required under section 353 of the  
6 Public Health Service Act or section 587R of this  
7 Act.

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

14 “(6) ANALYTE SPECIFIC REAGENTS.—The la-  
15 beling for analyte specific reagents shall bear the fol-  
16 lowing statement: ‘This product is intended solely  
17 for further development of an in vitro clinical test  
18 and is exempt from most FDA regulation. This  
19 product must be evaluated by the in vitro clinical  
20 test developer in accordance with applicable require-  
21 ments.’. If the labeling of an analyte specific reagent  
22 bears the statement set forth in this paragraph, it  
23 need not bear the information required by subsection  
24 (c)(1).

1           “(7) OVER-THE-COUNTER TEST SAMPLE COL-  
2           LECTION SYSTEMS LABELING.—The labeling for  
3           over-the-counter test sample collection systems for  
4           drugs of abuse testing shall bear the name and place  
5           of business of the developer included in the registra-  
6           tion listing under section 587I, in language appro-  
7           priate for the intended users.

8           “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-  
9           PILE.—

10           “(1) IN GENERAL.—The Secretary may grant  
11           an exception or alternative to any provision listed in  
12           this section, unless explicitly required by a statutory  
13           provision outside this subchapter, for specified lots,  
14           batches, or other units of an in vitro clinical test, if  
15           the Secretary determines that compliance with such  
16           labeling requirement could adversely affect the safe-  
17           ty, effectiveness, or availability of such products that  
18           are or will be included in the Strategic National  
19           Stockpile under section 319F–2 of the Public Health  
20           Service Act.

21           “(2) REGULATIONS.—The Secretary may issue  
22           regulations amending section 809.11 of title 21 of  
23           the Code of Federal Regulations or any successor  
24           regulation to apply in full or in part to in vitro clin-  
25           ical tests and in vitro clinical test developers.

1       “(f) GUIDANCE.—The Secretary may, in collabora-  
2 tion with developers, issue guidance on standardized, gen-  
3 eral content and format for in vitro clinical test labeling  
4 to help ensure compliance with applicable requirements in  
5 this subsection.

6       **“SEC. 587L. ADVERSE EVENT REPORTING.**

7       “(a) APPLICABILITY.—

8               “(1) IN GENERAL.—Each in vitro clinical test  
9 developer shall establish and maintain a system for  
10 reporting adverse events in accordance with sub-  
11 section (b), except as provided in section 587A.

12               “(2) REGULATIONS.—The Secretary shall pro-  
13 mulgate regulations to implement this section, in-  
14 cluding information necessary to be reported to en-  
15 sure the analytical and clinical validity of in vitro  
16 clinical tests, and the safety of articles for taking or  
17 deriving specimens from the human body.

18       “(b) ADVERSE EVENT REPORTING REQUIRE-  
19 MENTS.—Each developer shall report to the Secretary  
20 whenever information that reasonably suggests that one  
21 of the developer’s in vitro clinical tests is associated with  
22 an adverse event becomes known to the developer.

23       “(c) REPORTS.—Reports required under this section  
24 shall be submitted as follows:

1           “(1) An individual adverse event report shall be  
2 submitted for the following events not later than—

3           “(A) 5 calendar days after an in vitro clin-  
4 ical test developer receives or otherwise becomes  
5 aware of information that reasonably suggests  
6 the adverse event involves a patient death; or

7           “(B) 5 calendar days after an in vitro clin-  
8 ical test developer receives or otherwise becomes  
9 aware of information that reasonably suggests  
10 the event presents an imminent threat to public  
11 health.

12           “(2) Quarterly reports shall be submitted for all  
13 other adverse events, if any, and no later than the  
14 end of the quarter following the quarter in which the  
15 adverse event information was received by the in  
16 vitro clinical test developer.

17           “(d) DEFINITIONS.—In this section—

18           “(1) the term ‘adverse event’—

19           “(A) means—

20           “(i) death of, or serious injury to, a  
21 specific patient or user for which it is rea-  
22 sonably believed that an in vitro clinical  
23 test error contributed to such death or se-  
24 rious injury; or



1           “(ii) an in vitro clinical test error that  
2           may have reasonable likelihood to cause se-  
3           rious injury or death; and

4           “(B) excludes laboratory errors that are  
5           subject to the requirements of section 353 of  
6           the Public Health Service Act and corrective or  
7           preventive actions to prevent such errors;

8           “(2) the term ‘in vitro clinical test error’—

9           “(A) means a failure in an in vitro clinical  
10          test to meet the analytical or clinical validity  
11          standard or otherwise perform as intended by  
12          the developer; and

13          “(B) includes an inaccurate false result  
14          that reaches a health care provider, patient, or  
15          consumer, except that such term excludes any  
16          such event or error related to laboratory oper-  
17          ations pursuant to section 353 of the Public  
18          Health Service Act; and

19          “(3) the term ‘serious injury’ means—

20          “(A) a significant delay in a critical diag-  
21          nosis or causing the absence, delay, or dis-  
22          continuation of critical medical treatment or  
23          that irreversibly or seriously and negatively al-  
24          ters the course of the disease or condition; or

25          “(B) an injury that—

1 “(i) is life threatening;

2 “(ii) results in permanent impairment  
3 of a body function or permanent damage  
4 to a body structure; or

5 “(iii) necessitates medical or surgical  
6 intervention to preclude permanent impair-  
7 ment of a body function or permanent  
8 damage to a body structure.

9 **“SEC. 587M. CORRECTIONS AND REMOVALS.**

10 “(a) IN GENERAL.—The Secretary shall promulgate  
11 regulations to implement this section, including informa-  
12 tion necessary to be reported to ensure the analytical and  
13 clinical validity of in vitro clinical tests, and the safety of  
14 specimen receptacles.

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

16 “(1) IN GENERAL.—Each in vitro clinical test  
17 developer or importer shall report to the Secretary  
18 any correction or removal of an in vitro clinical test  
19 undertaken by such developer or importer if the re-  
20 moval or correction was undertaken—

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

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

1           “(2) EXCEPTION.—No report of the correction  
2           or removal of an in vitro clinical test is required  
3           under paragraph (1) if a report of the correction or  
4           removal is required under, and has been submitted  
5           under, section 587L.

6           “(c) TIMING.—A developer or importer shall submit  
7           any report required under this subsection to the Secretary  
8           within 15 business days of initiating such correction or  
9           removal.

10          “(d) RECORDKEEPING.—A developer or importer of  
11          an in vitro clinical test who undertakes a correction or re-  
12          moval of an in vitro clinical test which is not required to  
13          be reported under this subsection shall keep a record of  
14          such correction or removal.

15          “(e) RECALL COMMUNICATIONS.—Upon the vol-  
16          untary reporting of a correction or removal by the devel-  
17          oper—

18                 “(1) the Secretary shall classify such correction  
19                 or removal under this section within 15 calendar  
20                 days; and

21                 “(2) not later than 45 calendar days after the  
22                 developer or other responsible party notifies the Sec-  
23                 retary that it has completed a recall action, the Sec-  
24                 retary shall provide the developer or other respon-  
25                 sible party with a written statement closing the re-

1 call action or stating the reasons the Secretary can-  
2 not close the recall at that time.

3 “(f) LIMITATION.—The developer is not required to  
4 report a correction or removal of an in vitro clinical test  
5 based solely on an adverse event report under section  
6 587L that captures an error within the approved perform-  
7 ance standards for such test.

8 “(g) DEFINITIONS.—For purposes of this section—

9 “(1) the term ‘correction’ means the repair,  
10 modification, adjustment, relabeling, destruction, or  
11 inspection (including patient monitoring) of an in  
12 vitro clinical test without its physical removal from  
13 its point of use to another location, and does not in-  
14 clude routine servicing; and

15 “(2) the term ‘removal’ means the physical re-  
16 moval of an in vitro clinical test from its point of use  
17 to another location for repair, modification, adjust-  
18 ment, relabeling, destruction, or inspection, and does  
19 not include routine servicing.

20 **“SEC. 587N. RESTRICTED IN VITRO CLINICAL TESTS.**

21 “(a) APPLICABILITY.—

22 “(1) IN GENERAL.—The Secretary, in issuing  
23 an approval of an in vitro clinical test under section  
24 587B of a category described in paragraph (3) may  
25 require that such test be restricted to sale, distribu-

1       tion, or use upon such conditions as the Secretary  
2       may prescribe under paragraph (2).

3               “(2) CONDITIONS PRESCRIBED BY THE SEC-  
4       RETARY.—The conditions prescribed by the Sec-  
5       retary under this paragraph, with respect to an in  
6       vitro clinical test described in paragraph (3), are  
7       those conditions which the Secretary determines due  
8       to the potentiality for harmful effect of such test (in-  
9       cluding any resulting absence, delay, or discontinu-  
10      ation of appropriate medical treatment), are nec-  
11      essary to assure the analytical or clinical validity of  
12      the test, or the safety of a specimen receptacle.

13              “(3) IN VITRO CLINICAL TESTS SUBJECT TO  
14      RESTRICTIONS.—The restrictions authorized under  
15      this section may be applied by the Secretary to any  
16      high-risk in vitro clinical test, prescription home-use  
17      in vitro clinical test, direct-to-consumer in vitro clin-  
18      ical test, or over-the-counter in vitro clinical test.

19              “(b) LABELING AND ADVERTISING OF A RESTRICTED  
20      IN VITRO CLINICAL TEST.—The label, labeling, and ad-  
21      vertising of an in vitro clinical test to which restrictions  
22      apply under subsection (a) shall bear such appropriate  
23      statements of the restrictions as the Secretary may pre-  
24      scribe in the approval, provisional approval, technology  
25      certification, or regulation, as applicable.

1       “(c) REQUIREMENTS PRIOR TO ENACTMENT.—An in  
2 vitro clinical test that was offered, sold, or distributed as  
3 a restricted device prior to the enactment date of this sub-  
4 chapter shall continue to comply with the applicable re-  
5 strictions under section 515 or section 520(e) until the  
6 effective date of restrictions issued under subsection (a).

7       **“SEC. 5870. APPEALS.**

8       “(a) SIGNIFICANT DECISION.—

9               “(1) IN GENERAL.—The Secretary shall provide  
10 a substantive summary of the scientific and regu-  
11 latory rationale for any significant decision of the  
12 Center for Devices and Radiological Health regard-  
13 ing submission of an application for, or a review of,  
14 an in vitro clinical test under section 587B or sec-  
15 tion 587D or regarding an exemption under section  
16 587A, including documentation of significant con-  
17 troversies or differences of opinion and the resolu-  
18 tion of such controversies or differences of opinion.

19               “(2) PROVISION OF DOCUMENTATION.—Upon  
20 request, the Secretary shall furnish a substantive  
21 summary described in paragraph (1) to the person  
22 who has made, or is seeking to make, a submission  
23 described in such paragraph.

24               “(3) APPLICATION OF LEAST BURDENSOME RE-  
25 QUIREMENTS.—The substantive summary required

1 under this subsection shall include a brief statement  
2 regarding how the least burdensome requirements  
3 were considered and applied consistent with section  
4 587B(j), as applicable.

5 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

6 “(1) REQUEST FOR SUPERVISORY REVIEW OF  
7 SIGNIFICANT DECISION.—Any person may request a  
8 supervisory review of the significant decision de-  
9 scribed in subsection (a)(1). Such review may be  
10 conducted at the next supervisory level or higher  
11 above the agency official who made the significant  
12 decision.

13 “(2) SUBMISSION OF REQUEST.—A person re-  
14 questing a supervisory review under paragraph (1)  
15 shall submit such request to the Secretary not later  
16 than 30 days after the decision for which the review  
17 is requested and shall indicate in the request wheth-  
18 er such person seeks an in-person meeting or a tele-  
19 conference review.

20 “(3) TIMEFRAME.—The Secretary shall sched-  
21 ule an in-person or teleconference review, if so re-  
22 quested, not later than 30 days after such request  
23 is made. The Secretary shall issue a decision to the  
24 person requesting a review under this subsection not  
25 later than 45 days after the request is made under

1 paragraph (1), or, in the case of a person who re-  
2 quests an in-person meeting or teleconference, 30  
3 days after such meeting or teleconference.

4 “(c) ADVISORY PANELS.—The process established  
5 under subsection (a) shall permit the appellant to request  
6 review by an advisory committee established under section  
7 513 or 587G. The Secretary shall provide a response to  
8 an appellant under this subsection not later than 45 days  
9 after the requested advisory committee is convened.

10 **“SEC. 587P. ACCREDITED PERSONS.**

11 “(a) IN GENERAL.—

12 “(1) REVIEW OF APPLICATIONS.—

13 “(A) ACCREDITATION FOR APPLICATION  
14 REVIEW.—Subject to subparagraph (C), during  
15 the period beginning on the date of enactment  
16 of the Verifying Accurate Leading-edge IVCT  
17 Development Act of 2021 and ending 2 years  
18 after the date of enactment of such Act, the  
19 Secretary shall accredit persons for any of the  
20 following purposes:

21 “(i) Reviewing applications for pre-  
22 market approval under section 587B and  
23 applications for technology certification  
24 under section 587D.



1           “(ii) Making recommendations to the  
2           Secretary with respect to an approval of an  
3           application under section 587B or issuance  
4           of a technology certification order under  
5           section 587D.

6           “(B) REQUIREMENT REGARDING REVIEW  
7           RECOMMENDATIONS.—

8           “(i) IN GENERAL.—In making a rec-  
9           ommendation to the Secretary under this  
10          section, an accredited person shall notify  
11          the Secretary in writing of the reasons for  
12          the recommendation concerning the appli-  
13          cation.

14          “(ii) TIME PERIOD FOR REVIEW.—  
15          Not later than 30 calendar days after the  
16          date on which the Secretary is notified of  
17          a recommendation under this section with  
18          respect to an application for premarket ap-  
19          proval or technology certification, the Sec-  
20          retary shall make a determination with re-  
21          spect to the application.

22          “(C) LACK OF APPLICATIONS WITHIN 2-  
23          YEAR TIMEFRAME.—If the Secretary does not  
24          receive applications from persons that meet the

1 criteria under subsection (c) within such period,  
2 the Secretary—

3 “(i) may accredit persons under this  
4 paragraph after the 2-year period de-  
5 scribed in subparagraph (A); and

6 “(ii) shall issue a public notice on the  
7 website of the Food and Drug Administra-  
8 tion calling for applications for such ac-  
9 creditation.

10 “(2) INSPECTIONS.—

11 “(A) ACCREDITATION FOR INSPECTIONS.—

12 Subject to subparagraph (B), during the period  
13 beginning on the date of enactment of the  
14 Verifying Accurate Leading-edge IVCT Devel-  
15 opment Act of 2021 and ending 2 years after  
16 the date of enactment of such Act, the Sec-  
17 retary shall accredit persons for the purpose of  
18 conducting inspections of in vitro clinical test  
19 developers and other persons required to reg-  
20 ister pursuant to section 587I.

21 “(B) LACK OF APPLICATIONS WITHIN 2-  
22 YEAR TIMEFRAME.—If no persons who meet the  
23 criteria for such accreditation apply during the  
24 2-year period described in subparagraph (A),  
25 the Secretary—

1           “(i) may accredit persons under this  
2           subparagraph after such period; and

3           “(ii) shall issue a public notice on the  
4           website of the Food and Drug Administra-  
5           tion calling for applications for such ac-  
6           creditation.

7           “(C) EFFECT OF ACCREDITATION.—

8           “(i) IN GENERAL.—Persons accredited  
9           under subparagraph (A) to conduct inspec-  
10          tions, when conducting such inspections,  
11          shall record in writing their specific obser-  
12          vations and shall present their observations  
13          to the designated representative of the in-  
14          spected establishment.

15          “(ii) INSPECTION REPORT REQUIRE-  
16          MENTS.—Each person accredited under  
17          this paragraph shall prepare and submit to  
18          the Secretary an inspection report in a  
19          form and manner designated by the Sec-  
20          retary for conducting inspections, taking  
21          into consideration the goals of inter-  
22          national harmonization of quality systems  
23          standards. Any official classification of the  
24          inspection shall be determined by the Sec-  
25          retary. Any statement or representation

1           made by an employee or agent of an estab-  
2           lishment to a person accredited to conduct  
3           inspections shall be subject to section 1001  
4           of title 18, United States Code.

5           “(D) SAVINGS CLAUSE.—Nothing in this  
6           section affects the authority of the Secretary to  
7           inspect any in vitro clinical test developer or  
8           other person registered under section 587I.

9           “(E) INSPECTION LIMITATIONS.—The Sec-  
10          retary shall ensure that inspections carried out  
11          under this section are not duplicative of inspec-  
12          tions carried out under section 353 of the Pub-  
13          lic Health Service Act. Inspections under this  
14          section shall be limited to the data and informa-  
15          tion necessary—

16                 “(i) for routine surveillance activities  
17                 associated with applications under sections  
18                 587B and 587D; or

19                 “(ii) to meet the requirements to re-  
20                 ceive premarket approval under section  
21                 587B or a technology certification order  
22                 under section 587D, as applicable.

23          “(b) ACCREDITATION.—

24                 “(1) ACCREDITATION PROGRAM.—

1           “(A) IN GENERAL.—The Secretary may  
2 provide for accreditation under this section  
3 through programs administered by the Food  
4 and Drug Administration, by other non-Federal  
5 government agencies, or by qualified nongovern-  
6 mental organizations. A person may be accred-  
7 ited for the review of both applications sub-  
8 mitted under sections 587B and 587D as de-  
9 scribed in subsection (a)(1)(A) and to conduct  
10 inspection activities under subsection (a)(2)(A),  
11 or for a subset of such review or activities.

12           “(B) ELIGIBLE PERSONS.—Not later than  
13 180 days after the date of enactment of the  
14 Verifying Accurate Leading-edge IVCT Devel-  
15 opment Act of 2021, the Secretary shall issue  
16 draft guidance on the criteria that the Sec-  
17 retary will use to accredit or deny accreditation  
18 to a person who requests such accreditation  
19 under subsection (a), and not later than one  
20 year after the close of the comment period for  
21 the draft guidance issued in this section, issue  
22 final guidance.

23           “(C) REQUIREMENTS.—

24           “(i) IN GENERAL.—The Secretary  
25 shall not accredit or maintain accreditation

1 for a person unless such person meets the  
2 minimum qualifications required under  
3 subsection (c).

4 “(ii) SCOPE OF ACCREDITATION.—

5 The accreditation of a person under this  
6 section shall specify the particular activi-  
7 ties under subsection (a) for which such  
8 person is accredited.

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 “(2) ACCREDITATION PROCESS.—

17 “(A) ACCREDITATION PROCESS GUID-

18 ANCE.—The Secretary shall—

19 “(i) not later than 180 days after the  
20 date of enactment of the Verifying Accu-  
21 rate Leading-edge IVCT Development Act  
22 of 2021, issue draft guidance specifying  
23 the process for submitting a request for  
24 each type of accreditation and reaccredita-  
25 tion under this section, including the form

1           and content of information to be submitted  
2           in such a request; and

3           “(ii) not later than 1 year after the  
4           close of the comment period for the draft  
5           guidance, issue final guidance.

6           “(B) RESPONSE TO REQUEST.—The Sec-  
7           retary shall respond to a request for accredita-  
8           tion or reaccreditation within 60 calendar days  
9           of the receipt of the request. The Secretary’s  
10          response may be to accredit or reaccredit the  
11          person, to deny accreditation, or to request ad-  
12          ditional information in support of the request.  
13          If the Secretary requests additional informa-  
14          tion, the Secretary shall respond within 60 cal-  
15          endar days of receipt of such additional infor-  
16          mation to accredit or deny the accreditation.

17          “(C) TYPE OF ACCREDITATION.—The ac-  
18          creditation or reaccreditation of a person shall  
19          specify the particular activity or activities under  
20          subsection (a) for which such person is accred-  
21          ited, and shall include any limitation to certain  
22          eligible in vitro clinical tests.

23          “(D) AUDIT.—The Secretary may audit  
24          the performance of persons accredited under  
25          this section for purposes of ensuring that such

1 persons continue to meet the published criteria  
2 for accreditation, and may modify the scope or  
3 particular activities for which a person is ac-  
4 credited if the Secretary determines that such  
5 person fails to meet one or more criteria for ac-  
6 creditation.

7 “(E) SUSPENSION OR WITHDRAWAL.—The  
8 Secretary may suspend or withdraw accredita-  
9 tion of any person accredited under this section,  
10 after providing notice and an opportunity for an  
11 informal hearing, when such person is substan-  
12 tially not in compliance with the requirements  
13 of this section or the published criteria for ac-  
14 creditation, or poses a threat to public health,  
15 or fails to act in a manner that is consistent  
16 with the purposes of this section.

17 “(F) REACCREDITATION.—Accredited per-  
18 sons may be initially accredited for up to 4  
19 years. After expiration of such initial period,  
20 persons may be recredited for unlimited addi-  
21 tional 4-year periods, as determined by the Sec-  
22 retary.

23 “(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

24 “(1) ELIGIBILITY.—An accredited person, at a  
25 minimum, shall—



1           “(A) not be an employee of the Federal  
2 Government;

3           “(B) not engage in the activities of a de-  
4 veloper, as defined in section 587(7);

5           “(C) not be a person required to register  
6 under section 587I, unless such person has es-  
7 tablished sufficient processes and protocols to  
8 separate activities to develop in vitro clinical  
9 tests and the activities for which such person  
10 would be accredited under subsection (a) and  
11 discloses applicable information under this sec-  
12 tion;

13           “(D) not be owned or controlled by, and  
14 shall have no organizational, material or finan-  
15 cial affiliation with, an in vitro clinical test de-  
16 veloper or other person required to register  
17 under section 587I;

18           “(E) be a legally constituted entity per-  
19 mitted to conduct the activities for which it  
20 seeks accreditation;

21           “(F) ensure that the operations of such  
22 person are in accordance with generally accept-  
23 ed professional and ethical business practices;  
24 and

1           “(G) include in its request for accredita-  
2           tion a commitment to, at the time of accredita-  
3           tion and at any time it is performing activities  
4           pursuant to this section—

5                   “(i) certify that the information re-  
6                   ported to the Secretary accurately reflects  
7                   the data or protocol reviewed, and the doc-  
8                   umented inspection findings, as applicable;

9                   “(ii) limit work to that for which com-  
10                  petence and capacity are available;

11                  “(iii) treat information received or  
12                  learned, records, reports, and recommenda-  
13                  tions as proprietary information of the per-  
14                  son submitting such information; and

15                  “(iv) in conducting the activities for  
16                  which the person is accredited in respect to  
17                  a particular in vitro clinical test, protect  
18                  against the use of any employee or consult-  
19                  ant who has a financial conflict of interest  
20                  regarding that in vitro clinical test.

21           “(2) WAIVER.—The Secretary may waive any  
22           requirements in subparagraph (A), (B), (C), or (D)  
23           of paragraph (1) upon making a determination that  
24           such person has implemented other appropriate con-

1 trols sufficient to ensure a competent and impartial  
2 review.

3 “(d) COMPENSATION OF ACCREDITED PERSONS.—

4 “(1) IN GENERAL.—Compensation of an ac-  
5 credited person who reviews an application for pre-  
6 market approval submitted under section 587B or  
7 an application for technical certification submitted  
8 under section 587D shall be determined by agree-  
9 ment between the accredited person and the person  
10 who engages the services of the accredited person,  
11 and shall be paid by the person who engages such  
12 services.

13 “(2) INSPECTION ACCREDITATION.—Compensa-  
14 tion of an accredited person who is conducting an  
15 inspection under section 704 shall be determined by  
16 agreement between the accredited person and the  
17 person who engages the services of the accredited  
18 person, and shall be paid by the person who engages  
19 such services.

20 “(e) COOPERATIVE AGREEMENTS.—The Secretary is  
21 authorized to enter into cooperative arrangements with of-  
22 ficials of foreign countries to ensure that adequate and  
23 effective means are available for purposes of determining,  
24 from time to time, whether in vitro clinical tests intended  
25 for use in the United States by a person whose facility

1 is located outside the United States shall be refused ad-  
2 mission on any of the grounds set forth in section 801(a).

3 “(f) INFORMATION SHARING AGREEMENTS.—An ac-  
4 credited person may enter into an agreement with a test  
5 developer to provide information to the comprehensive test  
6 information system under section 587T, including any re-  
7 quirements under section 587I.

8 **“SEC. 587Q. RECOGNIZED STANDARDS.**

9 “(a) IN GENERAL.—The Secretary may by order es-  
10 tablish performance standards for an in vitro clinical test  
11 or tests with the same indication for use to provide reason-  
12 able assurance of the analytical validity, clinical validity,  
13 or as applicable safety, of that in vitro clinical test or tests  
14 with the same indications for use.

15 “(b) OTHER STANDARDS.—The Secretary may recog-  
16 nize all or part of appropriate standards established by  
17 nationally or internationally recognized standard develop-  
18 ment organizations for which a person may submit a dec-  
19 laration of conformity in order to meet a requirement  
20 under this subchapter to which that standard is applicable.  
21 In recognizing a standard, any person requesting recogni-  
22 tion of a standard or seeking to use a recognized standard,  
23 the Secretary shall follow the processes and requirements,  
24 in accordance with section 514(c). Standards for in vitro  
25 diagnostic devices previously recognized under section

1 514(c) shall be considered recognized standards under this  
2 section. The application of any such consensus standard  
3 shall only apply prospectively. The Secretary shall issue  
4 guidance establishing the criteria and process for such rec-  
5 ognition and adoption.

6 “(c) ORDER PROCESS.—In establishing a standard  
7 under subsection (a), the Secretary shall issue a draft  
8 order proposing to establish a standard and shall provide  
9 for a comment period of not less than 60 calendar days.  
10 The Secretary may seek the recommendation of an advi-  
11 sory committee under section 587G concerning a proposed  
12 standard either prior to or after issuance of a proposed  
13 order. After considering the comments and within 90 days  
14 of the close of the comment period, the Secretary shall  
15 issue a final order adopting the proposed standard, adopt-  
16 ing a modification of the proposed standard or terminating  
17 the proceeding.

18 “(d) AMENDMENT PROCESS.—The procedures estab-  
19 lished in this section or in guidance issued under this sec-  
20 tion shall apply to amendment of an existing standard.

21 **“SEC. 587R. INVESTIGATIONAL USE.**

22 “(a) IN GENERAL.—Except as provided in subsection  
23 (c), an in vitro clinical test for investigational use shall  
24 be exempt from the requirements of this subchapter other  
25 than sections 587A, 587O, and 587U.

1       “(b) REGULATIONS.—Not later than 2 years after  
2 the date of enactment of the Verifying Accurate Leading-  
3 edge IVCT Development Act of 2021, the Secretary shall  
4 promulgate regulations to implement this section.

5       “(c) APPLICATION FOR INVESTIGATIONAL USE.—

6           “(1) IN GENERAL.—The following shall apply  
7 with respect to in vitro clinical tests for investiga-  
8 tional use:

9           “(A) STREAMLINING APPLICATIONS SUB-  
10 MITED UNDER THIS SECTION.—Requirements  
11 with respect to such tests shall be completed in  
12 accordance with current, at the time of submit-  
13 ting the application, investigational use require-  
14 ments for institutional review boards and cur-  
15 rent processes for any analytical or clinical vali-  
16 dation.

17           “(B) VARIATION.—The requirements in  
18 the regulations promulgated under this section  
19 shall take into account variations based on—

20           “(i) the scope and duration of clinical  
21 testing to be conducted under investigation  
22 that is the subject of such application;

23           “(ii) the number of human subjects  
24 that are to be involved in such testing;

1           “(iii) the need to permit changes to be  
2           made in the in vitro clinical test involved  
3           during testing conducted in accordance  
4           with a plan required under paragraph  
5           (3)(B); or

6           “(iv) whether the clinical testing of  
7           such in vitro clinical test is for the purpose  
8           of developing data to obtain approval to  
9           offer such test.

10           “(C) SIGNIFICANT RISK STUDIES.—In the  
11           case of an in vitro clinical test the investiga-  
12           tional use of which poses a significant risk, a  
13           sponsor of an investigation of such a test seek-  
14           ing an investigational use exemption shall sub-  
15           mit to the Secretary an investigational use ap-  
16           plication with respect to the test in accordance  
17           with paragraphs (2) and (3). For purposes of  
18           this subparagraph, the term ‘significant risk’  
19           means, with respect to an in vitro clinical test  
20           that is a high-risk test, and that the use of the  
21           test—

22           “(i) is a use of substantial importance  
23           in performing an activity or activities de-  
24           scribed in subsection (ss)(1)(A) for, a seri-  
25           ous or life-threatening disease or condition

1 without confirmation of the diagnosis by a  
2 medically established means;

3 “(ii) requires an invasive sampling  
4 procedure that presents a significant risk  
5 to the human subject; or

6 “(iii) otherwise presents a reasonably  
7 foreseeable serious risk to the health of a  
8 human subject.

9 “(D) NON-SIGNIFICANT RISK TESTS.—In  
10 the case of an in vitro clinical test, the inves-  
11 tigational use of which does not pose a signifi-  
12 cant risk—

13 “(i) the sponsor of such investigation  
14 shall—

15 “(I) conduct such investigation in  
16 compliance with an investigational  
17 plan specified in paragraph (5) and  
18 labeling specified in paragraph  
19 (3)(A)(ii);

20 “(II) ensure each investigator ob-  
21 tains informed consent under part 50  
22 of title 21, Code of Federal Regula-  
23 tions (or any successor regulations),  
24 subject to the exceptions set forth in  
25 paragraphs (5)(A)(iii) and (5)(B);



1                   “(III) submit a listing to the Sec-  
2                   retary of such investigation; and

3                   “(IV) maintain records with re-  
4                   spect to all requirements in this sub-  
5                   paragraph; and

6                   “(ii) the sponsor may rely on any ex-  
7                   ception or exemption identified in para-  
8                   graph (5)(B) or as established by the Sec-  
9                   retary in regulations issued under sub-  
10                  section (b).

11                  “(2) APPLICATION CONTENT.—An investiga-  
12                  tional use application shall be submitted in such  
13                  time and manner and contain such information as  
14                  the Secretary may require in regulation, and shall  
15                  include an investigational plan for proposed clinical  
16                  testing and assurances that the sponsor submitting  
17                  the application will—

18                         “(A) establish and maintain records rel-  
19                         evant to the investigation of such in vitro clin-  
20                         ical test; and

21                         “(B) submit to the Secretary annual re-  
22                         ports of data obtained as a result of the inves-  
23                         tigational use of the in vitro clinical test during  
24                         the period covered by the exemption that the

1 Secretary reasonably determines will enable the  
2 Secretary—

3 “(i) to ensure compliance with the  
4 conditions for the exemption specified in  
5 paragraph (3);

6 “(ii) to review the progress of the in-  
7 vestigation involved; and

8 “(iii) to evaluate the analytical valid-  
9 ity and clinical validity of such test.

10 “(3) CONDITIONS FOR EXEMPTION.—

11 “(A) IN GENERAL.—A request for an in-  
12 vestigational use exemption with respect to sig-  
13 nificant risk tests shall be granted only if each  
14 of the following conditions is met:

15 “(i) The risks to the subjects of the in  
16 vitro clinical test are outweighed by the an-  
17 ticipated benefits to the subjects and the  
18 importance of the knowledge to be gained,  
19 and adequate assurance of informed con-  
20 sent is provided in accordance with para-  
21 graph (5)(A)(iii).

22 “(ii) The proposed labeling for the in  
23 vitro clinical test involved clearly and con-  
24 spicuously states ‘For investigational use’.

1           “(iii) Such other requirements the  
2           Secretary determines to be necessary for  
3           the protection of the public health and  
4           safety as long as the requirements do not  
5           unduly delay investigation after finding  
6           that the results of such investigation estab-  
7           lish sufficient data to support clinical or  
8           analytical validity.

9           “(B) CERTAIN SIGNIFICANT RISK IN VITRO  
10          CLINICAL TESTS FOR AN UNMET NEED.—As a  
11          condition for granting an exemption under this  
12          paragraph, the Secretary shall not impose a  
13          limit on the sample size for a significant risk in  
14          vitro clinical test that meets the requirements  
15          of section 587C, as long as such test is devel-  
16          oped within a laboratory that is certified to con-  
17          duct high-complexity testing under section 353  
18          of the Public Health Service Act.

19          “(4) COORDINATION WITH INVESTIGATIONAL  
20          NEW DRUG APPLICATIONS.—Any requirement for  
21          the submission of a report to the Secretary pursuant  
22          to a request for an investigational new drug exemp-  
23          tion involving an in vitro clinical test shall supersede  
24          the reporting requirement in paragraph (2)(B), but  
25          only to the extent the requirement with respect to

1 the request for exemption with respect to the drug  
2 is duplicative of the reporting requirement under  
3 such paragraph.

4 “(5) INVESTIGATION PLAN REQUIREMENTS.—

5 “(A) IN GENERAL.—With respect to an in-  
6 vestigational plan submitted under paragraph  
7 (2)(A), the sponsor submitting such plan  
8 shall—

9 “(i) in the case of such a plan sub-  
10 mitted to an institutional review com-  
11 mittee, promptly notify the Secretary of  
12 the approval or the suspension or termi-  
13 nation of the approval of such plan by an  
14 institutional review committee;

15 “(ii) in the case of an in vitro clinical  
16 test made available to investigators for  
17 clinical testing, assurance that all inves-  
18 tigators will comply with this section, regu-  
19 lations promulgated or revised under this  
20 section, and applicable human subjects regu-  
21 lations; and

22 “(iii) submit an assurance to the Sec-  
23 retary that informed consent will be ob-  
24 tained from each human subject (or the  
25 representative of such subject) of proposed

1 clinical testing involving such in vitro clin-  
2 ical test, except in the case that—

3 “(I) there is a life-threatening  
4 situation involving the human subject  
5 of such testing which necessitates the  
6 use of such in vitro clinical test;

7 “(II) it is not feasible to obtain  
8 informed consent from the subject;  
9 and

10 “(III) there is not sufficient time  
11 to obtain such consent from a rep-  
12 resentative of such subject.

13 “(B) EXCEPTION.—The informed consent  
14 of human subjects shall not be required with re-  
15 spect to clinical testing conducted as part of an  
16 investigation, if—

17 “(i) the clinical testing uses remnants  
18 of specimens collected for routine clinical  
19 care or analysis that would have been dis-  
20 carded, leftover specimens that were pre-  
21 viously collected for other research pur-  
22 poses, or specimens obtained from speci-  
23 men repositories;

24 “(ii) the identity of the subject of the  
25 specimen is not known to, and may not

1 readily be ascertained by, the investigator  
2 or any other individual associated with the  
3 investigation, including the sponsor;

4 “(iii) any clinical information that ac-  
5 companies the specimens does not make  
6 the specimen source identifiable to the in-  
7 vestigator or any other individual associ-  
8 ated with the investigation, including the  
9 sponsor;

10 “(iv) the individuals caring for the  
11 human subjects as patients are different  
12 from, and do not share information about  
13 the patient with, the individuals conducting  
14 the investigation; and

15 “(v) the specimens are provided to the  
16 investigators without personally identifiable  
17 information and the supplier of the speci-  
18 mens has established policies and proce-  
19 dures to prevent the release of personally  
20 identifiable information.

21 “(d) REVIEW OF APPLICATIONS.—

22 “(1) IN GENERAL.—The Secretary may issue  
23 an order approving an investigation as proposed, ap-  
24 proving it with conditions or modifications, or dis-  
25 approving it.

1           “(2) FAILURE TO ACT.—Unless the Secretary,  
2 not later than the date that is 30 calendar days  
3 after the date of the submission of an investigational  
4 use exemption request that meets the requirements  
5 of subsection (c)(2), issues an order under sub-  
6 section (d)(1) and notifies the sponsor submitting  
7 the application, the request shall be treated as  
8 granted as of such date without further action by  
9 the Secretary.

10           “(3) DISAPPROVAL.—The Secretary may deny  
11 an investigational use request submitted under this  
12 subsection if the Secretary determines that the in-  
13 vestigation with respect to which the request is sub-  
14 mitted does not conform to the requirements of sub-  
15 section (c)(3). A listing of such denial submitted to  
16 the sponsor with respect to such a request shall con-  
17 tain the order of disapproval and a complete state-  
18 ment of the reasons for the Secretary’s denial of the  
19 request.

20           “(e) WITHDRAWAL OF APPROVAL.—

21           “(1) IN GENERAL.—The Secretary may, by ad-  
22 ministrative order, withdraw an exemption granted  
23 under this section with respect to an in vitro clinical  
24 test, including an exemption granted based on the  
25 Secretary’s failure to act pursuant to subsection

1 (d)(2), if the Secretary determines that the test does  
2 not meet the applicable conditions under subsection  
3 (c)(3) for such exemption.

4 “(2) OPPORTUNITY TO BE HEARD.—

5 “(A) IN GENERAL.—Subject to subpara-  
6 graph (B), an order withdrawing the exemption  
7 granted under this section may be issued only  
8 after the Secretary provides the applicant or  
9 sponsor of the test with an opportunity for an  
10 informal hearing.

11 “(B) EXCEPTION.—An order referred to in  
12 subparagraph (A) with respect to an exemption  
13 granted under this subsection may be issued on  
14 a preliminary basis before the provision of an  
15 opportunity for an informal hearing if the Sec-  
16 retary determines that the continuation of test-  
17 ing under the exemption will result in an unrea-  
18 sonable risk to the public health. The Secretary  
19 will provide an opportunity for an informal  
20 hearing promptly following any preliminary ac-  
21 tion under this subparagraph.

22 “(f) CHANGES.—

23 “(1) IN GENERAL.—The regulations promul-  
24 gated under subsection (b) shall provide, with re-  
25 spect to an in vitro clinical test for which an exemp-



1       tion under this subsection is in effect, procedures  
2       and conditions under which the changes to the test  
3       are allowed without the additional determination on  
4       a request for an exemption or submission of a sup-  
5       plement to such a request. Such regulations shall  
6       provide that such a change may be made if—

7               “(A) the sponsor or applicant determines,  
8               on the basis of credible information (as defined  
9               by the Secretary) that the change meets the  
10              conditions specified in paragraph (2); and

11              “(B) the sponsor or applicant submits to  
12              the Secretary, not later than 5 calendar days  
13              after making the change, a notice of the  
14              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 (if any)  
25                      involved 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;

10                  “(ii) the scientific soundness of a plan  
11                  submitted under subsection (c)(5); or

12                  “(iii) the rights, safety, or welfare of  
13                  the human subjects (if any) involved in the  
14                  investigation.

15                  “(g) CLINICAL HOLD.—

16                  “(1) IN GENERAL.—At any time, the Secretary  
17                  may impose a clinical hold with respect to an inves-  
18                  tigation of an in vitro clinical test if the Secretary  
19                  makes a determination described in paragraph (2).  
20                  The Secretary shall, in imposing such clinical hold,  
21                  specify the basis for the clinical hold, including the  
22                  specific information available to the Secretary which  
23                  served as the basis for such clinical hold, and con-  
24                  firm such determination in writing. The applicant or

1 sponsor may immediately appeal any such deter-  
2 mination pursuant to section 587O.

3 “(2) DETERMINATION.—For purposes of para-  
4 graph (1), a determination described in this sub-  
5 paragraph with respect to a clinical hold is a deter-  
6 mination that—

7 “(A) the in vitro clinical test involved rep-  
8 resents an unreasonable risk to the safety of  
9 the persons who are the subjects of the clinical  
10 investigation, taking into account the qualifica-  
11 tions of the clinical investigators, information  
12 about the in vitro clinical test, the design of the  
13 clinical investigation, the condition for which  
14 the in vitro clinical test is to be investigated,  
15 and the health status of the subjects involved;

16 “(B) the clinical hold should be issued for  
17 such other reasons as the Secretary may by  
18 regulation establish; or

19 “(C) any written request to the Secretary  
20 from the sponsor of an investigation that a clin-  
21 ical hold be removed shall receive a decision, in  
22 writing and specifying the reasons therefor,  
23 within 30 days after receipt of such request.  
24 Any such request shall include sufficient infor-

1           mation to support the removal of such clinical  
2           hold.

3 **“SEC. 587S. COLLABORATIVE COMMUNITIES FOR IN VITRO**  
4 **CLINICAL TESTS.**

5           “(a) IN GENERAL.—

6           “(1) For the purposes of facilitating community  
7           solutions and decision making with respect to in  
8           vitro clinical tests, the Secretary may participate in  
9           collaborative communities comprised of public and  
10          private participants that may provide recommenda-  
11          tions and other advice to the Secretary on the devel-  
12          opment and regulation of in vitro clinical tests.

13          “(2) A collaborative community under this sec-  
14          tion shall have broad representation of interested  
15          private and public-sector stakeholder communities  
16          and may include patients, care partners, academics,  
17          health care professionals, health care systems,  
18          payors, Federal and State agencies, entities respon-  
19          sible for accrediting clinical laboratories, inter-  
20          national regulatory bodies, test developers, or other  
21          interested entities or communities.

22          “(b) GUIDANCE.—The Secretary shall issue a draft  
23          guidance not later than 180 days after the date of enact-  
24          ment of the Verifying Accurate Leading-edge IVCT Devel-  
25          opment Act of 2021, addressing the participation process

1 and framework to build consensus, and how the Secretary  
2 may consider, review, and implement recommendations  
3 under subsection (c).

4 “(c) RECOMMENDATIONS.—A collaborative commu-  
5 nity for in vitro clinical tests may make recommendations  
6 to the Secretary on matters including—

7 “(1) mitigating measures for in vitro clinical  
8 tests;

9 “(2) standards development activities and per-  
10 formance standards for in vitro clinical tests or  
11 groups of such tests;

12 “(3) scientific and clinical evidence to support  
13 new claims for in vitro clinical tests;

14 “(4) new technologies and methodologies re-  
15 lated to in vitro clinical tests;

16 “(5) stakeholder communication and engage-  
17 ment; and

18 “(6) development of effective policies and proc-  
19 esses, including to develop tests, and to regulate  
20 such tests in accordance with least burdensome re-  
21 quirements described in section 587B(j).

22 “(d) USE BY SECRETARY.—

23 “(1) IN GENERAL.—The Secretary may adopt  
24 recommendations made under subsection (b), or oth-  
25 erwise incorporate the feedback from collaborative

1 communities into regulatory decision making,  
2 through rulemaking or guidance, as appropriate.

3 “(2) CLARIFICATION.—The Secretary is not re-  
4 quired to adopt recommendations submitted by col-  
5 laborative communities.

6 “(e) TRANSPARENCY.—The Secretary shall—

7 “(1) publish on the website of the Food and  
8 Drug Administration matters for which it is seeking  
9 comments or recommendations, in a timely manner;

10 “(2) maintain a list of all collaborative commu-  
11 nities in which the Secretary participates and make  
12 such list available on the website of the Food and  
13 Drug Administration; and

14 “(3) post on the website of the Food and Drug  
15 Administration at least once every year a report on  
16 the recommendations it has adopted and rec-  
17 ommendations it has not adopted from collaborative  
18 communities.

19 “(f) PARTICIPATION.—The Secretary may participate  
20 in a collaborative community only if such community re-  
21 quires members to disclose conflicts of interest and has  
22 established a process to address conflicts of interest.

23 “(g) EXEMPTION.—The collaborative communities  
24 established and used in accordance with this section shall

1 be exempt from the Federal Advisory Committee Act (5  
2 U.S.C. App.).

3 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

4 “(a) PURPOSE.—For the purposes of improving the  
5 transparency of information on in vitro clinical tests and  
6 allowing patients and health care providers better access  
7 to information about in vitro clinical tests, the Secretary  
8 shall establish a comprehensive test information system.

9 “(b) ESTABLISHMENT.—Not later than 2 years after  
10 the date of enactment of the Verifying Accurate Leading-  
11 edge IVCT Development Act of 2021, the Secretary shall  
12 make available a comprehensive test information system  
13 for in vitro clinical tests that is designed to—

14 “(1) provide a transparent interface on the  
15 website of the Food and Drug Administration for  
16 stakeholders, to the extent permitted by applicable  
17 law, to access the—

18 “(A) regulatory pathway designation infor-  
19 mation for each in vitro clinical test or tests  
20 with the same indications for use;

21 “(B) registration and listing information  
22 provided by developers under section 587I, in-  
23 cluding the use of a link for labels;

24 “(C) adverse event reports submitted  
25 under section 587L;

1           “(D) reports of corrections and removals  
2           submitted under section 587M; and

3           “(E) other information pertaining to an in  
4           vitro clinical test or tests with the same indica-  
5           tions for use, as the Secretary determines ap-  
6           propriate; and

7           “(2) provide a secure portal for electronic sub-  
8           mission, including applications and other in vitro  
9           clinical test submissions, registration and listing in-  
10          formation, and adverse event reports.

11          “(c) SUBMISSION FUNCTION.—The comprehensive  
12          test information system shall serve as the electronic sub-  
13          mission service for test developers submitting information  
14          for applications under sections 587B and 587D.

15          **“SEC. 587U. PREEMPTION.**

16          “(a) IN GENERAL.—No State, Tribal, or local gov-  
17          ernment (or political subdivision thereof) may establish or  
18          continue in effect any requirement related to the develop-  
19          ment, manufacture, labeling, distribution, sale, or use of  
20          an in vitro clinical test that is different from, or in addi-  
21          tion to, the requirements of this subchapter.

22          “(b) EXCEPTIONS.—Subsection (a) shall not be con-  
23          strued to affect the authority of a State, Tribal, or local  
24          government—



1           “(1) to license laboratory personnel, health care  
2 practitioners, or health care facilities or to regulate  
3 any aspect of a health care practitioner-patient rela-  
4 tionship; or

5           “(2) to enforce laws of general applicability,  
6 such as zoning laws, environmental laws, labor laws,  
7 and general business laws.

8           “(c) CLARIFICATION.—This section shall not be con-  
9 strued to shift liability to health care practitioners or other  
10 users.

11 **“SEC. 587V. ADULTERATION.**

12           “An in vitro clinical test shall be deemed to be adul-  
13 terated:

14           “(1) If it consists in whole or in part of any  
15 filthy, putrid, or decomposed substance.

16           “(2) If it has been developed, prepared, packed,  
17 or held under insanitary conditions whereby it may  
18 have been contaminated with filth, or whereby it  
19 may have been rendered injurious to health.

20           “(3) If its container or package is composed, in  
21 whole or in part, of any poisonous or deleterious  
22 substance which may render the contents injurious  
23 to health.

1           “(4) If it bears or contains, for purposes of  
2 coloring only, a color additive which is unsafe within  
3 the meaning of section 721(a).

4           “(5) If its analytical or clinical validity, or with  
5 respect to a specimen receptacle, its safety, or its  
6 strength, purity, or quality, differs from or falls  
7 below that which it purports or is represented to  
8 possess.

9           “(6) If it is required to be, declared to be, pur-  
10 ports to be, or is represented as being, in conformity  
11 with any performance standard established or recog-  
12 nized under section 587Q and is not in all respects  
13 in conformity with such standard.

14           “(7) If it is required to be in conformity with  
15 a mitigating measure established under section  
16 587E and is not in all respects in conformity with  
17 such mitigating measure.

18           “(8) If it fails to have an approved premarket  
19 application under section 587B unless such in vitro  
20 clinical test can be lawfully offered—

21                   “(A) for clinical use pursuant to an exemp-  
22 tion under section 587A;

23                   “(B) for emergency use pursuant to an au-  
24 thorization under section 564; or

1           “(C) for investigational use pursuant to  
2           section 587R.

3           “(9) If it is not in conformity with any condi-  
4           tion established under section 587B, 587D, or 564.

5           “(10) If it purports to be an in vitro clinical  
6           test that is offered for clinical use subject to an ex-  
7           emption under section 587A and it fails to meet or  
8           maintain any criteria, condition, or requirement of  
9           such exemption.

10          “(11) If it has been granted an exemption  
11          under section 587R for investigational use, and the  
12          person granted such exemption or any investigator  
13          who uses such in vitro clinical test under such ex-  
14          emption fails to comply with a requirement pre-  
15          scribed by or under such section.

16          “(12) If it fails to meet the quality require-  
17          ments prescribed in or established under section  
18          587J (as applicable), or the methods used in, or fa-  
19          cilities or controls used for, its development, manu-  
20          facture, packing, storage, or installation are not in  
21          conformity with applicable requirements established  
22          under such section.

23          “(13) If it has been developed, manufactured,  
24          processed, packed or held in any establishment, fac-  
25          tory, or warehouse and the owner, operator or agent

1 of such establishment, factory, or warehouse delays,  
2 denies, or limits an inspection, or refuses to permit  
3 entry or inspection.

4 “(14) If it is not in compliance with any restric-  
5 tion required under section 587N.

6 **“SEC. 587W. MISBRANDING.**

7 “An in vitro clinical test shall be deemed to be mis-  
8 branded:

9 “(1) If its labeling is false or misleading in any  
10 particular.

11 “(2) If in a package form unless it bears a label  
12 containing—

13 “(A) the name and place of business of the  
14 test developer, manufacturer, packer, or dis-  
15 tributor; and

16 “(B) an accurate statement of the quantity  
17 of contents in terms of weight, measure, or nu-  
18 merical count with respect to small packages,  
19 unless an exemption is granted by the Secretary  
20 by the issuance of guidance.

21 “(3) If any word, statement, or other informa-  
22 tion required by or under authority of this Act to  
23 appear on the label or labeling, including a test re-  
24 port, is not prominently placed thereon with such  
25 conspicuousness (as compared with other words,

1 statements, designs, or devices, in the labeling) and  
2 in such terms as to render it likely to be read and  
3 understood by the ordinary individual under cus-  
4 tomary conditions of purchase and use.

5 “(4) Unless its labeling bears adequate direc-  
6 tions for use and such adequate warnings as are  
7 necessary for the protection of users of the in vitro  
8 clinical test and recipients of the results of such in  
9 vitro clinical test, including patients, consumers, do-  
10 nors, and related health care professionals. Required  
11 labeling for in vitro clinical tests intended for use in  
12 health care facilities or by a health care professional  
13 may be made available solely by electronic means,  
14 provided that the labeling complies with all applica-  
15 ble requirements of law, and that the test developer,  
16 manufacturer, or distributor affords such users the  
17 opportunity to request the labeling in paper form,  
18 and after such request, promptly provides the re-  
19 quested information without additional cost.

20 “(5) If it causes serious or adverse health con-  
21 sequences or death, including through absence,  
22 delay, or discontinuation in diagnosis or treatment,  
23 when used in the manner prescribed, recommended,  
24 or suggested in the labeling thereof.

1           “(6) If it was developed or manufactured in an  
2           establishment not duly registered under section 587I  
3           or it was not included in a listing under section  
4           587I, in accordance with timely reporting require-  
5           ments under this subchapter.

6           “(7) In the case of any in vitro clinical test sub-  
7           ject to restrictions under section 587N, (1) if its ad-  
8           vertising is false or misleading in any particular, (2)  
9           if it is offered for clinical use, sold, distributed, or  
10          used in violation of such restrictions, or (3) unless  
11          the test developer, manufacturer, or distributor in-  
12          cludes in all advertisements and other descriptive  
13          printed matter that such person issues or causes to  
14          be issued, a brief statement of the intended uses of  
15          the in vitro clinical test and relevant warnings, pre-  
16          cautions, side effects, and contraindications. This  
17          subsection shall not be applicable to any printed  
18          matter that the Secretary determines to be labeling  
19          as defined in section 201(m) or section 587K.

20          “(8) If it was subject to a mitigating measure  
21          established under section 587E, unless it bears such  
22          labeling as may be prescribed in such mitigating  
23          measure.

1           “(9) If it was subject to a standard established  
2           under section 587Q, unless it bears such labeling as  
3           may be prescribed in such standard.

4           “(10) Unless it bears such labeling as may be  
5           prescribed by or established under an applicable la-  
6           beling requirement under this Act.

7           “(11) If there was a failure or refusal to comply  
8           with any requirement prescribed under section 587I  
9           or 587X, or to comply with a requirement under sec-  
10          tion 587Y, or to provide any report, material, or in-  
11          formation required under this subchapter.

12 **“SEC. 587X. POSTMARKET SURVEILLANCE.**

13          “(a) IN GENERAL.—

14               “(1) IN GENERAL.—In addition to other appli-  
15               cable requirements under this Act, the Secretary  
16               may issue an order requiring a developer to conduct  
17               postmarket surveillance of a single in vitro clinical  
18               test as a condition of approval under section 587B.

19               “(2) EXEMPT TESTS.—The Secretary may  
20               order postmarket surveillance for tests exempt pur-  
21               suant to section 587A for which the failure of the  
22               in vitro clinical test to meet the applicable standard  
23               for approval is likely to result in serious or adverse  
24               health consequences or death from use of the single  
25               in vitro clinical test.

1           “(3) CONSIDERATION.—In determining whether  
2           to require a developer to conduct postmarket surveil-  
3           lance of an in vitro clinical test, the Secretary shall  
4           take into consideration the benefits and risks for the  
5           patient and the least burdensome principles under  
6           section 587B.

7           “(b) SURVEILLANCE APPROVAL.—

8           “(1) Each developer required to conduct a sur-  
9           veillance of an in vitro clinical test shall submit,  
10          within 30 days of receiving an order from the Sec-  
11          retary, a plan for the required surveillance. The Sec-  
12          retary, within 60 days of the receipt of such plan,  
13          shall determine if the person designated to conduct  
14          the surveillance has the appropriate qualifications  
15          and experience to undertake such surveillance and if  
16          the plan will result in useful data that can reveal un-  
17          foreseen adverse events or other information nec-  
18          essary to protect the health of patients or the public.

19          “(2) The developer shall commence surveillance  
20          under this section not later than 15 months after  
21          the day on which the Secretary orders such postmar-  
22          ket surveillance, unless the Secretary determines  
23          more time is needed to commence surveillance.

24          “(3) The Secretary may order a prospective  
25          surveillance period of up to 3 years. Any determina-



1       tion by the Secretary that a longer period is nec-  
2       essary shall be made by mutual agreement between  
3       the Secretary and the manufacturer or, if no agree-  
4       ment can be reached, after the completion of a dis-  
5       pute resolution process.

6       **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

7       “(a) IN GENERAL.—All presubmissions and submis-  
8       sions to the Food and Drug Administration with respect  
9       to an in vitro clinical test shall include an electronic copy  
10      of such presubmission or submission, and, with respect to  
11      the information required under sections 587B and 587D,  
12      shall utilize the system described in section 587T.

13      “(b) ELECTRONIC FORMAT.—Beginning on such date  
14      as the Secretary specifies in final guidance issued under  
15      subsection (c), presubmissions and submissions for in vitro  
16      clinical tests (and any appeals of action taken by the Sec-  
17      retary with respect to such presubmissions and submis-  
18      sions) shall be submitted solely in such electronic format  
19      as specified by the Secretary in such guidance.

20      “(c) GUIDANCE.—The Secretary shall issue guidance  
21      implementing this section. In such guidance, the Secretary  
22      may—

23              “(1) provide standards for the electronic copy  
24              required under subsection (a) or the submission in  
25              electronic format required under subsection (b);

1           “(2) set forth criteria for waivers of or exemp-  
2           tions from the requirements of subsection (a) or (b);  
3           and

4           “(3) provide any other information for the effi-  
5           cient implementation and enforcement of this sec-  
6           tion.

7   **“SEC. 587Z. POSTMARKET REMEDIES.**

8           “(a) SAFETY NOTICE.—

9           “(1) IN GENERAL.—If the Secretary determines  
10          that an in vitro clinical test presents an unreason-  
11          able risk of substantial harm to the public health,  
12          and notification under this subsection is necessary to  
13          eliminate the unreasonable risk of such harm and no  
14          more practicable means is available under the provi-  
15          sions of this Act (other than this section) to elimi-  
16          nate the risk, the Secretary may issue such order as  
17          may be necessary to ensure that adequate safety no-  
18          tice is provided in an appropriate form, by the per-  
19          sons and means best suited under the circumstances,  
20          to all health care professionals who prescribe, order,  
21          or use the in vitro clinical test and to any other per-  
22          son (including developers, manufacturers, importers,  
23          distributors, retailers, and users) who should prop-  
24          erly receive such notice.

1           “(2) NOTICE TO INDIVIDUALS.—An order  
2 under this subsection shall require that the individ-  
3 uals subject to the risk with respect to which the  
4 order is to be issued be included in the persons to  
5 be notified of the risk unless the Secretary deter-  
6 mines that notice to such individuals would present  
7 a greater danger to the health of such individuals  
8 than no such notice. If the Secretary makes such a  
9 determination with respect to such individuals, the  
10 order shall advise the health care professionals who  
11 prescribed, ordered, or used the in vitro clinical test  
12 provide notification to the individuals for whom the  
13 health professionals prescribed, ordered, or used  
14 such test, of the risk presented by such in vitro clin-  
15 ical test and of any action which may be taken by  
16 or on behalf of such individuals to eliminate or re-  
17 duce such risk. Before issuing an order under this  
18 subsection, the Secretary shall consult with the per-  
19 sons required to give notice under the order.

20           “(b) REPAIR, REPLACEMENT, OR REFUND.—

21           “(1) DETERMINATION AFTER AN INFORMAL  
22 HEARING.—

23           “(A) IN GENERAL.—If, after affording op-  
24 portunity for an informal hearing, the Secretary  
25 determines that—

1           “(i) an in vitro clinical test presents  
2           an unreasonable risk of substantial harm  
3           to the public health;

4           “(ii) there are reasonable grounds to  
5           believe that the in vitro clinical test was  
6           not properly developed or manufactured  
7           considering the state of the art as it ex-  
8           isted at the time of its development or  
9           manufacture;

10          “(iii) there are reasonable grounds to  
11          believe that the unreasonable risk was not  
12          caused by failure of a person other than a  
13          developer, manufacturer, importer, dis-  
14          tributor, or retailer of the in vitro clinical  
15          test to exercise due care in the installation,  
16          maintenance, repair, or use of the in vitro  
17          clinical test; and

18          “(iv) the notice authorized by sub-  
19          section (a) would not by itself be sufficient  
20          to eliminate the unreasonable risk and ac-  
21          tion described in paragraph (2) of this sub-  
22          section is necessary to eliminate such risk,  
23          the Secretary may order the developer, manu-  
24          facturer, importer, or any distributor of such in  
25          vitro clinical test, or any combination of such

1 persons, to submit to him within a reasonable  
2 time a plan for taking one or more of the ac-  
3 tions described in paragraph (2). An order  
4 issued under the preceding sentence which is di-  
5 rected to more than one person shall specify  
6 which person may decide which action shall be  
7 taken under such plan and the person specified  
8 shall be the person who the Secretary deter-  
9 mines bears the principal, ultimate financial re-  
10 sponsibility for action taken under the plan un-  
11 less the Secretary cannot determine who bears  
12 such responsibility or the Secretary determines  
13 that the protection of the public health requires  
14 that such decision be made by a person (includ-  
15 ing a health professional or user of the in vitro  
16 clinical test) other than the person the Sec-  
17 retary determines bears such responsibility.

18 “(B) SECRETARY APPROVAL OF PLAN.—  
19 Within 30 calendar days of issuing an order  
20 under subparagraph (A), the Secretary shall ap-  
21 prove a plan submitted pursuant to an order  
22 issued under subparagraph (A) unless the Sec-  
23 retary determines (after affording opportunity  
24 for an informal hearing) that the action or ac-  
25 tions to be taken under the plan or the manner

1 in which such action or actions are to be taken  
2 under the plan will not assure that the unrea-  
3 sonable risk with respect to which such order  
4 was issued will be eliminated. If the Secretary  
5 disapproves a plan, the Secretary shall order a  
6 revised plan to be submitted within a reason-  
7 able time. If the Secretary determines (after af-  
8 fording opportunity for an informal hearing)  
9 that the revised plan is unsatisfactory or if no  
10 revised plan or no initial plan has been sub-  
11 mitted to the Secretary within the prescribed  
12 time, the Secretary shall (i) prescribe a plan to  
13 be carried out by the person or persons to  
14 whom the order issued under subparagraph (A)  
15 was directed, or (ii) after affording an oppor-  
16 tunity for an informal hearing, by order pre-  
17 scribe a plan to be carried out by a person who  
18 is a manufacturer, importer, distributor, or re-  
19 tailer of the in vitro clinical test with respect to  
20 which the order was issued but to whom the  
21 order under subparagraph (A) was not directed.

22 “(2) ACTIONS ON A PLAN.—The actions which  
23 may be taken under a plan submitted under an  
24 order issued under paragraph (1) are as follows:

1           “(A) To repair the in vitro clinical test so  
2           that it does not present the unreasonable risk  
3           of substantial harm with respect to which the  
4           order under paragraph (1)(A) was issued.

5           “(B) To replace the in vitro clinical test  
6           with a like or equivalent test which is in con-  
7           formity with all applicable requirements of this  
8           Act.

9           “(C) To refund the purchase price of the  
10          in vitro clinical test (less a reasonable allowance  
11          for use if such in vitro clinical test has been in  
12          the possession of the user for one year or more  
13          at the time of notice ordered under subsection  
14          (a), or at the time the user receives actual no-  
15          tice of the unreasonable risk with respect to  
16          which the order was issued under paragraph  
17          (1)(A), whichever occurs first).

18          “(3) NO CHARGE.—No charge shall be made to  
19          any person (other than a developer, manufacturer,  
20          importer, distributor or retailer) for using a remedy  
21          described in paragraph (2) and provided under an  
22          order issued under paragraph (1), and the person  
23          subject to the order shall reimburse each person  
24          (other than a developer, manufacturer, importer,  
25          distributor, or retailer) who is entitled to such a

1       remedy for any reasonable and foreseeable expenses  
2       actually incurred by such person in availing himself  
3       of such remedy.

4       “(c) REIMBURSEMENT.—An order issued under sub-  
5       section (b)(1)(A) with respect to an in vitro clinical test  
6       may require any person who is a developer, manufacturer,  
7       importer, distributor, or retailer of the in vitro clinical test  
8       to reimburse any other person who is a developer, manu-  
9       facturer, importer, distributor, or retailer of such in vitro  
10      clinical test for such other person’s expenses actually in-  
11      curred in connection with carrying out the order if the  
12      Secretary determines such reimbursement is required for  
13      the protection of the public health. Any such requirement  
14      shall not affect any rights or obligations under any con-  
15      tract to which the person receiving reimbursement or the  
16      person making such reimbursement is a party.

17      “(d) RECALL AUTHORITY.—

18             “(1) IN GENERAL.—If the Secretary finds that  
19      there is a reasonable probability that an in vitro  
20      clinical test approved under section 587B would  
21      cause serious, adverse health consequences or death,  
22      including by the absence, delay, or discontinuation of  
23      appropriate medical treatment, the Secretary shall  
24      issue an order requiring the appropriate person (in-  
25      cluding the developers, manufacturers, importers,



1 distributors, or retailers of the in vitro clinical  
2 test)—

3 “(A) to immediately cease distribution of  
4 such in vitro clinical test; and

5 “(B) to immediately notify health profes-  
6 sionals and user facilities of the order and to  
7 instruct such professionals and facilities to  
8 cease use of such in vitro clinical test.

9 “(2) INFORMAL HEARING.—The order issued  
10 under paragraph (1)(A), shall provide the person  
11 subject to the order with an opportunity for an in-  
12 formal hearing, to be held not later than 10 calendar  
13 days after the date of the issuance of the order, on  
14 the actions required by the order and on whether the  
15 order should be amended to require a recall of such  
16 in vitro clinical test. If, after providing an oppor-  
17 tunity for such a hearing, the Secretary determines  
18 that inadequate grounds exist to support the actions  
19 required by the order, the Secretary shall vacate the  
20 order.

21 “(3) AMENDED ORDER.—

22 “(A) IN GENERAL.—If, after providing an  
23 opportunity for an informal hearing under  
24 paragraph (2), the Secretary determines that  
25 the order should be amended to include a recall

1 of the in vitro clinical test with respect to which  
2 the order was issued, the Secretary shall, except  
3 as provided in subparagraph (B), amend the  
4 order to require a recall. The Secretary shall  
5 specify a timetable in which the recall will occur  
6 and shall require periodic reports describing the  
7 progress of the recall.

8 “(B) REQUIREMENTS.—An amended order  
9 under subparagraph (A)—

10 “(i) shall not include recall of the in  
11 vitro clinical test from individuals;

12 “(ii) shall not include recall of an in  
13 vitro clinical test from test user facilities if  
14 the Secretary determines that the risk of  
15 recalling such in vitro clinical test from the  
16 facilities presents a greater health risk  
17 than the health risk of not recalling the in  
18 vitro clinical test from use; and

19 “(iii) shall provide for notice to indi-  
20 viduals subject to the risks associated with  
21 the use of such in vitro clinical test. In  
22 providing the notice required by this  
23 clause, the Secretary may use the assist-  
24 ance of health professionals who pre-

1           scribed, ordered, or used such an in vitro  
2           clinical test for individuals.

3           “(4) CLARIFICATION.—The remedy provided by  
4           this subsection shall be in addition to remedies pro-  
5           vided by subsections (b) and (c).”.

6 **SEC. 4. ENFORCEMENT AND OTHER PROVISIONS.**

7           (a) PROHIBITED ACTS.—Section 301 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
9 ed—

10           (1) in paragraphs (a), (b), (c), (g), (k), (q), (r),  
11           and (y), by inserting “in vitro clinical test,” after  
12           “device,” each place it appears;

13           (2) in paragraph (y) by inserting “or 587P”  
14           after “section 523” each place it appears; and

15           (3) by adding at the end, the following:

16           “(fff)(1) The introduction or delivery for introduction  
17 into interstate commerce of an in vitro clinical test in vio-  
18 lation of section 587B(a).

19           “(2) The false, fraudulent, or deceptive claiming for  
20 an in vitro clinical test of an exemption from the pre-  
21 market review required under section 587B.

22           “(3) When claiming an exemption under section  
23 587A from the premarket review required under section  
24 587B, the failure to maintain complete and accurate docu-  
25 mentation for the exemption as required under section

1 587A or the failure to provide labeling required under sec-  
2 tion 587A.

3 “(4) With respect to an in vitro clinical test, the sub-  
4 mission of any report that is required by or under this  
5 Act that is false or misleading in any material respect.

6 “(5) The making of a false, fraudulent, or materially  
7 deceptive analytical or clinical claim for an in vitro clinical  
8 test—

9 “(A) in any application, report, or notification  
10 submitted to the Secretary under this Act; or

11 “(B) in the labeling or advertising of an in vitro  
12 clinical test.

13 “(6) The failure to comply with a condition of ap-  
14 proval, performance standard, mitigating measure, or re-  
15 striction established in an order approving an application  
16 or supplement under section 587B; the failure to perform  
17 a risk analysis required by section 587B; the failure to  
18 submit an annual report required under section 587B(k);  
19 or the failure to complete postmarket studies required  
20 under section 587V.

21 “(7) The marketing of an in vitro clinical test in vio-  
22 lation of—

23 “(A) an order issued by the Secretary under  
24 section 587A; or

25 “(B) any requirement under section 587A.

1       “(8) With respect to technology certification under  
2 section 587D, the refusal to permit, or unreasonable delay  
3 in permitting, an inspection authorized under section  
4 587D(f)(3)(G); the failure to comply with applicable re-  
5 quirements to submit an application or report under sec-  
6 tion 587D(e); or the failure to comply with applicable  
7 maintenance requirements under section 587D(h).

8       “(9) The failure to comply with an applicable miti-  
9 gating measure established under section 587E or to  
10 maintain the documentation required under section  
11 587E(b); or the failure to comply with a performance  
12 standard established under section 587Q.

13       “(10) The failure to register in accordance with sec-  
14 tion 587I, the failure to provide information required  
15 under section 587I(b), or the failure to maintain or submit  
16 information required under section 587I(c).

17       “(11) The failure to submit a report required under  
18 section 587L or 587M; the failure to comply with a re-  
19 striction imposed under section 587N; or the failure to  
20 comply with labeling and advertising requirements under  
21 section 587N(b).

22       “(12) The failure to comply with the requirements  
23 of section 587P (relating to accredited persons).

24       “(13) The failure to comply with any requirement  
25 prescribed or established under section 587R; the failure

1 to furnish any notification, information, material, or re-  
2 port required under section 587R; or the failure to comply  
3 with an order issued under section 587R.”.

4 (b) PENALTIES.—Section 303(f)(1) of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)) is  
6 amended—

7 (1) in subparagraph (A), by inserting “or in  
8 vitro clinical tests” after “devices”; and

9 (2) in subparagraph (B)(i)—

10 (A) by inserting “, or 587J or 587L,”  
11 after “520(f)”; and

12 (B) by inserting “, or who violates section  
13 587M(b) with respect to a correction report”  
14 after “risk to public health”.

15 (c) SEIZURE.—Section 304 of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

17 (1) in subsection (a)(2)—

18 (A) by striking “and” before “(E) Any”;

19 and

20 (B) by inserting “, and (F) Any adulter-  
21 ated or misbranded in vitro clinical test” after  
22 “tobacco product”;

23 (2) in subsection (d)(1), by inserting “in vitro  
24 clinical test,” after “device,”; and

25 (3) in subsection (g)—

1 (A) in paragraph (1), by inserting “, in  
2 vitro clinical test,” after “device” each place it  
3 appears; and

4 (B) in paragraph (2)—

5 (i) in subparagraph (A), by inserting  
6 “, in vitro clinical test,” after “device”;  
7 and

8 (ii) in subparagraph (B), by inserting  
9 “or in vitro clinical test” after “device”  
10 each place it appears.

11 (d) DEBARMENT, TEMPORARY DENIAL OF AP-  
12 PROVAL, AND SUSPENSION.—Section 306 of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is  
14 amended by adding at the end the following:

15 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-  
16 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND  
17 REVIEWS.—

18 “(1) IN GENERAL.—If the Secretary finds that  
19 a person has been convicted of a felony under sec-  
20 tion 301(gg), 301(fff)(2), 301(fff)(5), or 301(fff)(8),  
21 the Secretary shall debar such person from being ac-  
22 credited under section 587P and from carrying out  
23 activities under an agreement described in section  
24 803(b).

1           “(2) DEBARMENT PERIOD.—The Secretary  
2 shall debar a person under paragraph (1) for the fol-  
3 lowing periods:

4           “(A) The period of debarment of a person  
5 (other than an individual) shall not be less than  
6 1 year or more than 10 years, but if an act  
7 leading to a subsequent debarment under such  
8 paragraph occurs within 10 years after such  
9 person has been debarred under such para-  
10 graph, the period of debarment shall be perma-  
11 nent.

12           “(B) The debarment of an individual shall  
13 be permanent.

14           “(3) TERMINATION OF DEBARMENT; JUDICIAL  
15 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),  
16 (e), (i), (j), and (l)(1) apply with respect to a person  
17 (other than an individual) or an individual who is  
18 debarred under paragraph (1) to the same extent  
19 and in the same manner as such subsections apply  
20 with respect to a person who is debarred under sub-  
21 section (a)(1), or an individual who is debarred  
22 under subsection (a)(2), respectively.”.

23           (e) JUDICIAL REVIEW.—Section 517(a) of the Fed-  
24 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a))  
25 is amended—



1 (1) in paragraph (8), by striking “or” at the  
2 end;

3 (2) in paragraph (9), by inserting “or” after  
4 the comma at the end; and

5 (3) before the matter that follows paragraph  
6 (9), by inserting the following:

7 “(10) an order issued pursuant to section  
8 587B, 587D, 587R, or 587S.”.

9 (f) EXPANDED ACCESS TO UNAPPROVED THERAPIES  
10 AND DIAGNOSTICS.—Section 561 of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-  
12 ed—

13 (1) in subsections (a) through (d)—

14 (A) by striking “or investigational devices”  
15 each place it appears and inserting “, investiga-  
16 tional devices, or investigational in vitro clinical  
17 tests”; and

18 (B) by striking “or investigational device”  
19 each place it appears (other than the second  
20 such place in paragraph (3)(A)) and inserting  
21 “, investigational device, or investigational in  
22 vitro clinical test”;

23 (2) in subsection (b)(4) by striking “or 520(g)”  
24 and inserting “, 520(g), or 587R” each place it ap-  
25 pears;

1 (3) in subsection (c)—

2 (A) by amending the subsection heading to  
3 read: “TREATMENT INVESTIGATIONAL NEW  
4 DRUG APPLICATIONS, TREATMENT INVESTIGA-  
5 TIONAL DEVICE EXEMPTIONS, AND TREAT-  
6 MENT INVESTIGATIONAL IN VITRO CLINICAL  
7 TEST EXEMPTIONS”;

8 (B) in paragraph (3)(A), by striking “or  
9 investigational device exemption in effect under  
10 section 520(g)” and inserting “, investigational  
11 device exemption in effect under section 520(g),  
12 or investigational in vitro clinical test exemption  
13 under section 587R”;

14 (C) by striking “or treatment investiga-  
15 tional device exemption” each place it appears  
16 and inserting “, treatment investigational device  
17 exemption, or treatment investigational in vitro  
18 clinical test exemption”; and

19 (D) in the matter following paragraph (7)  
20 by striking “or 520(g)” each place it appears  
21 and inserting “, 520(g) or 587R”; and

22 (4) by amending subsection (e) to read as fol-  
23 lows:

24 “(e) DEFINITIONS.—In this section, the terms ‘inves-  
25 tigational drug’, ‘investigational device’, ‘investigational in

1 vitro clinical test’, ‘treatment investigational new drug ap-  
2 plication’, ‘treatment investigational device exemption’,  
3 and ‘treatment investigational in vitro clinical test exemp-  
4 tion’ shall have the meanings given the terms in regula-  
5 tions prescribed by the Secretary.”.

6 (g) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section  
7 569A(b) of the Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 360bbb–8a(b)) is amended by inserting “an in  
9 vitro clinical test, as defined in subsection (ss) of such sec-  
10 tion,” before “or a biological product”.

11 (h) PATIENT PARTICIPATION IN MEDICAL PRODUCT  
12 DISCUSSION.—The heading of subsection (a) of section  
13 569C of the Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 360bbb–8c) is amended by striking “DRUGS AND  
15 DEVICES” and inserting “DRUGS, DEVICES, AND IN  
16 VITRO CLINICAL TESTS”.

17 (i) REGULATIONS AND HEARINGS.—Section  
18 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic  
19 Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting  
20 “and in vitro clinical tests” after “devices”.

21 (j) FACTORY INSPECTION.—Section 704 of the Fed-  
22 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other  
23 than subsection (g)) is amended—

1           (1) by striking “drugs or devices” each place it  
2 appears and inserting “drugs, devices, or in vitro  
3 clinical tests”;

4           (2) in subsection (a)(1), in the third sentence,  
5 by striking “or chapter IX” and inserting “section  
6 587R or chapter IX”;

7           (3) in subsection (a)(2)(B)—

8                 (A) by inserting “or in vitro clinical tests”  
9 after “prescribe or use devices”; and

10                (B) by inserting “or in vitro clinical tests”  
11 after “process devices”;

12           (4) by inserting “in vitro clinical test,” after  
13 “device,” each place it appears;

14           (5) after making the amendments in para-  
15 graphs (1) and (2), by inserting “in vitro clinical  
16 tests,” after “devices,” each place it appears;

17           (6) in subsection (e), by inserting “, or section  
18 587L, 587M, or 587R,” after “section 519 or  
19 520(g)”;

20           (7) in subsection (f)(3)—

21                 (A) in subparagraph (A), by striking “or”  
22 at the end;

23                 (B) in subparagraph (B), by striking the  
24 period at the end and inserting “; or”;

1 (C) after subparagraph (B), by inserting  
2 the following:

3 “(C) is accredited under section 587P.”.

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) IMPORTS AND EXPORTS.—Section 801 of the  
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)  
12 is amended—

13 (1) in subsection (a)—

14 (A) by inserting “in vitro clinical tests,”  
15 after “devices,” each place it appears; and

16 (B) by inserting “in the case of an in vitro  
17 clinical test, the test does not conform to the  
18 applicable requirements of section 587J, or”  
19 after “requirements of section 520(f), or”;

20 (2) in subsection (d)(3)—

21 (A) in subparagraph (A)—

22 (i) in the matter preceding clause (i),  
23 by inserting “and no component of an in  
24 vitro clinical test or other article of in vitro

1 clinical test that requires further pro-  
2 cessing,” after “health-related purposes”;

3 (ii) in clause (i), by striking “drug or  
4 device” and inserting “drug, device, or in  
5 vitro clinical test”; and

6 (iii) in clause (i)(I), by inserting “in  
7 vitro clinical test,” after “device,”; and

8 (B) in subparagraph (B), by inserting “in  
9 vitro clinical test,” after “device,”; and

10 (3) in subsection (e)(1), by inserting “in vitro  
11 clinical test,” after “device,”.

12 (n) OFFICE OF INTERNATIONAL RELATIONS.—Sec-  
13 tion 803 of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 383) is amended—

15 (1) in subsection (b)—

16 (A) in the matter preceding paragraph (1),  
17 by inserting “and in vitro clinical tests” after  
18 “devices”; and

19 (B) in paragraph (1), by inserting “quality  
20 requirements established under section 587J;  
21 and” at the end; and

22 (2) in subsection (c)—

23 (A) in paragraph (2), by inserting “in vitro  
24 clinical tests,” after “devices,”; and

1 (B) in paragraph (4), by inserting “or in  
2 vitro clinical tests” after “devices”.

3 (o) RECOGNITION OF FOREIGN GOVERNMENT IN-  
4 SPECTIONS.—Section 809(a)(1) of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-  
6 ed by inserting “, or section 587I” after “510(h)”.

7 (p) FOOD AND DRUG ADMINISTRATION.—Section  
8 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. 393(b)(2)) is amended—

10 (1) in subparagraph (D), by striking “and” at  
11 the end;

12 (2) in subparagraph (E), by striking the semi-  
13 colon at the end and inserting “; and”; and

14 (3) by adding at the end the following:

15 “(F) in vitro clinical tests are analytically  
16 and clinically valid;”.

17 (q) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)  
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 399b(b)) is amended—

20 (1) in paragraph (1), by inserting “in vitro clin-  
21 ical tests,” after “devices,”; and

22 (2) in paragraph (4), by striking “and device  
23 manufacturers” and inserting “device manufactur-  
24 ers, and in vitro clinical test developers,”.

1 (r) COUNTERMEASURE PROVISIONS OF THE  
2 PHSA.—Title III of the PHSA is amended—

3 (1) in section 319F–2(c)(1)(B) (42 U.S.C.  
4 247d–6b(c)(1)(B)) is amended—

5 (A) by striking “or device” and inserting  
6 “device”; and

7 (B) by inserting “or an in vitro clinical  
8 test (as that term is defined in section 201(ss)  
9 of the Federal Food, Drug, and Cosmetic Act  
10 (21 U.S.C. 321(ss)))” after “Act (21 U.S.C.  
11 321(h))”;

12 (2) in section 319F–1(a)(2) (42 U.S.C. 247d–  
13 6a(a)(2)), by inserting “an in vitro clinical tests (as  
14 that term is defined in section 201(ss) of the Fed-  
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
16 321(ss)),” before “or device”; and

17 (3) in section 319F–3(i)(7) (42 U.S.C. 247d–  
18 6d(i)(7)), by inserting “an in vitro clinical tests (as  
19 that term is defined in section 201(ss) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
21 321(ss)),” before “or device”.

22 **SEC. 5. TRANSITION.**

23 (a) IMPLEMENTATION.—

24 (1) EFFECTIVE DATE.—



1 (A) IN GENERAL.—Except as otherwise  
2 provided in this section, the amendments made  
3 by this Act apply 4 years after the date of en-  
4 actment of this Act (in this section and in sub-  
5 chapter J of chapter V of the Federal Food,  
6 Drug, and Cosmetic Act, as added by this Act,  
7 referred to in this section as the “effective date  
8 of this Act”).

9 (B) EXCEPTION.—The Secretary of Health  
10 and Human Services (in this section referred to  
11 as the “Secretary”) may take the actions de-  
12 scribed in paragraph (2), and may expend such  
13 funds as the Secretary determines necessary to  
14 ensure an orderly transition.

15 (2) ACTIONS.—The Secretary shall, prior to the  
16 date on which the amendments made by this Act  
17 generally apply pursuant to paragraph (1)—

18 (A) within 1 year of the date of enactment  
19 of this Act hold the public meetings described  
20 in subchapter J of chapter V of the Federal  
21 Food, Drug, and Cosmetic Act, as added by  
22 section 3;

23 (B) within 2 years of the date of enact-  
24 ment of this Act promulgate final regulations

1 required under sections 587B, 587D, 587L,  
2 587M, 587V, and 587W; and

3 (C) within 2 years of the date of enact-  
4 ment of this Act issue final guidance on appli-  
5 cability requirements under section 587A.

6 (3) APPLICABILITY OF REGULATIONS.—Not-  
7 withstanding the date on which guidance or regula-  
8 tions are issued under paragraph (2), no guidance or  
9 regulations issued pursuant to the amendments  
10 made by this Act shall take effect until the effective  
11 date of this Act, as described in paragraph (1), ex-  
12 cept as otherwise provided for transitional tests  
13 under this section.

14 (b) APPLICATION OF AUTHORITIES TO IN VITRO  
15 CLINICAL TESTS UNTIL AND AFTER EFFECTIVE DATE  
16 OF THIS ACT.—Except as provided in subsections (c) and  
17 (d), for any in vitro clinical test as defined in section  
18 201(ss) of the Federal Food, Drug, and Cosmetic Act, as  
19 added by this Act, the following authorities shall apply:

20 (1) TESTS OFFERED PRIOR TO ENACTMENT.—

21 An in vitro clinical test that meets the criteria for  
22 a grandfathered test as set forth in section  
23 587A(c)(2) of the Federal Food, Drug, and Cos-  
24 metic Act, as added by section 3, may continue to  
25 be offered for clinical use and shall be subject only

1 to applicable provisions of section 353 of the Public  
2 Health Service Act and section 587A(a)(4) of the  
3 Federal Food, Drug, and Cosmetic Act, as added by  
4 section 3.

5 (2) TESTS APPROVED OR CLEARED ON OR  
6 AFTER THE DATE OF ENACTMENT BUT PRIOR TO  
7 THE EFFECTIVE DATE.—Before any in vitro clinical  
8 test as defined in section 201(ss) of the Federal  
9 Food, Drug, and Cosmetic Act, as added by this  
10 Act, is first offered, sold, or distributed after the  
11 date of enactment of this Act, but prior to the effec-  
12 tive date of this Act, such product or test shall be  
13 considered a transitional test as described under  
14 subsection (c) and comply with the applicable device  
15 provisions of the Federal Food, Drug, and Cosmetic  
16 Act (21 U.S.C. 301 et seq.) and the Public Health  
17 Service Act (42 U.S.C. 201 et seq.).

18 (3) TESTS UNDER FDA REVIEW BEGINNING ON  
19 OR AFTER THE DATE OF ENACTMENT OF THIS ACT  
20 BUT PRIOR TO IMPLEMENTATION.—For any in vitro  
21 clinical test as defined in section 201(ss) of the Fed-  
22 eral Food, Drug, and Cosmetic Act, as added by this  
23 Act, for which a submission for marketing authoriza-  
24 tion under section 515, clearance under section  
25 510(k), authorization under section 513(f)(2), ap-

1       proval under section 520(m), or emergency use au-  
2       thorization under section 564 of the Federal Food,  
3       Drug, and Cosmetic Act (21 U.S.C. 360e, 360(k),  
4       360e(f)(2), 360j(m), 360bbb-3) or approval under  
5       the Public Health Service Act (42 U.S.C. 201 et  
6       seq.) is pending on the effective date of this Act, the  
7       Secretary may review and take action on such sub-  
8       mission after the effective date of this Act according  
9       to the statutory provision under which such submis-  
10      sion was submitted.

11      (c) APPLICATION OF AUTHORITIES TO TRANSI-  
12      TIONAL AND GRANDFATHERED IN VITRO CLINICAL  
13      TESTS.—

14           (1) DEFINITION.—For purposes of this section,  
15      the term “transitional in vitro clinical test” means  
16      an in vitro clinical test, as defined in section 201(ss)  
17      of the Federal Food, Drug, and Cosmetic Act, as  
18      added by this Act, that—

19           (A) is offered for clinical use during the  
20      period beginning on the date of enactment of  
21      this Act and ending on the date that is 90 days  
22      after the effective 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 for use only within that  
3 certified laboratory or another laboratory within  
4 the organization under common ownership; and

5 (C) is not approved under section 515,  
6 cleared under section 510(k), authorized under  
7 section 513(f)(2), subject to an exemption  
8 under section 520(m), or authorized under sec-  
9 tion 564 of the Federal Food, Drug, and Cos-  
10 metic Act (21 U.S.C. 360e, 360(k), 360c(f)(2),  
11 360j(m), 360bbb-3) or approval under the Pub-  
12 lic Health Service Act (42 U.S.C. 201 et seq.).

13 (2) PREMARKET REVIEW OR TECHNOLOGY CER-  
14 TIFICATION.—A transitional in vitro clinical test  
15 that is the subject of an application for premarket  
16 review under section 587B of the Federal Food,  
17 Drug, and Cosmetic Act or technology certification  
18 application under section 587D of such Act, as  
19 added by this Act, that is submitted prior to the ef-  
20 fective date of this Act may continue to be offered,  
21 sold, or distributed until completion of the Sec-  
22 retary's review of the premarket application or tech-  
23 nology certification application.

24 (d) CONVERSION.—

1           (1) DEEMED PREMARKET APPROVAL.—Any in  
2           vitro clinical test (as defined in section 201(ss) of  
3           the Federal Food, Drug, and Cosmetic Act, as  
4           added by this Act) with a premarket approval under  
5           section 515, a clearance under section 510(k), an  
6           authorization under section 513(f), or a licensure  
7           under section 351 of the Public Health Service Act  
8           (42 U.S.C. 262) is deemed to have an approved ap-  
9           plication under section 587B of the Federal Food,  
10          Drug, and Cosmetic Act, as added by this Act, be-  
11          ginning on the later of—

12                       (A) the effective date of this Act; or

13                       (B) such other date, not later than 3 years  
14                       after such effective date, as the person respon-  
15                       sible for the device selects.

16          (2) DEEMED INVESTIGATIONAL USE AP-  
17          PROVAL.—Any in vitro clinical test (as defined in  
18          section 201(ss) of the Federal Food, Drug, and Cos-  
19          metic Act, as added by this Act) that has an ap-  
20          proved investigational device exemption under sec-  
21          tion 520(g) of the Federal Food, Drug, and Cos-  
22          metic Act (21 U.S.C. 360j(g)) is deemed to have an  
23          approved investigational use under section 587Q of  
24          such Act, as added by this Act, beginning on the ef-  
25          fective date of this Act.

1 (e) INSTRUMENTS.—An instrument (as defined in  
2 section 587 of the Federal Food, Drug, and Cosmetic Act,  
3 as added by this Act) that was purchased prior to the date  
4 of enactment of this Act and was not cleared, authorized,  
5 or approved by the Food and Drug Administration or part  
6 of an instrument family that was cleared, authorized, or  
7 approved by the Food and Drug Administration at the  
8 time of purchase may continue to be used by the purchaser  
9 to develop and introduce into interstate commerce an in  
10 vitro clinical test during the period beginning on the date  
11 of enactment of this Act and ending 5 years after such  
12 date of enactment. Beginning at the end of such period,  
13 any new in vitro clinical test that is developed and intro-  
14 duced into interstate commerce shall be based on an in-  
15 strument (as defined in section 587(11) of the Federal  
16 Food, Drug, and Cosmetic Act, as added by section 3)  
17 that complies with the requirements of the Federal Food,  
18 Drug, and Cosmetic Act, as amended by this Act.

19 (f) RELATION TO IN VITRO CLINICAL TEST PROVI-  
20 SION.—This section applies notwithstanding section  
21 587A(a)(1)(C) of the Federal Food, Drug, and Cosmetic  
22 Act, as added by this Act.

23 **SEC. 6. EMERGENCY USE AUTHORIZATION.**

24 Section 564 of the Federal Food, Drug, and Cosmetic  
25 Act (21 U.S.C. 360bbb–3) is amended—

1 (1) in paragraphs (1) and (4)(C) of subsection  
2 (a), by inserting “in vitro clinical test,” before “or  
3 biological product” each place such term appears;  
4 and

5 (2) in subsection (e)(3)—

6 (A) in subparagraph (B), by striking  
7 “and” at the end;

8 (B) in subparagraph (C), by striking the  
9 period and inserting “; and”; and

10 (C) by adding at the end the following:

11 “(D) quality system requirements (with re-  
12 spect to in vitro clinical tests) under section  
13 587J.”.

14 **SEC. 7. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

15 Section 511A of the Federal Food, Drug, and Cos-  
16 metic Act (21 U.S.C. 360a-2) is amended—

17 (1) in subsection (a)(1)(C)—

18 (A) by striking “or approve under section  
19 515” and inserting “approve under section 515,  
20 or approve, exempt, or issue a technology cer-  
21 tification order under subchapter J”; and

22 (B) by striking “testing devices” and in-  
23 serting “tests”;



1           (2) in subsection (c)(5), by striking “drug or  
2           device” each place it appears and inserting “drug,  
3           device, or in vitro clinical test”;

4           (3) in subsection (e)—

5                 (A) in the heading, by striking “TESTING  
6                 DEVICES” and inserting “IN VITRO CLINICAL  
7                 TESTS”;

8                 (B) in paragraph (1)—

9                     (i) by striking “and 515,” and insert-  
10                     ing “515, 587B, and 587D”;

11                    (ii) by striking “antimicrobial suscep-  
12                    tibility testing device” and inserting “anti-  
13                    microbial susceptibility in vitro clinical  
14                    test”; and

15                    (iii) by striking “such device” and in-  
16                    serting “such test”;

17                 (C) in paragraph (2)—

18                     (i) in the heading, by striking “TEST-  
19                     ING DEVICES” and inserting “IN VITRO  
20                     CLINICAL TESTS”; and

21                     (ii) by amending subparagraph (C) to  
22                     read as follows:

23                     “(C) The antimicrobial susceptibility in  
24                     vitro clinical test meets all other requirements  
25                     to be approved under section 587B or exempted

1 from premarket review under section 587D.”;  
2 and

3 (D) after making the amendments in sub-  
4 paragraphs (B)(ii), (B)(iii), and (C)(ii), by  
5 striking “device” each place it appears and in-  
6 serting “in vitro clinical test”;

7 (4) in subsection (f), by amending paragraph  
8 (1) to read as follows:

9 “(1) The term ‘antimicrobial susceptibility in  
10 vitro clinical test’ means an in vitro clinical test that  
11 utilizes susceptibility test interpretive criteria to de-  
12 termine and report the in vitro susceptibility of cer-  
13 tain microorganisms to a drug (or drugs).”; and

14 (5) in subsection (g)(2)—

15 (A) by amending the matter preceding sub-  
16 paragraph (A) to read as follows:

17 “(2) with respect to clearing under section  
18 510(k), classifying under section 513(f)(2), approv-  
19 ing under section 515 or section 587B, or exempting  
20 from approval requirements under section 587D—”;  
21 and

22 (B) in subparagraph (A)—

23 (i) by striking “device” and inserting  
24 “in vitro clinical test”; and

1                   (ii) by striking “antimicrobial suscep-  
2                   tibility testing device” and inserting “anti-  
3                   microbial susceptibility in vitro clinical  
4                   test”.

5 **SEC. 8. COMBINATION PRODUCTS.**

6           (a) IN GENERAL.—Section 503(g) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is  
8 amended—

9                   (1) in paragraph (1)—

10                   (A) in subparagraph (A)—

11                   (i) by inserting “(except for a com-  
12                   bination product constituted of a device  
13                   and an in vitro clinical test)” after “agency  
14                   center,”; and

15                   (ii) by inserting “in vitro clinical  
16                   test,” before “or biological product”; and

17                   (B) in subparagraph (D)—

18                   (i) in the matter preceding clause (i),  
19                   by striking “. If the Secretary determines”  
20                   and inserting “, except for a combination  
21                   product constituted of a device and an in  
22                   vitro clinical test. For other combination  
23                   products, if the Secretary determines”; and

24                   (ii) in clause (ii)—

1 (I) by inserting “or in vitro clin-  
2 ical test” after “device”; and

3 (II) by inserting “and in vitro  
4 clinical tests” before “shall”;

5 (2) in paragraph (3), by striking “safety and  
6 effectiveness or substantial equivalence” and insert-  
7 ing “safety and effectiveness, substantial equiva-  
8 lence, or analytical validity and clinical validity” be-  
9 fore “for the approved constituent part”;

10 (3) in paragraph (4)—

11 (A) in subparagraph (A), by striking “or  
12 513(f)(2) (submitted in accordance with para-  
13 graph (5))” and inserting “513(f)(2) (sub-  
14 mitted in accordance with paragraph (5)),  
15 587B, or an exempt test under section 587A, as  
16 applicable”; and

17 (B) in subparagraph (B), by inserting “or  
18 587B” after “section 515”;

19 (4) in paragraph (5)(A), by striking “or  
20 510(k)” and inserting “, 510(k), or 587B”;

21 (5) in paragraph (7), by striking “or substan-  
22 tial equivalence” and inserting “, substantial equiva-  
23 lence, or analytical validity and clinical validity”;

24 (6) in paragraph (8), by adding at the end the  
25 following:

1           “(I) This paragraph shall not apply to a  
2           combination product constituted of a device and  
3           an in vitro clinical test.”; and

4           (7) in paragraph (9)—

5           (A) in subparagraph (C)(i), by striking “or  
6           520(g)” and inserting “520(g), or 587B”; and

7           (B) in subparagraph (D), by striking “or  
8           520” and inserting “520, or 587B”.

9           (b) CLASSIFICATION OF PRODUCTS.—Section 563 of  
10          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11          360bbb–2) is amended by adding at the end the following:

12          “(d) EXEMPTION.—This section shall not apply to a  
13          combination product constituted of a device and an in  
14          vitro clinical test.”.

15          **SEC. 9. RESOURCES.**

16          (a) FINDINGS.—Congress finds that the fees author-  
17          ized by this section will be dedicated to meeting the goals  
18          identified in the letters from the Secretary of Health and  
19          Human Services to the Committee on Health, Education,  
20          Labor, and Pensions of the Senate and the Committee on  
21          Energy and Commerce of the House of Representatives,  
22          as set forth in the Congressional Record.

23          (b) ESTABLISHMENT OF USER FEE PROGRAM.—

24                  (1) DEVELOPMENT OF USER FEES FOR IN  
25          VITRO CLINICAL TESTS.—

1 (A) IN GENERAL.—Beginning not later  
2 than October 1, 2021, the Secretary of Health  
3 and Human Services (in this section referred to  
4 as the “Secretary”) shall develop recommenda-  
5 tions to present to Congress with respect to the  
6 goals, and plans for meeting the goals, for the  
7 process of the review of in vitro clinical test ap-  
8 plications submitted under subchapter J of  
9 chapter V of the Federal Food, Drug, and Cos-  
10 metic Act, as added by this Act, for the first 5  
11 fiscal years after fiscal year 2022. In developing  
12 such recommendations, the Secretary shall con-  
13 sult with—

14 (i) the Committee on Energy and  
15 Commerce of the House of Representa-  
16 tives;

17 (ii) the Committee on Health, Edu-  
18 cation, Labor, and Pensions of the Senate;

19 (iii) scientific and academic experts;

20 (iv) health care professionals;

21 (v) representatives of patient and con-  
22 sumer advocacy groups; and

23 (vi) the regulated industry.

24 (B) PRIOR PUBLIC INPUT.—Prior to begin-  
25 ning negotiations with the regulated industry

1 on the authorization of such subchapter J, the  
2 Secretary shall—

3 (i) publish a notice in the Federal  
4 Register requesting public input on the au-  
5 thorization of user fees;

6 (ii) hold a public meeting at which the  
7 public may present its views on the author-  
8 ization, including specific suggestions for  
9 the recommendations submitted under sub-  
10 paragraph (E);

11 (iii) provide a period of 30 days after  
12 the public meeting to obtain written com-  
13 ments from the public suggesting changes  
14 to such subchapter J; and

15 (iv) publish any comments received  
16 under clause (iii) on the website of the  
17 Food and Drug Administration.

18 (C) PERIODIC CONSULTATION.—Not less  
19 frequently than once every month during nego-  
20 tiations with the regulated industry, the Sec-  
21 retary shall hold discussions with representa-  
22 tives of patient and consumer advocacy groups  
23 to continue discussions of the authorization  
24 under such subchapter J and to solicit sugges-  
25 tions to be included in the recommendations

1 transmitted to Congress under subparagraph  
2 (E).

3 (D) PUBLIC REVIEW OF RECOMMENDA-  
4 TIONS.—After negotiations with the regulated  
5 industry, the Secretary shall—

6 (i) present the recommendations de-  
7 veloped under subparagraph (A) to the  
8 Committee on Health, Education, Labor,  
9 and Pensions of the Senate and the Com-  
10 mittee on Energy and Commerce of the  
11 House of Representatives;

12 (ii) publish such recommendations in  
13 the Federal Register;

14 (iii) provide for a period of 30 days  
15 for the public to provide written comments  
16 on such recommendations;

17 (iv) hold a meeting at which the pub-  
18 lic may present its views on such rec-  
19 ommendations; and

20 (v) after consideration of such public  
21 views and comments, revise such rec-  
22 ommendations as necessary.

23 (E) TRANSMITTAL OF RECOMMENDA-  
24 TIONS.—



1 (i) IN GENERAL.—Not later than  
2 June 1, 2021, the Secretary shall transmit  
3 to Congress the revised recommendations  
4 under subparagraph (A), a summary of the  
5 views and comments received under such  
6 subparagraph, and any changes made to  
7 the recommendations in response to such  
8 views and comments.

9 (ii) RECOMMENDATION REQUIRE-  
10 MENTS.—The recommendations trans-  
11 mitted under this subparagraph shall—

12 (I) include the number of full-  
13 time equivalent employees per fiscal  
14 year that are agreed to be hired to  
15 carry out the goals included in such  
16 recommendations for each year of the  
17 5-year period;

18 (II) provide that the amount of  
19 operating reserve balance in the user  
20 fee program established under this  
21 section is not more than the equiva-  
22 lent of 10 weeks of operating reserve;

23 (III) require the development of  
24 a strategic plan for any surplus within  
25 the operating reserve account above

1 the 10-week operating reserve within  
2 2 years of the establishment of the  
3 program;

4 (IV) include an operating reserve  
5 adjustment such that, if the Secretary  
6 has an operating reserve balance in  
7 excess of 10 weeks of such operating  
8 reserves, the Secretary shall decrease  
9 such fee revenue and fees to provide  
10 for not more than 10 weeks of such  
11 operating reserves;

12 (V) if an adjustment is made as  
13 described in subclause (IV), provide  
14 the rationale for the amount of the  
15 decrease in fee revenue and fees shall  
16 be contained in the Federal Register;  
17 and

18 (VI) provide that the fees as-  
19 sessed and collected for the full-time  
20 equivalent employees at the Center for  
21 Devices and Radiological Health, with  
22 respect to which the majority of time  
23 reporting data indicates are dedicated  
24 to the review of in vitro clinical tests,  
25 are not supported by the funds au-

1                   thorized to be collected and assessed  
2                   under section 738 of the Federal  
3                   Food, Drug, and Cosmetic Act (21  
4                   U.S.C. 379j).

5                   (F) PUBLICATION OF RECOMMENDA-  
6                   TIONS.—The Secretary shall publish on the  
7                   website of the Food and Drug Administration  
8                   the revised recommendations under subpara-  
9                   graph (A), a summary of the views and com-  
10                  ments received under subparagraphs (B)  
11                  through (D), and any changes made to the rec-  
12                  ommendations originally proposed by the Sec-  
13                  retary in response to such views and comments.

14                  (G) MINUTES OF NEGOTIATION MEET-  
15                  INGS.—

16                  (i) PUBLIC AVAILABILITY.—Before  
17                  transmitting the recommendations devel-  
18                  oped under subparagraphs (A) through (F)  
19                  to Congress, the Secretary shall make pub-  
20                  licly available, on the website of the Food  
21                  and Drug Administration, minutes of all  
22                  negotiation meetings conducted under this  
23                  subsection between the Food and Drug Ad-  
24                  ministration and the regulated industry.

1                   (ii) CONTENT.—The minutes de-  
2                   scribed under clause (i) shall summarize  
3                   any substantive proposal made by any  
4                   party to the negotiations, any significant  
5                   controversies or differences of opinion dur-  
6                   ing the negotiations, and the resolution of  
7                   any such controversy or difference of opin-  
8                   ion.

9                   (2) ESTABLISHMENT OF USER FEE PRO-  
10                  GRAM.—Effective on October 1, 2021, provided that  
11                  the Secretary transmits the recommendations under  
12                  paragraph (1)(E), the Secretary is authorized to col-  
13                  lect user fees relating to the submission of in vitro  
14                  clinical test applications submitted under subchapter  
15                  J of chapter V of the Federal Food, Drug, and Cos-  
16                  metic Act, as added by this Act. Fees under such  
17                  program shall be assessed and collected only if the  
18                  requirements under paragraph (4) are met.

19                  (3) AUDIT.—

20                  (A) IN GENERAL.—On the date that is 2  
21                  years after first receiving a user fee applicable  
22                  to submission of an in vitro clinical test applica-  
23                  tion submitted under subchapter J of chapter V  
24                  of the Federal Food, Drug, and Cosmetic Act,  
25                  as added by this Act, and on a biennial basis

1           thereafter until October 1, 2027, the Secretary  
2           shall perform an audit of the costs of reviewing  
3           such applications under such subchapter J.  
4           Such an audit shall compare the costs of re-  
5           viewing such applications under such sub-  
6           chapter J to the amount of the user fee applica-  
7           ble to such applications.

8           (B) ALTERATION OF USER FEE.—If the  
9           audit performed under subparagraph (A) indi-  
10          cates that the user fees applicable to applica-  
11          tions submitted under such subchapter J exceed  
12          30 percent of the costs of reviewing such appli-  
13          cations, the Secretary shall alter the user fees  
14          applicable to applications submitted under such  
15          subchapter J such that the user fees do not ex-  
16          ceed such percentage.

17          (C) ACCOUNTING STANDARDS.—The Sec-  
18          retary shall perform an audit under subpara-  
19          graph (A) in conformance with the accounting  
20          principles, standards, and requirements pre-  
21          scribed by the Comptroller General of the  
22          United States under section 3511 of title 31,  
23          United States Code, to ensure the validity of  
24          any potential variability.

1           (4) CONDITIONS.—The user fee program de-  
2           scribed in this subsection shall take effect only if the  
3           Food and Drug Administration issues draft guidance  
4           related to the review requirements for in vitro diag-  
5           nostic tests that would be subject to premarket re-  
6           view under section 587B of the Federal Food, Drug,  
7           and Cosmetic Act, as added by section 3, the review  
8           requirements for test categories eligible for tech-  
9           nology certification under section 587D of such Act,  
10          as added by section 3, and the parameters for the  
11          test categories that would be exempt from any re-  
12          view under subchapter J of chapter V of such Act.

13           (5) USER FEE PROGRAM DEFINITIONS AND RE-  
14          SOURCE REQUIREMENTS.—

15           (A) IN GENERAL.—The term “process for  
16           the review of in vitro clinical test applications”  
17           means the following activities of the Secretary  
18           with respect to the review of premarket applica-  
19           tions under section 587B of the Federal Food,  
20           Drug, and Cosmetic Act (as added by section  
21           3), technology certification applications under  
22           section 587D of such Act (as added by section  
23           3), and supplements for such applications:

24                   (i) The activities necessary for the re-  
25                   view of premarket applications, premarket

1 reports, and supplements to such applica-  
2 tions.

3 (ii) The issuance of action letters that  
4 allow the marketing of in vitro clinical  
5 tests or which set forth in detail the spe-  
6 cific deficiencies in such applications, re-  
7 ports, supplements, or submissions and,  
8 where appropriate, the actions necessary to  
9 place them in condition for approval.

10 (iii) The inspection of manufacturing  
11 establishments and other facilities under-  
12 taken as part of the Secretary's review of  
13 pending premarket applications, technology  
14 certifications, and supplements.

15 (iv) Monitoring of research conducted  
16 in connection with the review of such appli-  
17 cations, supplements, and submissions.

18 (v) Review of in vitro clinical test ap-  
19 plications subject to section 351 of the  
20 Public Health Service Act (42 U.S.C.  
21 262), investigational new drug applications  
22 under section 505(i) of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C.  
24 355(i)), or investigational test exemptions  
25 under section 587A(m) of the Federal

1 Food, Drug, and Cosmetic Act (as added  
2 by section 3), and activities conducted in  
3 anticipation of the submission of such ap-  
4 plications under section 505(i) of the Fed-  
5 eral Food, Drug, and Cosmetic Act or in-  
6 vestigational use under section 587R of the  
7 Federal Food, Drug, and Cosmetic Act (as  
8 added by section 3).

9 (vi) The development of guidance, pol-  
10 icy documents, or regulations to improve  
11 the process for the review of premarket ap-  
12 plications, technology certification applica-  
13 tions, and supplements.

14 (vii) The development of voluntary  
15 test methods, consensus standards, or  
16 mandatory performance standards in con-  
17 nection with the review of such applica-  
18 tions, supplements, or submissions and re-  
19 lated activities.

20 (viii) The provision of technical assist-  
21 ance to in vitro clinical test developers in  
22 connection with the submission of such ap-  
23 plications, reports, supplements, or submis-  
24 sions.



1 (ix) Any activity undertaken in con-  
2 nection with the initial classification or re-  
3 classification of an in vitro clinical test in  
4 connection with any requirement for ap-  
5 proval of an in vitro clinical test.

6 (x) Evaluation of postmarket studies  
7 required as a condition of an approval of  
8 a premarket application of an in vitro clin-  
9 ical test.

10 (xi) Compiling, developing, and re-  
11 viewing information on relevant in vitro  
12 clinical tests to identify issues with the ap-  
13 plicable standard for premarket applica-  
14 tions, technology certification applications,  
15 and supplements.

16 (B) RESOURCE REQUIREMENTS.—Fees col-  
17 lected and assessed under this section shall be  
18 used for the process for the review of in vitro  
19 clinical test applications, as described in sub-  
20 paragraph (A), and shall—

21 (i) be subject to the limitation under  
22 section 738(g)(3) of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C.  
24 379j(g)(3)), in the same manner that fees  
25 collected and assessed under section

1 737(9)(C) of such Act (21 U.S.C.  
2 379i(9)(C)) are subject to such limitation;

3 (ii) include travel expenses for officers  
4 and employees of the Food and Drug Ad-  
5 ministration only if the Secretary deter-  
6 mines that such travel is directly related to  
7 an activity described in subparagraph (A);  
8 and

9 (iii) not be allocated to purposes de-  
10 scribed under section 722(a) of the Con-  
11 solidated Appropriations Act, 2018 (Public  
12 Law 115–141).

13 (c) REPORTS.—

14 (1) PERFORMANCE REPORT.—

15 (A) IN GENERAL.—

16 (i) GENERAL REQUIREMENTS.—Be-  
17 ginning with fiscal year 2021, for each fis-  
18 cal year for which fees are collected under  
19 this section, the Secretary shall prepare  
20 and submit to the Committee on Health,  
21 Education, Labor, and Pensions of the  
22 Senate and the Committee on Energy and  
23 Commerce of the House of Representatives  
24 annual reports concerning the progress of  
25 the Food and Drug Administration in

1 achieving the goals identified in the rec-  
2 ommendations transmitted to Congress by  
3 the Secretary pursuant to subsection  
4 (b)(1)(E) during such fiscal year and the  
5 future plans of the Food and Drug Admin-  
6 istration for meeting the goals.

7 (ii) ADDITIONAL INFORMATION.—Be-  
8 ginning with fiscal year 2021, the annual  
9 report under this subparagraph shall in-  
10 clude the progress of the Food and Drug  
11 Administration in achieving the goals, and  
12 future plans for meeting the goals, includ-  
13 ing—

14 (I) the number of premarket ap-  
15 plications filed under section 587B of  
16 the Federal Food, Drug, and Cos-  
17 metic Act during the applicable fiscal  
18 year;

19 (II) the number of technology  
20 certification applications submitted  
21 under section 587D of the Federal  
22 Food, Drug, and Cosmetic Act during  
23 the applicable fiscal year for each re-  
24 view division; and

1 (III) the number of breakthrough  
2 designations under section 587C of  
3 the Federal Food, Drug, and Cos-  
4 metic Act during the applicable fiscal  
5 year.

6 (iii) REAL-TIME REPORTING.—

7 (I) IN GENERAL.—Not later than  
8 30 calendar days after the end of the  
9 second quarter of fiscal year 2021,  
10 and not later than 30 calendar days  
11 after the end of each quarter of each  
12 fiscal year thereafter, the Secretary  
13 shall post the data described in sub-  
14 clause (II) on the website of the Food  
15 and Drug Administration for such  
16 quarter and on a cumulative basis for  
17 such fiscal year, and may remove du-  
18 plicative data from the annual report  
19 under this subparagraph.

20 (II) DATA.—The Secretary shall  
21 post the following data in accordance  
22 with subclause (I):

23 (aa) The number and titles  
24 of draft and final guidance on  
25 topics related to the process for

1 the review of in vitro clinical  
2 tests, and whether such guid-  
3 ances were issued as required by  
4 statute or pursuant to the rec-  
5 ommendations transmitted to  
6 Congress by the Secretary pursu-  
7 ant to subsection (b)(1)(E).

8 (bb) The number and titles  
9 of public meetings held on topics  
10 related to the process for the re-  
11 view of in vitro clinical tests, and  
12 if such meetings were required by  
13 statute or pursuant to the rec-  
14 ommendations transmitted to  
15 Congress by the Secretary pursu-  
16 ant to subsection (b)(1)(E).

17 (iv) RATIONALE FOR IVCT USER FEE  
18 PROGRAM CHANGES.—Beginning with fis-  
19 cal year 2022, the Secretary shall include  
20 in the annual performance report under  
21 paragraph (1)—

22 (I) data, analysis, and discussion  
23 of the changes in the number of full-  
24 time equivalents hired as agreed upon  
25 in the recommendations transmitted

1 to Congress by the Secretary pursuant  
2 to subsection (b)(1)(E) and the num-  
3 ber of full-time equivalents funded by  
4 budget authority at the Food and  
5 Drug Administration by each division  
6 within the Center for Devices and Ra-  
7 diological Health, the Center for Bio-  
8 logics Evaluation and Research, the  
9 Office of Regulatory Affairs, and the  
10 Office of the Commissioner;

11 (II) data, analysis, and discus-  
12 sion of the changes in the fee revenue  
13 amounts and costs for the process for  
14 the review of in vitro clinical tests, in-  
15 cluding identifying drivers of such  
16 changes; and

17 (III) for each of the Center for  
18 Devices and Radiological Health, the  
19 Center for Biologics Evaluation and  
20 Research, the Office of Regulatory Af-  
21 fairs, and the Office of the Commis-  
22 sioner, the number of employees for  
23 whom time reporting is required and  
24 the number of employees for whom  
25 time reporting is not required.

1 (v) ANALYSIS.—For each fiscal year,  
2 the Secretary shall include in the report  
3 under clause (i) an analysis of the fol-  
4 lowing:

5 (I) The difference between the  
6 aggregate number of premarket appli-  
7 cations filed under section 587B or  
8 section 587D of the Federal Food,  
9 Drug, and Cosmetic Act and the ag-  
10 gregate number of major deficiency  
11 letters, not approvable letters, and de-  
12 nials for such applications issued by  
13 the agency, accounting for—

14 (aa) the number of applica-  
15 tions filed under each of sections  
16 587B and 587D of the Federal  
17 Food, Drug, and Cosmetic Act  
18 during one fiscal year for which a  
19 decision is not scheduled to be  
20 made until the following fiscal  
21 year; and

22 (bb) the aggregate number  
23 of applications under each of sec-  
24 tions 587B and 587D of the  
25 Federal Food, Drug, and Cos-

1            metic Act for each fiscal year  
2            that did not meet the goals as  
3            identified by the recommenda-  
4            tions transmitted to Congress by  
5            the Secretary pursuant to sub-  
6            section (b)(1)(E).

7            (II) Relevant data to determine  
8            whether the Center for Devices and  
9            Radiological Health has met perform-  
10            ance enhancement goals identified by  
11            the recommendations transmitted to  
12            Congress by the Secretary pursuant to  
13            subsection (b)(1)(E).

14           (III) The most common causes  
15           and trends for external or other cir-  
16           cumstances affecting the ability of the  
17           Food and Drug Administration to  
18           meet review time and performance en-  
19           hancement goals identified by the rec-  
20           ommendations transmitted to Con-  
21           gress by the Secretary pursuant to  
22           subsection (b)(1)(E).

23           (B) PUBLICATION.—With regard to infor-  
24           mation to be reported by the Food and Drug  
25           Administration to industry on a quarterly and



1 annual basis pursuant to recommendations  
2 transmitted to Congress by the Secretary pur-  
3 suant to subsection (b)(1)(E), the Secretary  
4 shall make such information publicly available  
5 on the website of the Food and Drug Adminis-  
6 tration not later than 60 days after the end of  
7 each quarter or 120 days after the end of each  
8 fiscal year, respectively, to which such informa-  
9 tion applies.

10 (C) UPDATES.—The Secretary shall in-  
11 clude in each report under subparagraph (A)  
12 information on all previous cohorts for which  
13 the Secretary has not given a complete response  
14 on all in vitro clinical test premarket applica-  
15 tions and technology certification orders and  
16 supplements, premarket, and technology certifi-  
17 cation notifications in the cohort.

18 (2) CORRECTIVE ACTION REPORT.—Beginning  
19 with fiscal year 2022, for each fiscal year for which  
20 fees are collected under this section, the Secretary  
21 shall prepare and submit a corrective action report  
22 to the Committee on Health, Education, Labor, and  
23 Pensions and the Committee on Appropriations of  
24 the Senate and the Committee on Energy and Com-  
25 merce and the Committee on Appropriations of the

1 House of Representatives. The report shall include  
2 the following information, as applicable:

3 (A) GOALS MET.—For each fiscal year, if  
4 the Secretary determines, based on the analysis  
5 under paragraph (1)(A)(v), that each of the  
6 goals identified by the recommendations trans-  
7 mitted to Congress by the Secretary pursuant  
8 to subsection (b)(1)(E) for the applicable fiscal  
9 year have been met, the corrective action report  
10 shall include recommendations on ways in which  
11 the Secretary can improve and streamline the in  
12 vitro clinical test premarket application and  
13 technology certification review process.

14 (B) GOALS MISSED.—For each of the goals  
15 identified by the letters described in rec-  
16 ommendations transmitted to Congress by the  
17 Secretary pursuant to subsection (b)(1)(E) for  
18 the applicable fiscal year that the Secretary de-  
19 termines to not have been met, the corrective  
20 action report shall include—

21 (i) a justification for such determina-  
22 tion;

23 (ii) a description of the types of cir-  
24 cumstances, in the aggregate, under which  
25 applications or reports submitted under

1 sections 587B and 587D of the Federal  
2 Food, Drug, and Cosmetic Act missed the  
3 review goal times but were approved dur-  
4 ing the first cycle review, as applicable;

5 (iii) a summary and any trends with  
6 regard to the circumstances for which a re-  
7 view goal was missed; and

8 (iv) the performance enhancement  
9 goals that were not achieved during the  
10 previous fiscal year and a description of ef-  
11 forts the Food and Drug Administration  
12 has put in place for the fiscal year in  
13 which the report is submitted to improve  
14 the ability of such agency to meet each  
15 such goal for the such fiscal year.

16 (3) FISCAL REPORT.—For fiscal years 2021  
17 and annually thereafter, not later than 120 days  
18 after the end of each fiscal year during which fees  
19 are collected under this subpart, the Secretary shall  
20 prepare and submit to the Committee on Health,  
21 Education, Labor, and Pensions of the Senate and  
22 the Committee on Energy and Commerce of the  
23 House of Representatives, a report on the implemen-  
24 tation of the authority for such fees during such fis-  
25 cal year and the use, by the Food and Drug Admin-

1       istration, of the fees collected during such fiscal year  
2       for which the report is made.

3               (A) 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               (B) OPERATING RESERVE.—Such report  
9               shall provide the amount of operating reserve  
10              balance available each year, and any planned al-  
11              locations or obligations of such balance that is  
12              above 10 weeks of operating reserve for the pro-  
13              gram.

14             (4) PUBLIC AVAILABILITY.—The Secretary  
15             shall make the reports required under paragraphs  
16             (1) through (3) available to the public on the website  
17             of the Food and Drug Administration.

18             (5) ENHANCED COMMUNICATION.—

19               (A) COMMUNICATIONS WITH CONGRESS.—  
20               Each fiscal year, as applicable and requested,  
21               representatives from the Centers with expertise  
22               in the review of in vitro clinical tests shall meet  
23               with representatives from the Committee on  
24               Health, Education, Labor, and Pensions of the  
25               Senate and the Committee on Energy and Com-

1 merce of the House of Representatives to report  
2 on the contents described in the reports under  
3 this section.

4 (B) PARTICIPATION IN CONGRESSIONAL  
5 HEARING.—Each fiscal year, as applicable and  
6 requested, representatives from the Food and  
7 Drug Administration shall participate in a pub-  
8 lic hearing before the Committee on Health,  
9 Education, Labor, and Pensions of the Senate  
10 and the Committee on Energy and Commerce  
11 of the House of Representatives, to report on  
12 the contents described in the reports under this  
13 section. Such hearing shall occur not later than  
14 120 days after the end of each fiscal year for  
15 which fees are collected under this section.

○