

116TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

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

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Mr. BURR (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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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 2020” or the “VALID Act of 2020”.

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

## “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) an article for taking, deriving, hold-  
19 ing, or transporting specimens from the human  
20 body (as defined in section 587(16));

21 “(iv) software, excluding software that is  
22 excluded by section 520(o) from the definition  
23 of a device under section 201(h), and excluding  
24 modifications that are exempt in accordance  
25 with section 587A(1)(2)(A); and

1           “(v) subject to subparagraph (2), a compo-  
2           nent or part of a test, a test protocol, an instru-  
3           ment, an article, or software described in any of  
4           clauses (A) through (D) of such subparagraph,  
5           whether alone or in combination, including re-  
6           agents, calibrators, and controls.

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

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

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

23           “(C) General purpose laboratory equipment, in-  
24           cluding certain pre-analytical equipment, as deter-  
25           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, means that an undetected inac-  
19                 curate result from such test or category—

20                         “(i) presents potential unreasonable  
21                         risk for serious or irreversible harm or  
22                         death to a patient or patients, or would  
23                         otherwise cause serious harm to the public  
24                         health; or

1                   “(ii) is potentially likely to result in  
2                   the absence, delay, or discontinuation of  
3                   life-supporting or life-sustaining medical  
4                   treatment.

5                   “(B) EXCEPTION.—The term ‘high-risk’  
6                   does not include an in vitro clinical test de-  
7                   scribed in subparagraph (A) if mitigating meas-  
8                   ures are established and applied to sufficiently  
9                   mitigate the risk of inaccurate results as de-  
10                  scribed in subparagraph (A), including—

11                  “(i) the degree to which the tech-  
12                  nology for the intended use of the in vitro  
13                  clinical test is well-characterized, and the  
14                  criteria for performance of the test are  
15                  well-established to be sufficient for the in-  
16                  tended use; and

17                  “(ii) the clinical circumstances under  
18                  which the in vitro clinical test is used, and  
19                  the availability of other tests (such as con-  
20                  firmatory or adjunctive tests) or relevant  
21                  material standards.

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

1           “(A) Substance or substances measured by  
2           the in vitro clinical test, such as an analyte,  
3           protein, or pathogen.

4           “(B) Test method.

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

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

10          “(E) Context of use, such as in a clinical  
11          laboratory, in a health care facility, prescription  
12          home use, over-the-counter use, or direct-to-  
13          consumer testing.

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

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

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

4           “(B) have the same intended use or uses  
5           and function;

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

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

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

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

21                 “(B) includes—

22                         “(i) performing pre-analytical and  
23                         post-analytical processes for an in vitro  
24                         clinical test;

1                   “(ii) conducting standard operating  
2                   procedures; and

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

7                   “(14) LOW-RISK.—The term ‘low-risk’, with re-  
8                   spect to an *in vitro* clinical test or category of *in*  
9                   *vitro* clinical tests, means that—

10                   “(A) an undetected inaccurate result from  
11                   such *in vitro* clinical test, or such category of  
12                   *in vitro* clinical tests, when used as intended—

13                   “(i) would cause minimal or no harm,  
14                   or minimal or no disability, or immediately  
15                   reversible harm, or would lead to only a re-  
16                   mote risk of adverse patient impact or ad-  
17                   verse public health impact; or

18                   “(ii) could cause non-life threatening  
19                   injury, harm that is medically reversible, or  
20                   a delay in necessary treatment; or

21                   “(B) mitigating measures are sufficient to  
22                   ensure the test meets the requirements of sub-  
23                   paragraph (A)

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

1           “(A) means requirements that the Sec-  
2           retary determines, based on available evidence,  
3           are necessary—

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

7                   “(ii) to mitigate the risk of harm en-  
8           suing from an inaccurate result or mis-  
9           interpretation of any result; and

10           “(B) includes, as appropriate, applicable  
11           requirements regarding labeling, performance  
12           standards, performance testing, submission of  
13           clinical data, advertising, website posting of in-  
14           formation, clinical studies, postmarket surveil-  
15           lance, user comprehension studies, training, and  
16           conformance to standards.

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

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

24                   “(A) means a developer’s grouping of in  
25           vitro clinical tests that do not significantly dif-

1           fer in control mechanisms, energy sources, or  
2           operating principals and for which design, de-  
3           velopment, and manufacturing, including ana-  
4           lytical and clinical validation as applicable, of  
5           the tests would be addressed in a similar man-  
6           ner or through similar procedures; and

7           “(B) may include clot detection, colori-  
8           metric (non-immunoassay), electrochemical  
9           (non-immunoassay), enzymatic (non-  
10          immunoassay), flow cytometry, fluorometry  
11          (non-immunoassay), immunoassay, mass spec-  
12          trometry or chromatography (such as HPLC),  
13          microbial culture, next generation sequencing  
14          (also known as ‘NGS’), nephelometric or turbidi-  
15          metric (non-immunoassay), singleplex or mul-  
16          tiplex non-NGS nucleic acid analysis, single-  
17          based technology, spectroscopy, and any other  
18          technology, as the Secretary determines appro-  
19          priate.

20          “(18) TEST.—The term ‘test’, unless otherwise  
21          provided, means an in vitro clinical test.

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

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

1           “(i) that has been generated and eval-  
2           uated by persons qualified by training or  
3           experience to do so, using procedures gen-  
4           erally accepted by other persons so quali-  
5           fied; and

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

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

- 13               “(i) peer-reviewed literature;  
14               “(ii) clinical guidelines;  
15               “(iii) reports of significant human ex-  
16               perience with an in vitro clinical test;  
17               “(iv) bench studies;  
18               “(v) case studies or histories;  
19               “(vi) clinical data;  
20               “(vii) consensus standards;  
21               “(viii) reference standards;  
22               “(ix) data registries;  
23               “(x) postmarket data;  
24               “(xi) real world data;  
25               “(xii) clinical trials; and



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

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

12                 “(A) Peer-reviewed literature.

13                 “(B) Practice guidelines.

14                 “(C) Consensus standards.

15                 “(D) Recognized standards of care.

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

17                 “(F) Scientific publication by multiple  
18          sites.

19                 “(G) Adoption by the scientific or clinical  
20          community.

21                 “(H) Real world data.

22          **“SEC. 587A. APPLICABILITY.**

23                 “(a) IN GENERAL.—

24                 “(1) APPLICABILITY OF THIS SUBCHAPTER.—

1           “(A) IN GENERAL.—An in vitro clinical  
2 test shall be subject to the requirements of this  
3 subchapter, except as otherwise provided this  
4 subchapter.

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

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

16                   “(i) applies expressly to in vitro clin-  
17 ical tests; or

18                   “(ii) describes the authority of the  
19 Secretary when regulating such in vitro  
20 clinical tests or subset of in vitro clinical  
21 tests, with respect to—

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

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

1           “(2) LABORATORIES AND BLOOD AND TISSUE  
2 ESTABLISHMENTS.—

3           “(A) RELATION TO LABORATORY CERTIFI-  
4 CATION PURSUANT TO SECTION 353 OF THE  
5 PHSA.—Nothing in this subchapter shall be  
6 construed to modify the authority of the Sec-  
7 retary with respect to laboratories or clinical  
8 laboratories under section 353 of the Public  
9 Health Service Act.

10           “(B) AVOIDING DUPLICATION.—In imple-  
11 menting this subchapter, the Secretary shall  
12 avoid issuing or enforcing regulations that are  
13 duplicative of regulations under section 353..

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

24           “(3) PRACTICE OF MEDICINE.—

1           “(A) IN GENERAL.—Nothing in this sub-  
2 chapter shall be construed to limit or interfere  
3 with the authority of a health care practitioner  
4 to prescribe or administer any legally marketed  
5 in vitro clinical test for any condition or disease  
6 within a health care practitioner-patient rela-  
7 tionship pursuant to applicable Federal or State  
8 law.

9           “(B) RULES OF CONSTRUCTION.—

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

16           “(ii) PROMOTION OF UNAPPROVED  
17 USES.—Nothing in this paragraph shall be  
18 construed to alter any prohibition on the  
19 promotion of unapproved uses of legally  
20 marketed in vitro clinical tests.

21           “(4) SPECIAL RULE.—

22           “(A) PREMARKET REVIEW APPLICABLE.—  
23 Notwithstanding the exemptions from pre-  
24 market review under section 587B set forth in  
25 subsections (b), (c), (d), (e), (f), (g), (h), (j),

1 and (k) an in vitro clinical test (including any  
2 article for taking or deriving specimens) shall  
3 be subject to the requirements of section 587B  
4 if the Secretary determines, in accordance with  
5 subparagraph (B), that—

6 “(i)(I) there is insufficient valid sci-  
7 entific evidence to support the analytical  
8 validity or the clinical validity of such in  
9 vitro clinical test; and

10 “(II) such in vitro clinical test is  
11 being offered by its developer with materi-  
12 ally deceptive or fraudulent analytical or  
13 clinical claims;

14 “(ii) it is reasonably possible that  
15 such in vitro clinical test will cause serious  
16 adverse health consequences; or

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

24 “(B) PROCESS.—

1                   “(i) REQUEST FOR INFORMATION.—If  
2                   the Secretary has valid scientific evidence  
3                   indicating that the criteria listed in sub-  
4                   paragraph (A) apply to an in vitro clinical  
5                   test, the Secretary may request that the  
6                   developer of the test submit information—

7                                 “(I) pertaining to such criteria;  
8                                 and

9                                 “(II) establishing the basis for  
10                                any claimed exemption from pre-  
11                                market review.

12                   “(ii) DEADLINE FOR SUBMITTING IN-  
13                   FORMATION.—Upon receiving a request for  
14                   information under clause (i), the developer  
15                   of an in vitro clinical test shall submit the  
16                   information within 30 days of such receipt.

17                   “(iii) REVIEW DEADLINE.—Upon re-  
18                   ceiving a submission under clause (ii), the  
19                   Secretary shall—

20                                “(I) review the submitted infor-  
21                                mation within 60 calendar days of  
22                                such receipt; and

23                                “(II) determine whether the cri-  
24                                teria listed in subparagraph (A) apply  
25                                to the in vitro clinical test.

1                   “(iv)   PREMARKET   REVIEW   RE-  
2                   QUIRED.—

3                   “(I)   IN GENERAL.—If the Sec-  
4                   retary finds that the criteria listed in  
5                   subparagraph (A) apply to the in vitro  
6                   clinical test, the developer shall—

7                   “(aa)   promptly, and not  
8                   later than 90 days after the date  
9                   of receipt of such information,  
10                  submit an application for pre-  
11                  market review of the test under  
12                  section 587B; or

13                  “(bb)   cease to market the  
14                  test.

15                  “(II)   EXTENSION.—The Sec-  
16                  retary may grant an extension to a  
17                  developer of the 90-day time period  
18                  under subclause (I)(aa), as appro-  
19                  priate.

20                  “(v)   CONTINUED   MARKETING.—Dur-  
21                  ing the period beginning on the date of a  
22                  request for information under clause (ii)  
23                  and ending on the date of the disposition  
24                  of an application for premarket review of  
25                  the in vitro clinical test under section

1 587B, the developer of the test may con-  
2 tinue to market the test for clinical use,  
3 unless the Secretary issues an order to the  
4 developer under clause (vi) to immediately  
5 cease distribution of the test.

6 “(vi) ORDER TO CEASE DISTRIBUTION.—  
7

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



1                   “(aa) cease distribution of  
2                   the test pending approval of an  
3                   application for premarket review  
4                   of the test under section 587B;  
5                   and

6                   “(bb) notify health profes-  
7                   sionals and other user facilities of  
8                   the order to cease distribution  
9                   and advise health care profes-  
10                  sionals to cease use of such in  
11                  vitro clinical test.

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

1 by the order, the Secretary shall ter-  
2minate the order within 30 days of  
3the hearing. Upon terminating an  
4order, the Secretary shall provide  
5written notice of such termination to  
6the developer.

7 “(vii) AMENDMENT TO REQUIRE RE-  
8CALL.—If the Secretary determines that  
9an order issued under clause (vi) should be  
10amended to include a recall of the in vitro  
11clinical test with respect to which the order  
12was issued, the Secretary shall amend the  
13order to require a recall. In such amended  
14order, the Secretary shall specify a time-  
15table in which the in vitro clinical test re-  
16call will occur and shall require periodic re-  
17ports to the Secretary describing the  
18progress of the recall. Upon termination of  
19the recall, the Secretary shall provide writ-  
20ten notice of such termination to the devel-  
21oper.

22 “(viii) EFFECT OF TEST APPROVAL.—  
23Any order issued under this paragraph  
24with respect to an in vitro clinical test  
25shall cease to be in effect if such test is

1 granted approval under section 587B, pro-  
2 vided that the in vitro clinical test is devel-  
3 oped and offered for clinical use in accord-  
4 ance with such approval.

5 “(5) EMERGENCY USE.—

6 “(A) IN GENERAL.—In the case of a public  
7 health emergency under section 319 of the Pub-  
8 lic Health Service Act, an in vitro clinical test  
9 is exempt from the requirements of this sub-  
10 chapter and may be lawfully marketed in ac-  
11 cordance with subparagraph (B).

12 “(B) CRITERIA.—An in vitro clinical test  
13 may be lawfully marketed in accordance with  
14 the exemption described in subparagraph (A) if  
15 such test—

16 “(i) is authorized for an emergency  
17 use under section 564(b); or

18 “(ii) is developed and used in labora-  
19 tories for which a certificate is in effect  
20 under section 353 of the Public Health  
21 Service Act to conduct high-complexity  
22 testing and the developer—

23 “(I) is pursuing an emergency  
24 use authorization under section 564  
25 and provides updates to the Secretary

1 on efforts to pursue such authoriza-  
2 tion;

3 “(II) validates such in vitro clin-  
4 ical test prior to use;

5 “(III) notifies the Secretary of  
6 the assay validation; and

7 “(IV) includes a statement to-  
8 gether with the results of the test that  
9 reads: ‘This IVCT was developed for  
10 use as a part of a response to a public  
11 health emergency. This test has not  
12 been reviewed by the Food and Drug  
13 Administration.’.

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

22 “(D) STREAMLINING OF APPLICATION RE-  
23 VIEW.—A developer may include any data or in-  
24 formation already submitted to the Secretary  
25 within the emergency use authorization as a

1 part of a premarket application under section  
2 587B or a technology certification application  
3 under section 587D.

4 “(b) COMPONENTS AND PARTS.—

5 “(1) EXEMPTION.—

6 “(A) IN GENERAL.—Subject to subpara-  
7 graph (B), a component, part, or raw material  
8 described in section 201(ss)(1)(F) is exempt  
9 from the requirements of this subchapter if it  
10 is—

11 “(i) intended for further development  
12 as described in paragraph (2); or

13 “(ii) is otherwise to be regulated  
14 based on its risk when used as intended by  
15 the developer, notwithstanding its subse-  
16 quent use by a developer as a component,  
17 part, or raw material of another in vitro  
18 clinical test.

19 “(B) INAPPLICABILITY TO OTHER  
20 TESTS.—Notwithstanding subparagraph (A), an  
21 in vitro clinical test that is described in section  
22 201(ss)(1)(B) and that uses a component or  
23 part described in such subparagraph shall be  
24 subject to the requirements of this subchapter,

1           unless the test is otherwise exempted under this  
2           section.

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

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

9                   “(B) in the case of such a test that is in-  
10                  troduced or delivered for introduction into  
11                  interstate commerce after the date of enactment  
12                  of the Verifying Accurate Leading-edge IVCT  
13                  Development Act of 2020, the labeling of such  
14                  test bears the following statement: ‘This prod-  
15                  uct is intended solely for further development of  
16                  an in vitro clinical test and is exempt from  
17                  FDA regulation. This product must be evalu-  
18                  ated by the in vitro clinical test developer if it  
19                  is used with or in the development of an in vitro  
20                  clinical test.’.

21           “(c) GRANDFATHERED TESTS.—

22                   “(1) EXEMPTION.—An in vitro clinical test that  
23                  meets the criteria set forth in paragraph (2) is ex-  
24                  empt from the requirements of this subchapter, ex-  
25                  cept as provided under section 587A(a)(4), the reg-

1       istration and listing requirements under section  
2       587I, and the adverse reporting requirements under  
3       section 587L, and may be lawfully marketed subject  
4       to the other applicable requirements of this Act, if—

5               “(A) each test report template for the test  
6               bears a statement of adequate prominence that  
7               reads as follows: ‘This in vitro clinical test was  
8               developed and first introduced prior to the date  
9               of enactment of the Verifying Accurate Lead-  
10              ing-edge IVCT Development Act of 2020 and  
11              has not been reviewed by the Food and Drug  
12              Administration.’; and

13             “(B) the developer of the test—

14               “(i) maintains documentation dem-  
15               onstrating that the test meets and con-  
16               tinues to meet the criteria set forth in  
17               paragraph (2); and

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

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

23               “(A)(i) was first offered for clinical use by  
24               such laboratory before the date of enactment of

1 the Verifying Accurate Leading-edge IVCT De-  
2 velopment Act of 2020;

3 “(ii) was developed by a clinical laboratory  
4 for which a certificate is in effect under section  
5 353 of the Public Health Service Act that  
6 meets the requirements under section 353 for  
7 performing high-complexity testing; and

8 “(iii) is performed—

9 “(I) in the same clinical laboratory in  
10 which it was developed;

11 “(II) by another clinical laboratory for  
12 which a certificate is in effect under sec-  
13 tion 353 within the same corporate organi-  
14 zation and having common ownership by  
15 the same parent corporation; or

16 “(III) by a laboratory within a public  
17 health laboratory network coordinated or  
18 managed by the Centers for Disease Con-  
19 trol and Prevention;

20 “(B) does not have in effect an approval  
21 under section 515, a clearance under section  
22 510(k), an authorization under section  
23 513(f)(2), or an approval under section 520(m);  
24 and



1           “(C) is not modified on or after the date  
2           of enactment of the Verifying Accurate Lead-  
3           ing-edge IVCT Development Act of 2020 by its  
4           initial developer (or another person) in a man-  
5           ner such that the test is a new in vitro clinical  
6           test under subsection (l).

7           “(3) MODIFICATIONS.—In the case of a modi-  
8           fication to an vitro clinical test that is exempt as  
9           specified in paragraph (1) or determines that such  
10          modification is otherwise not subject to premarket  
11          review pursuant to section 587A(l), the test con-  
12          tinues to qualify for such exemption if the person  
13          modifying such test—

14                 “(A) documents each such modification  
15                 and maintains a summary of the basis for such  
16                 determination; and

17                 “(B) provides such documentation and  
18                 summary to the Secretary upon request or in-  
19                 spection.

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

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

1           “(A)(i) was offered for clinical use prior to  
2           the date of enactment of the Verifying Accurate  
3           Leading-edge IVCT Development Act of 2020;  
4           and

5           “(ii) immediately prior to such date of en-  
6           actment was exempt pursuant to subsection (l)  
7           or (m)(2) of section 510 from the requirements  
8           for submission of a report under section 510(k);  
9           or

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

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

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

19           “(2) EFFECT ON SPECIAL CONTROLS.—For any  
20           in vitro clinical test, or category of in vitro clinical  
21           tests, that is exempt from premarket review based  
22           on the criteria in paragraph (2), any special control  
23           that applied to a device within a predecessor cat-  
24           egory immediately prior to the date of enactment of  
25           Verifying Accurate Leading-edge IVCT Development

1 Act of 2020 shall be deemed a mitigating measure  
2 applicable under section 587E to an in vitro clinical  
3 test within the successor category, except to the ex-  
4 tent such mitigating measure is withdrawn or  
5 changed in accordance with section 587E.

6 “(3) NEAR-PATIENT TESTING.—Not later than  
7 1 year after the date of enactment of the Verifying  
8 Accurate Leading-edge IVCT Development Act of  
9 2020, the Secretary shall issue draft guidance indi-  
10 cating categories of tests that shall be exempt from  
11 premarket review under section 587B when offered  
12 for near-patient testing (point of care), which were  
13 not exempt from submission of a report under sec-  
14 tion 510(k) pursuant to subsection (l) or (m)(2) of  
15 section 510 and regulations imposing limitations on  
16 exemption for in vitro devices intended for near-pa-  
17 tient testing (point of care).

18 “(e) LOW-RISK TESTS.—

19 “(1) EXEMPTION.—An in vitro clinical test is  
20 exempt from premarket review under section 587B  
21 and may be lawfully marketed subject to the other  
22 applicable requirements of this Act, including section  
23 587I(b)(6), if such test meets the definition of low-  
24 risk under section 587.

25 “(2) LIST OF LOW RISK TESTS.—

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

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

10           “(i) all in vitro clinical tests and cat-  
11 egories of in vitro clinical tests that are ex-  
12 empt from premarket review pursuant to  
13 subsection (d)(1) or (d)(3); and

14           “(ii) all in vitro clinical tests and cat-  
15 egories of in vitro clinical tests that are  
16 designated by the Secretary pursuant to  
17 subparagraph (C) as low-risk for purposes  
18 of this subsection.

19           “(C) DESIGNATION OF TESTS AND CAT-  
20 EGORIES.—Without regard to subchapter II of  
21 chapter 5 of title 5, United States Code, the  
22 Secretary may designate, in addition to the  
23 tests and categories described in subparagraph  
24 (B)(i), additional in vitro clinical tests, and cat-  
25 egories of in vitro clinical tests, as low-risk in

1           in vitro clinical tests for purposes of the exemption  
2           under this subsection. The Secretary may make  
3           such a designation on the Secretary’s own ini-  
4           tiative or in response to a request by any per-  
5           son. In making such a designation for a test or  
6           category of tests, the Secretary shall consider—

7                   “(i) whether the test, or category of  
8                   tests, is low-risk (as defined in section  
9                   587); and

10                   “(ii) such other factors as the Sec-  
11                   retary determines to be relevant to the pro-  
12                   tection of the public health.

13           “(f) MANUAL TESTS.—

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

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

1            requirements under section 353 for performing  
2            high-complexity testing;

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

8                  “(C) is not intended for testing donors, do-  
9            nations, and recipients of blood, blood compo-  
10          nents, human cells, tissues, cellular-based prod-  
11          ucts, or tissue-based products.

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

16                “(A) no component or part of such test, in-  
17          cluding any reagent, is introduced into inter-  
18          state commerce under the exemption under sub-  
19          section (b)(1) (relating to components or parts  
20          intended for further development), and any ar-  
21          ticle for taking or deriving specimens from the  
22          human body used in conjunction with the test  
23          remains subject to the requirements of this sub-  
24          chapter; or

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

4           “(g) HUMANITARIAN TEST EXEMPTION.—

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

9           “(A) such in vitro clinical test—

10           “(i) is intended for use for a disease  
11           or condition for which no more than  
12           10,000 (or such other number determined  
13           by the Secretary) individuals would be sub-  
14           ject to negative or positive diagnosis by  
15           such test in the United States per year;  
16           and

17           “(ii) is not intended to diagnose a  
18           contagious disease or condition that is  
19           highly likely to result in fatal or irrevers-  
20           ibly debilitating outcome and for which  
21           prompt and accurate diagnosis offers the  
22           opportunity to mitigate a public health im-  
23           pact of the condition; and

24           “(B) the developer of the test—

1                   “(i) maintains documentation (which  
2                   may include literature citations in special-  
3                   ized medical journals, textbooks, special-  
4                   ized medical society proceedings, govern-  
5                   mental statistics publications, or, if no  
6                   such studies or literature citations exist,  
7                   credible conclusions from appropriate re-  
8                   search or surveys) demonstrating that such  
9                   test meets and continues to meet the cri-  
10                   teria described in this paragraph; and

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

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

17                   “(h) CUSTOM TESTS AND LOW-VOLUME TESTS.—An  
18                   in vitro clinical test is exempt from premarket review  
19                   under section 587B, the quality requirements under sec-  
20                   tion 587J, and the notification requirements under section  
21                   587I, and may be lawfully marketed subject to the other  
22                   applicable requirements of this Act, if—

23                   “(1) such in vitro clinical test—

24                   “(A) is a low volume test performed in a  
25                   laboratory in which it was developed or devel-



1           oped in a laboratory within the same corporate  
2           organization with the laboratory in which such  
3           test is performed and is administered to no  
4           more than 5 patients per year, unless otherwise  
5           determined by the Secretary; or

6                   “(B) is a custom test developed or modi-  
7                   fied to diagnose a unique pathology or physical  
8                   condition of a specific patient for which no  
9                   other in vitro clinical test is commercially avail-  
10                  able in the United States, and is—

11                           “(i) not intended for use with respect  
12                           to other patients; and

13                           “(ii) after the development of the cus-  
14                           tom test, not included in any test menu,  
15                           template test report, or other promotional  
16                           materials, and not otherwise advertised;  
17                           and

18           “(2) the developer of the test—

19                   “(A) maintains documentation dem-  
20                   onstrating that such test meets and continues  
21                   to meet the applicable criteria described in  
22                   paragraph (1);

23                   “(B) makes such documentation, such as a  
24                   prescription order requesting the custom test

1 for an individual patient, available to the Sec-  
2 retary upon request; and

3 “(C) informs the Secretary, on an annual  
4 basis, in a manner prescribed by the Secretary  
5 by guidance, that such test was introduced into  
6 interstate commerce.

7 “(i) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

8 “(1) IN GENERAL.—The provisions of this sub-  
9 chapter shall not apply to a test intended by the de-  
10 veloper to be used solely for public health surveil-  
11 lance activities, including the collection and testing  
12 of information or biospecimens, conducted, sup-  
13 ported, requested, ordered, required, or authorized  
14 by a public health authority.

15 “(2) LIMITATION.—Such activities—

16 “(A) are limited to those necessary to  
17 allow a public health authority to identify, mon-  
18 itor, assess, or investigate potential public  
19 health signals, onsets of disease outbreaks, or  
20 conditions of public health importance (includ-  
21 ing trends, risk factors, patterns in diseases, or  
22 increases in injuries from using consumer prod-  
23 ucts); and

24 “(B) include those associated with pro-  
25 viding timely situational awareness and priority

1           setting during the course of a threat to the pub-  
2           lic health (including natural or man-made dis-  
3           asters and deliberate attacks on the United  
4           States).

5           “(3) EXCLUSION.—An in vitro clinical test is  
6           not excluded from the provisions of this subchapter  
7           if such test is intended for use in making clinical de-  
8           cisions for individual patients.

9           “(j) LAW ENFORCEMENT OR EMPLOYER TESTING.—  
10          An in vitro clinical test that is intended solely for use in  
11          forensic analysis, law enforcement activity, or employment  
12          purposes is exempt from the requirements of this Act. An  
13          in vitro clinical test that is intended for use in making  
14          clinical decisions for individual patients, or whose individ-  
15          ually identifiable results may be reported back to an indi-  
16          vidual patient or the patient’s health care provider, even  
17          if also intended for law enforcement or employment testing  
18          purposes, is not intended solely for use in law enforcement  
19          or employment testing for purposes of this subsection.

20          “(k) IN VITRO CLINICAL TESTS UNDER A TECH-  
21          NOLOGY CERTIFICATION ORDER.—An in vitro clinical test  
22          that is within the scope of a technology certification order,  
23          as described in section 587D(a)(2), is exempt from pre-  
24          market review under section 587B.

25          “(l) MODIFIED TESTS.—

1           “(1) IN GENERAL.—An in vitro clinical test  
2           that is modified, by the initial developer of the test  
3           or a different person, is a new in vitro clinical test  
4           subject to the requirements of this subchapter if the  
5           modification—

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

8                   “(B) causes the test to no longer comply  
9                   with applicable mitigating measures under sec-  
10                  tion 587E or restrictions under section 587N;  
11                  or

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

16           “(2) EXEMPTIONS.—Notwithstanding para-  
17           graph (1), an in vitro clinical test that is modified  
18           by the initial developer of the test or a different per-  
19           son is not a new in vitro clinical test if the modifica-  
20           tion—

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

1           “(B) is made pursuant to methods or cri-  
2           teria included in the change protocol premarket  
3           submission, amendment, or supplement ap-  
4           proved by the Secretary for the in vitro clinical  
5           test being modified;

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

8           “(D) is a specimen-related modification  
9           that is made to extend specimen stability or  
10          aligns with the data and information submitted  
11          in an approved application for premarket review  
12          under section 587B or an order issued under  
13          section 587D.

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

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

24                 “(B) provides such documentation to the  
25                 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            tice 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 subclause  
3           (A)(ii) are not met, then the technology certifi-  
4           cation order cannot be transferred and the  
5           transferee or purchaser of an in vitro clinical  
6           test must submit an application for technology  
7           certification and obtain a technology certifi-  
8           cation order prior to offering the test for clin-  
9           ical 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(10), an  
13 explanation of how the development and  
14 validation activities, as applicable, support  
15 that the test meets the applicable standard  
16 under 587(10), and a discussion of any ad-  
17 verse effects of the test on health and pro-  
18 posals to mitigate those risks, if any.

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

22 “(D) A bibliography of all published re-  
23 ports reasonably known to the applicant related  
24 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                 2020, 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; and

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 2020, 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 subsections  
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 address a  
22 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 (B) 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 matter listed in subparagraph  
17                           (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 in sub-  
24                       section (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).

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

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

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

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

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

23        “(b) ESTABLISHMENT OF PROGRAM.—The Secretary  
24        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           would 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 section 515B(e) when reviewing such  
19          tests. Any reference or authorization in section 515B(e)  
20          with respect to a device shall be deemed a reference or  
21          authorization with respect to an in vitro clinical test for  
22          purposes of this section.

23          “(f) GUIDANCE.—

24                   “(1) IN GENERAL.—Not later than one year  
25          after the date of enactment of the Verifying Accu-

1 rate Leading-edge IVCT Development Act of 2020,  
2 the Secretary shall issue draft guidance on the im-  
3 plementation of this section. Such guidance shall—

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

7 “(B) provide a template for request under  
8 subsection (d);

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

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

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

23 “(g) ANNUAL REPORT.—Unless otherwise specified  
24 by the Secretary, the requirements under section 587B(k)



1 apply to in vitro clinical tests designated under this sec-  
2 tion.

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

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

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

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

13 “(a) IN GENERAL.—

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

17 “(2) EXCEPTION.—An in vitro clinical test is  
18 exempt from premarket review under section 587B  
19 if the developer is eligible under this section and the  
20 in vitro clinical test—

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

23 “(B) falls within the scope of a technology  
24 certification order issued under this section,  
25 and such order is in effect.

1 “(b) ELIGIBILITY.—

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

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

10 “(i) such violation occurred more than  
11 5 years prior to the date on which such  
12 technology certification order is or would  
13 be sought;

14 “(ii) such violation has been resolved;  
15 or

16 “(iii) such violation is not pertinent to  
17 any in vitro clinical test within the scope of  
18 the technology certification order that such  
19 person seeks or would seek; or

20 “(B) such person fails to maintain re-  
21 quired certifications under section 353 of the  
22 Public Health Service Act;

23 “(C) has been found to have submitted in-  
24 formation that—

1 “(i) makes false or misleading state-  
2 ments about a technology certification  
3 order previously issued or an application  
4 approved under section 587B; or

5 “(ii) violates any requirement of this  
6 subchapter related to technology certifi-  
7 cation under this section or approval under  
8 section 587B, where such violation exposes  
9 persons to serious risk of illness, injury, or  
10 death.

11 “(2) ELIGIBLE IN VITRO CLINICAL TEST.—An  
12 in vitro clinical test is eligible under subsection  
13 (a)(2) for exemption from premarket review under  
14 section 587B unless—

15 “(A) such test is—

16 “(i) a component or part of an in  
17 vitro clinical test as described under sec-  
18 tion 201(ss)(1)(B)(v);

19 “(ii) an instrument under section  
20 201(ss)(1)(B)(ii);

21 “(iii) a specimen receptacle under sec-  
22 tion 201(ss)(1)(B)(iii); or

23 “(iv) an in vitro clinical test, including  
24 reagents used in such tests, intended for  
25 use for testing donors, donations, and re-

1           cipients of blood, blood components,  
2           human cells, tissues, cellular-based prod-  
3           ucts, or tissue-based products; or

4           “(B) unless otherwise permitted pursuant  
5           to section 587F, such test is—

6                   “(i) a first-of-a-kind in vitro clinical  
7           test;

8                   “(ii) a test system for home use;

9                   “(iii) a high risk in vitro clinical test;

10                   “(iv) a cross-referenced in vitro clin-  
11           ical test; or

12                   “(v) a direct-to-consumer in vitro clin-  
13           ical test.

14           “(c) PUBLIC MEETING AND INPUT.—

15                   “(1) PUBLIC DOCKET.—Not later than 30 days  
16           after the date of enactment of the Verifying Accu-  
17           rate Leading-edge IVCT Development Act of 2020,  
18           the Secretary shall establish a public docket to re-  
19           ceive comments concerning recommendations for im-  
20           plementation of this section, including criteria and  
21           procedures for subsections (e) through (j). The pub-  
22           lic docket shall remain open for the duration of time  
23           that this section remains in effect.

24                   “(2) PUBLIC MEETING.—Not later than 180  
25           days after the date of enactment of the Verifying

1 Accurate Leading-edge IVCT Development Act of  
2 2020, the Secretary shall convene a public meeting  
3 to which stakeholders from organizations rep-  
4 resenting patients and consumers, academia, and the  
5 in vitro clinical test industry are invited in order to  
6 discuss components of the technology certification  
7 process including application requirements, inspec-  
8 tions, alignment with third-party accreditors, and  
9 the definition of ‘technology’ under section 587(17).  
10 The public meeting shall be assigned a docket num-  
11 ber by the Commissioner of Food and Drugs and  
12 made available for the submission of public com-  
13 ments.

14 “(d) GUIDANCE.—In accordance with section 5 of the  
15 Verifying Accurate Leading-edge IVCT Development Act  
16 of 2020, the Secretary shall issue a draft guidance on  
17 technology review including describing criteria or proce-  
18 dures relating to technology review under this section,  
19 which shall be subject to public comment for a minimum  
20 of 60 days from issuance prior to finalizing such guidance  
21 documents after considering the comments received. The  
22 guidance shall include an outline of the application and  
23 recertification process, opportunities to meet with officials  
24 of the Food and Drug Administration, plans to streamline  
25 inspections, and a list of applicable technologies. The guid-

1   ance shall be updated as appropriate, and not less fre-  
2   quently than each time the Secretary identifies a unique  
3   technology.

4       “(e) APPLICATION FOR TECHNOLOGY CERTIFI-  
5   CATION.—

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

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

12           “(A) a statement identifying the scope of  
13   the proposed technology certification, which  
14   shall be no broader than a single technology in-  
15   tended to be offered under the application;

16           “(B) information showing that the person  
17   seeking a technology certification order is an el-  
18   igible person under subsection (b)(1);

19           “(C) information showing that the methods  
20   used in, and the facilities and controls used for,  
21   the development of eligible in vitro clinical tests  
22   covered by the scope of the technology certifi-  
23   cation conform to the applicable quality require-  
24   ments of section 587J;

1           “(D) procedures for analytical validation,  
2 including all procedures for validation,  
3 verification, and acceptance criteria, and an ex-  
4 planation as to how such procedures, when  
5 used, provide a reasonable assurance of analyt-  
6 ical validity of all eligible in vitro clinical tests  
7 within the proposed scope of technology certifi-  
8 cation order;

9           “(E) information showing that the person  
10 has an established clinical program, including  
11 procedures for clinical validation, including all  
12 procedures for validation, verification, and ac-  
13 ceptance criteria, and an explanation as to how  
14 such procedures, when used, provide a reason-  
15 able assurance of clinical validity of all eligible  
16 in vitro clinical tests within the proposed scope  
17 of technology certification order;

18           “(F) a notification under section 587I for  
19 each applicable in vitro clinical test that the de-  
20 veloper plans to offer initially upon receiving a  
21 technology certification order and that would be  
22 introduced or delivered for introduction into  
23 interstate commerce upon the issuance of the  
24 technology certification order;

1           “(G) information concerning one or more  
2 representative in vitro clinical tests, including—

3                   “(i) one of the tests within the scope  
4 of the technology certification application  
5 with the greatest analytical complexity at  
6 the time of the filing of the application  
7 under this section that would be introduced  
8 or delivered for introduction into interstate  
9 commerce upon the issuance of the tech-  
10 nology certification order to serve as the  
11 representative test and validate and run  
12 within the developer’s stated scope, and a  
13 rationale for such selection;

14                   “(ii) the information specified in sub-  
15 section (c) or (d) of section 587B for the  
16 representative in vitro clinical test or tests,  
17 except that raw data shall be provided for  
18 any such in vitro clinical test unless the  
19 Secretary determines otherwise;

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



1 developer includes in the application under  
2 subparagraphs (C), (D), (E), and (F); and

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

8 “(H) such other information relevant to  
9 the subject matter of the application as the Sec-  
10 retary may require; 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 “(f) ACTION ON AN APPLICATION FOR TECHNOLOGY  
17 CERTIFICATION.—

18 “(1) SECRETARY RESPONSE.—

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

23 “(i) issue a technology certification  
24 order granting the application, which shall  
25 specify the scope of the technology certifi-

1 cation, if the Secretary finds that all of the  
2 grounds in paragraph (3) are met; or

3 “(ii) deny the application if the Sec-  
4 retary finds (and sets forth the basis of  
5 such finding as part of or accompanying  
6 such denial) that one or more grounds for  
7 granting the application specified in para-  
8 graph (3) are not met.

9 “(B) EXTENSION.—The timeline described  
10 in subparagraph (A) may be extended by mu-  
11 tual agreement between the Secretary and the  
12 applicant.

13 “(2) DEFICIENT APPLICATIONS.—If, after re-  
14 ceipt of an application under this section, the Sec-  
15 retary determines that any portion of such applica-  
16 tion is deficient, the Secretary, not later than 90  
17 days after receipt of such application, shall provide  
18 to the applicant a description of such deficiencies  
19 and identify the information required to correct such  
20 deficiencies.

21 “(3) APPROVAL.—The Secretary shall grant a  
22 technology certification order under this section if,  
23 on the basis of the information submitted to the Sec-  
24 retary as part of the application and any other infor-

1           mation with respect to such applicant, the Secretary  
2           finds that—

3                   “(A) in accordance with subsection  
4                   (e)(2)(D), there is a showing of reasonable as-  
5                   surance of analytical validity for all eligible in  
6                   vitro clinical tests within the proposed scope of  
7                   the technology certification, as evidenced by the  
8                   procedures for analytical validation;

9                   “(B) in accordance with subsection  
10                   (e)(2)(E), there is a showing of reasonable as-  
11                   surance of clinical validity for all eligible in  
12                   vitro clinical tests within the proposed scope of  
13                   the technology certification, as evidenced by the  
14                   clinical program, including procedures for clin-  
15                   ical validation;

16                   “(C) the methods used in, or the facilities  
17                   or controls used for, the development of eligible  
18                   in vitro clinical tests covered by the proposed  
19                   scope of the technology certification conform to  
20                   the applicable requirements of section 587J;

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

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

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

5                 “(i) meets the applicable standard for  
6 approval; and

7                 “(ii) reasonably represent the range of  
8 procedures for analytical validation and  
9 clinical validation included in the applica-  
10 tion, as applicable; and

11           “(G) the applicant permits authorized em-  
12 ployees of the Food and Drug Administration  
13 or persons accredited under this Act an oppor-  
14 tunity to inspect at a reasonable time and in a  
15 reasonable manner the facilities and all perti-  
16 nent equipment, finished and unfinished mate-  
17 rials, containers, and labeling therein, including  
18 all things (including records, files, papers, and  
19 controls) bearing on whether an in vitro clinical  
20 test is adulterated, misbranded, or otherwise in  
21 violation of this Act, and permits such author-  
22 ized employees or persons accredited under this  
23 Act to view and to copy and verify all records  
24 pertinent to the application and the in vitro  
25 clinical test.

1           “(4) REVIEW OF DENIALS.—An applicant  
2 whose application has been denied may, by petition  
3 filed on or before the date that is 30 calendar days  
4 after the date upon which such applicant receives  
5 notice of such denial, obtain review thereof in ac-  
6 cordance with section 5870.

7           “(g) DURATION; SUBSEQUENT SUBMISSIONS.—

8           “(1) ORDER DURATION.—A technology certifi-  
9 cation order shall remain in effect until the earlier  
10 of—

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

13                   “(B) the withdrawal of such technology  
14 certification order under subsection (j).

15           “(2) EXPIRATION.—An initial technology cer-  
16 tification order issued under subsection (f)(3) shall  
17 expire on such date specified by the Secretary that  
18 is not later than 4 years after the date that such  
19 order is issued, except that if an application for re-  
20 newal under paragraph (3) has been received not  
21 later than 30 days prior to the expiration of such  
22 order under this paragraph, such order shall expire  
23 on the date on which the Secretary has granted or  
24 denied the application for renewal. Any such subse-  
25 quent renewal of a technology certification shall ex-

1       pire on such date specified by the Secretary that is  
2       not later than 4 years after the date that such tech-  
3       nology certification order is issued.

4           “(3) RENEWAL.—

5           “(A) IN GENERAL.—Any person with a  
6       technology certification order in effect with re-  
7       spect to development of in vitro clinical tests  
8       may seek renewal of such order provided that—

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

11          “(ii) none of the information specified  
12       in subsection (e)(2) has substantially  
13       changed, except as described in supple-  
14       ments approved under paragraph (4).

15          “(B) CONTENT.—An application for re-  
16       newal under this paragraph shall include infor-  
17       mation concerning one or more representative  
18       in vitro clinical tests in accordance with sub-  
19       section (e)(2)(G), except that such representa-  
20       tive test or tests shall be different from the rep-  
21       resentative test or tests relied upon as the rep-  
22       resentative assay in any prior technology certifi-  
23       cation that has not yet been reviewed, if appli-  
24       cable.

1           “(C) PROCESS.—The Secretary’s action on  
2           an application for renewal of technology certifi-  
3           cation under this paragraph shall be conducted,  
4           to the extent practicable, in coordination with  
5           inspections conducted under section 353 of the  
6           Public Health Service Act, and any order re-  
7           sulting from such renewal application shall be  
8           treated as a technology certification order for  
9           purposes of this subchapter.

10          “(4) SUPPLEMENTS AND REPORTS.—

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

19                         “(i) such person is an eligible person  
20                         under subsection (b)(1); and

21                         “(ii) that such change does not ex-  
22                         pand the scope of the technology certifi-  
23                         cation unless the Secretary deems appro-  
24                         priate.

1 A supplement may contain only information rel-  
2 evant to the change or changes. The Secretary's  
3 action on a supplement shall be in accordance  
4 with subsection (f), and any order resulting  
5 from such supplement shall be treated as an  
6 amendment to a technology certification order  
7 that is in effect.

8 “(B) REPORTS.—

9 “(i) IN GENERAL.—If a change de-  
10 scribed in subparagraph (A) is made in  
11 order to address a potential risk to public  
12 health by adding a new specification or  
13 test method, the person may immediately  
14 implement such change or changes and  
15 shall report such changes or changes to the  
16 Secretary within 30 days.

17 “(ii) CONTENT.—Any report to the  
18 Secretary under this subparagraph shall  
19 include—

20 “(I) a summary of the relevant  
21 change or changes;

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

24 “(III) a description of how the  
25 change or changes were evaluated.



1 “(iii) SUPPLEMENTAL REPORTS.—

2 Upon review of such report and a finding  
3 that the relevant change or changes are in-  
4 consistent with the standard specified  
5 under this subparagraph, the Secretary  
6 may require a supplement under subpara-  
7 graph (A).

8 “(h) MAINTENANCE REQUIREMENTS.—For the dura-  
9 tion of a technology certification order, a holder of a tech-  
10 nology certification order shall—

11 “(1) use the procedures included in the relevant  
12 application, supplement, or report under subsections  
13 (b) and (e);

14 “(2) ensure compliance with any applicable  
15 mitigating measures;

16 “(3) maintain, and provide to the Secretary  
17 upon request, records related to any in vitro clinical  
18 test offered without premarket review under the  
19 technology certification order, where those records  
20 are necessary to demonstrate compliance with appli-  
21 cable provisions of this subchapter; and

22 “(4) comply with the notification requirements  
23 under section 587I for each in vitro clinical test of-  
24 fered without premarket review under the technology  
25 certification order.

1 “(i) TEMPORARY HOLD.—

2 “(1) IN GENERAL.—Upon one or more findings  
3 under paragraph (4) and after promptly notifying  
4 the developer of such findings, the Secretary may  
5 issue a temporary hold prohibiting any holder of a  
6 technology certification order from introducing into  
7 interstate commerce an in vitro clinical test that was  
8 not previously the subject of a notification under  
9 section 587I. The temporary hold must identify the  
10 grounds for the temporary hold under paragraph (4)  
11 and the rationale for such finding.

12 “(2) NOTIFICATION TO THE DEVELOPER.—The  
13 Secretary shall not place a temporary hold under  
14 this subsection unless the Secretary has promptly  
15 notified the developer of such hold and provided 30  
16 calendar days for the developer to come into compli-  
17 ance with or resolve the findings under paragraph  
18 (4).

19 “(3) WRITTEN REQUESTS.—Any written re-  
20 quest to the Secretary from the holder of a tech-  
21 nology certification order that a temporary hold  
22 under paragraph (1) be removed shall receive a deci-  
23 sion, in writing and specifying the reasons therefore,  
24 within 90 days after receipt of such request. Any

1 such request shall include information to support the  
2 removal of the temporary hold.

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

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

9 “(B) labels or advertises one or more in  
10 vitro clinical tests with false or misleading  
11 claims; or

12 “(C) is no longer an eligible person under  
13 subsection (b)(1).

14 “(j) WITHDRAWAL.—The Secretary may, after due  
15 notice and opportunity for informal hearing, issue an  
16 order withdrawing a technology certification order if the  
17 Secretary finds that—

18 “(1) the application, supplement, or report  
19 under subsection (e) or (g) contains false or mis-  
20 leading information or fails to reveal a material fact;

21 “(2) such holder fails to correct false or mis-  
22 leading labeling or advertising upon the request of  
23 the Secretary;

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

4           “(4) the holder of such technology certification  
5           order fails to correct the grounds for temporary hold  
6           within a timeframe specified in the temporary hold  
7           order.

8           “(k) REPORTS TO CONGRESS.—

9           “(1) IN GENERAL.—Not later than one year  
10          after the effective date, and annually for 4 years  
11          thereafter, the Secretary shall prepare and submit to  
12          the Committee on Energy and Commerce of the  
13          House of Representatives and the Committee on  
14          Health, Education, Labor, and Pensions of the Sen-  
15          ate, and make publicly available, including through  
16          posting on the Internet website of the Food and  
17          Drug Administration, a report containing the infor-  
18          mation required under paragraph (2).

19          “(2) CONTENT.—

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

22                         “(i) the total number and type of ap-  
23                         plications for technology certifications  
24                         filed, granted, withdrawn or denied;

1           “(ii) the total number of technology  
2           certification orders put on temporary hold  
3           under subsection (i) and the number of  
4           technology certification orders withdrawn  
5           under subsection (j);

6           “(iii) the types of technologies for  
7           which technology certification orders were  
8           granted;

9           “(iv) the total number of laboratories  
10          and developers with technology certifi-  
11          cation orders in effect.

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

16          “(C) PERFORMANCE REPORTS.—The re-  
17          ports required under this section may be issued  
18          as a component of performance reports as re-  
19          quired under section 9 of the Verifying Accu-  
20          rate Leading-edge IVCT Development Act of  
21          2020.

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

23          “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

24                  “(1) ESTABLISHING, CHANGING, OR WITH-  
25          DRAWING.—

1           “(A) ESTABLISHMENT.—If the Secretary  
2 determines that the establishment of mitigating  
3 measures is necessary for either of the reasons  
4 described in clause (i) or (ii) of section  
5 587(15)(A) for any in vitro clinical test with  
6 the same indications for use, the Secretary may  
7 require that the in vitro clinical test comply  
8 with such mitigating measures.

9           “(B) PROCESS.—Notwithstanding sub-  
10 chapter II of chapter 5 of title 5, United States  
11 Code, the Secretary may—

12                   “(i) establish, change, or withdraw  
13 mitigating measures by—

14                           “(I) publishing a proposed ad-  
15 ministrative order in the Federal Reg-  
16 ister;

17                           “(II) providing an opportunity  
18 for public comment for a period of not  
19 less than 30 calendar days; and

20                           “(III) after consideration of any  
21 comments submitted, publishing a  
22 final administrative order in the Fed-  
23 eral Register; and

24                   “(ii) may establish mitigating meas-  
25 ures with respect to a category in a pre-

1 market approval order or technology cer-  
2 tification order.

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

5 “(A) IN GENERAL.—Any special controls  
6 or restrictions applicable to an in vitro clinical  
7 test with the same indications for use pursuant  
8 to section 587(10) based on prior regulation as  
9 a device approved under section 515, cleared or  
10 exempt under section 510(k), or classified  
11 under section 513(f)(2), including any such spe-  
12 cial controls or restrictions established during  
13 the period beginning on the date of enactment  
14 of the Verifying Accurate Leading-edge IVCT  
15 Development Act of 2020 and ending on the ef-  
16 fective date of such Act (as described in section  
17 5(b) of such Act)—

18 “(i) shall continue to apply to such  
19 approved, cleared, or exempted in vitro  
20 clinical test after such effective date; and

21 “(ii) are deemed to be mitigating  
22 measures as of the effective date of such  
23 approval, clearance, or exemption.

24 “(B) CHANGES.—The Secretary may es-  
25 tablish, change, or withdraw mitigating meas-

1           ures for such a test or indications for use the  
2           procedures under paragraph (1).

3           “(b) DOCUMENTATION.—

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

8           “(A) in accordance with section  
9           587B(c)(2)(G)(i), submit documentation to the  
10          Secretary as part of the application for the test  
11          under subsection (c) or (d) of section 587B  
12          demonstrating that such mitigating measures  
13          have been met;

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

18          “(C) after responding to any informal com-  
19          munications from the Secretary, make such  
20          documentation available to the Secretary upon  
21          request or inspection.

22          “(2) OTHER TESTS.—The developer of an in  
23          vitro clinical test that is marketed within the scope  
24          of a technology certification order or other exemp-



1           tion from premarket review under section 587B and  
2           to which mitigating measures apply shall—

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

8                   “(B) after responding to any informal  
9                   communications from the Secretary, make such  
10                  documentation available to the Secretary upon  
11                  request or inspection; and

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

15           “(c) MITIGATING MEASURES FOR CROSS-REF-  
16           ERENCED TESTS.—Not later than 1 year after the imple-  
17           mentation of the Verifying Accurate Leading-edge IVCT  
18           Development Act of 2020, the Secretary shall issue miti-  
19           gating measures for cross-referenced tests.

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

21                   “(a) TECHNOLOGY CERTIFICATION AND EXEMPTION  
22           DETERMINATIONS.—

23                   “(1) IN GENERAL.—Based on new information,  
24                   including the establishment of mitigating measures  
25                   under section 587E, and after considering available

1 evidence respecting tests with the same indications  
2 for use pursuant to section 587(10), the Secretary  
3 may, upon the initiative of the Secretary or upon pe-  
4 tition of an interested person—

5 “(A) revoke any exemption or requirement  
6 in effect under this subchapter with respect to  
7 such indications for use; or

8 “(B) determine that such indications for  
9 use are eligible for technology certification in  
10 accordance with section 587D(b)(2), or are oth-  
11 erwise exempt from premarket review under  
12 section 587B.

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

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

1           “(1) new clinical information indicates that the  
2           exemption of an in vitro clinical test or tests from  
3           premarket review under section 587B or exemption  
4           under section 587A has a reasonable probability of  
5           severe adverse health consequences, including the  
6           absence, delay, or discontinuation of appropriate  
7           medical treatment.

8           “(2) PROCESS.—Any action under this sub-  
9           section shall be made by publication of a notice of  
10          such proposed action in the Federal Register, con-  
11          sideration of comments to a public docket on such  
12          proposal, and publication of a final notice in the  
13          Federal Register, notwithstanding subchapter II of  
14          chapter 5 of title 5, United States Code.

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

16          “(a) IN GENERAL.—The Secretary may establish ad-  
17          visory committees or use advisory committee panels of ex-  
18          perts established before the date of enactment of this sec-  
19          tion for the purposes of providing expert scientific advice  
20          and making recommendations related to—

21                 “(1) the approval of an application for an in  
22                 vitro clinical test submitted under this subchapter,  
23                 including for evaluating, as applicable, the analytical  
24                 validity, clinical validity, and safety of in vitro clin-  
25                 ical tests;

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

5           “(3) quality requirements under section 587J  
6           or applying such requirements to in vitro clinical  
7           tests developed or imported by developers; or

8           “(4) such other purposes as the Secretary de-  
9           termines appropriate.

10          “(b) APPOINTMENTS.—

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

23           “(2) NONVOTING MEMBERS.—In addition to the  
24           individuals appointed pursuant to paragraph (1), the

1 Secretary shall appoint to each committee estab-  
2 lished under subsection (a), as nonvoting members—

3 “(A) a representative of consumer inter-  
4 ests; and

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

9 “(3) LIMITATION.—No individual who is in the  
10 regular full-time employee of the United States and  
11 engaged in the administration of this Act may be a  
12 member of any advisory committee established under  
13 subsection (a).

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

22 “(5) MEETINGS.—The Secretary shall ensure  
23 that scientific advisory committees meet regularly  
24 and at appropriate intervals so that any matter to  
25 be reviewed by such a committee can be presented

1 to the committee not more than 60 calendar days  
2 after the matter is ready for such review. Meetings  
3 of the committee may be held using electronic com-  
4 munication to convene the meetings.

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

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

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

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

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

22 “Before submitting a premarket application or tech-  
23 nology certification application for an in vitro clinical  
24 test—

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

6                   “(A) the submission process and the type  
7                   and amount of evidence expected to dem-  
8                   onstrate the applicable standard;

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

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

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

15                   “(A) within 60 calendar days after such  
16                   receipt, or within such time period as may be  
17                   agreed to by the developer, meet or confer with  
18                   the developer submitting the request; and

19                   “(B) within 15 calendar days after such  
20                   meeting or conference, provide to the developer  
21                   a written record or response describing the  
22                   issues discussed and conclusions reached in the  
23                   meeting or conference.

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

2 “(a) REGISTRATION OF ESTABLISHMENTS FOR IN  
3 VITRO CLINICAL TESTS.—

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

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

17 “(B) submit an initial registration con-  
18 taining the information required under subpara-  
19 graph (A) not later than—

20 “(i) the date of implementation of this  
21 section if such establishment is engaged in  
22 any activity described in subsection (b)(1)  
23 on the date of enactment of this section,  
24 unless the Secretary establishes by guid-  
25 ance a date later than such implementation



1 date for all or a category of such establish-  
2 ments; or

3 “(ii) 30 days prior to engaging in any  
4 activity described in subsection (b)(1) after  
5 enactment of this section, if such establish-  
6 ment is not engaged in any activity de-  
7 scribed in this paragraph on the date of  
8 enactment of this section.

9 “(2) REGISTRATION NUMBERS.—The Secretary  
10 may assign a registration number to any person or  
11 an establishment registration number to any estab-  
12 lishment registered in accordance with this section.  
13 Registration information shall be made publicly  
14 available by publication on the internet website  
15 maintained by the Food and Drug Administration,  
16 in accordance with subsection (d).

17 “(3) INSPECTION.—Every person or establish-  
18 ment that is required to be registered with the Sec-  
19 retary under this section shall be subject to inspec-  
20 tion pursuant to section 704.

21 “(b) LISTING INFORMATION FOR IN VITRO CLINICAL  
22 TESTS.—

23 “(1) IN GENERAL.—Each person who—

24 “(A) is a developer, a contract manufac-  
25 turer (including contract packaging), contract

1 sterilizer, repackager, relabeler, or distributor of  
2 an in vitro clinical test; and

3 “(B) introduces or proposes to begin the  
4 introduction or delivery for introduction into  
5 interstate commerce through an exemption  
6 under section 587A(f)(2)(b) or 587A(g) or  
7 through the filing of an application under sec-  
8 tion 587B or 587D,

9 shall submit a listing to the Secretary containing the  
10 information described in paragraph (2) in accord-  
11 ance with the applicable schedule described under  
12 subsection (c). Such listing shall be prepared in such  
13 form and manner as the Secretary may specify in  
14 guidance. Listing information shall be submitted  
15 through the comprehensive test information system  
16 in accordance with section 587T, as appropriate.

17 “(2) SUBMISSIONS.—Each developer submitting  
18 a listing under paragraph (1) shall electronically  
19 submit to the comprehensive test information system  
20 under section 587T the following information for  
21 each in vitro clinical test for which such person is  
22 a developer in the form and manner prescribed by  
23 the Secretary:

24 “(A) name of the establishment and its fa-  
25 cility registration number;

1           “(B) contact information for the official  
2 correspondent for the listing;

3           “(C) name (common name and trade  
4 name, if applicable) of the in vitro clinical test  
5 and its test listing number (when available).

6           “(D) CLIA certificate number for any lab-  
7 oratory certified by the Secretary under section  
8 263a of title 42 that meets the requirements for  
9 performing high-complexity testing that is the  
10 developer of the in vitro clinical test, and CLIA  
11 certificate number for any laboratory under  
12 common ownership that is performing the test  
13 developed by such test developer;

14           “(E) whether the in vitro clinical test is, as  
15 applicable, offered as a test approved under sec-  
16 tion 587B, offered under a technology certifi-  
17 cation order issued under section 587D, or of-  
18 fered as an in vitro clinical test under section  
19 587A;

20           “(F) indications for use information under  
21 section 587(10);

22           “(G) brief narrative description of the in  
23 vitro clinical test;

1           “(H) a brief summary of the analytical  
2           and clinical performance of the in vitro clinical  
3           test, and as applicable, the lot release criteria;

4           “(I) a brief description of conformance  
5           with any applicable mitigating measures, re-  
6           strictions, and standards;

7           “(J) representative labeling for the in vitro  
8           clinical test, as appropriate; and

9           “(K) a statement that the information sub-  
10          mitted is truthful and accurate.

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

18          “(4) ABBREVIATED LISTING.—A person who is  
19          not a developer but is otherwise required to register  
20          pursuant to subsection (a) shall submit an abbrev-  
21          viated listing to the Secretary containing the infor-  
22          mation described in subparagraphs (A) through (C)  
23          of paragraph (2), and the name of the developer.  
24          The information shall be submitted in accordance  
25          with the applicable schedule described under sub-

1 section (c). Such abbreviated listing shall be pre-  
2 pared in such form and manner as the Secretary  
3 may specify in guidance. Listing information shall be  
4 submitted to the comprehensive test information sys-  
5 tem in accordance with section 587T, as appro-  
6 priate.

7 “(5) GRANDFATHERED TESTS.—A developer of  
8 an in vitro clinical test developer offering a test that  
9 is grandfathered under section 587A(c) shall submit  
10 listing information required under subparagraphs  
11 (A) through (I) of paragraph (2).

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

16 “(7) EXEMPT TESTS.—A developer of an in  
17 vitro clinical test who introduces or proposes to  
18 begin the introduction or delivery for introduction  
19 into interstate commerce pursuant to an exemption  
20 under section 587A may submit listing information  
21 under this subsection.

22 “(c) TIMELINES FOR SUBMISSION.—

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

1           “(A) For an in vitro clinical test that was  
2 listed as a device under section 510(j) prior to  
3 the date of enactment of this section, a person  
4 shall maintain a device listing under section  
5 510 until such time as the system for submit-  
6 ting the notification information required under  
7 subsection (b) becomes available and thereafter  
8 shall submit the notification information no  
9 later than 1 year after the system for submit-  
10 ting the notification under this section becomes  
11 available.

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

19           “(C) For an in vitro clinical test that is  
20 not subject to subparagraph (A) or (B), a per-  
21 son shall submit the required notification infor-  
22 mation prior to offering, introducing, or mar-  
23 keting the in vitro clinical test as follows:

24                   “(i) For an in vitro clinical test that  
25 is not exempt from premarket approval

1 under section 587B, a person shall submit  
2 the required listing information no later  
3 than 30 business days after the date of ap-  
4 proval of the premarket approval applica-  
5 tion.

6 “(ii) For a developer who has received  
7 a technology certification order under sec-  
8 tion 587D, a person shall submit the re-  
9 quired listing information at least 30 busi-  
10 ness days after receiving such technology  
11 certification order.

12 “(2) UPDATES.—

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

19 “(B) ANNUAL UPDATES.—Each developer  
20 required to submit listing information under  
21 this section shall update its information annu-  
22 ally during the period beginning on October 1  
23 and ending on December 31 of each year as a  
24 component of the annual report submitted  
25 under sections 587B and 587D.

1       “(d) PUBLIC AVAILABILITY OF NOTIFICATION IN-  
2 FORMATION.—

3           “(1) IN GENERAL.—Notification information  
4 submitted pursuant to this section shall be made  
5 publicly available on the website of the Food and  
6 Drug Administration in accordance with paragraph  
7 (3).

8           “(2) CONFIDENTIALITY.—Notification informa-  
9 tion for an in vitro clinical test that is subject to  
10 premarket approval or technical certification shall  
11 remain confidential until such date as the in vitro  
12 clinical test receives the applicable premarket ap-  
13 proval or the developer receives a technology certifi-  
14 cation order.

15           “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY  
16 REQUIREMENTS.—The registration and listing infor-  
17 mation requirements described in subsections (a)  
18 and (b) shall not apply to the extent the Secretary  
19 determines that such information relates to—

20           “(A) trade secret or commercial confiden-  
21 tial information; or

22           “(B) national security or countermeasures  
23 or is restricted from disclosure pursuant to an-  
24 other provision of law.



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

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

6 “(a) APPLICABILITY.—

7 “(1) IN GENERAL.—Each developer and each  
8 other person required to register under section  
9 587I(b)(1) shall establish and maintain quality re-  
10 quirements in accordance with the applicable re-  
11 quirements set forth in subsection (b), except as pro-  
12 vided in section 587A.

13 “(2) CERTIFIED LABORATORY REQUIRE-  
14 MENTS.—A developer that operates a clinical labora-  
15 tory certified by the Secretary under section 353 of  
16 the Public Health Service Act that—

17 “(A) meets the requirements for per-  
18 forming high-complexity testing;

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

21 “(ii) modifies another developer’s in vitro  
22 clinical test in that certified laboratory in a  
23 manner described in section 587(6); and

24 “(C) develops an in vitro clinical test or in-  
25 dications for use that are for use only within

1           that certified laboratory or within another cer-  
2           tified laboratory with common ownership.

3           shall establish and maintain quality requirements  
4           that comply with the requirements set forth in sub-  
5           section (b)(2).

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

12          “(4) REGULATIONS.—The Secretary may pro-  
13          mulgate regulations to implement this section. In so  
14          promulgating regulations, the Secretary shall con-  
15          sider whether and to what extent international har-  
16          monization is appropriate.

17          “(b) QUALITY REQUIREMENTS.—

18                 “(1) QUALITY REQUIREMENTS FOR LABORA-  
19                 TORIES WITHOUT CLIA CERTIFICATION TO CONDUCT  
20                 HIGH-COMPLEXITY TESTS.—The quality require-  
21                 ments applicable under this section shall—

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

24                         “(B) apply only to the development, valida-  
25                         tion, production, preparation, propagation, or

1 assembly related to the design and associated  
2 manufacture and distribution of an in vitro clin-  
3 ical test offered under this subchapter;

4 “(C) not apply with respect to laboratory  
5 operations; and

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

8 “(i) management responsibility;

9 “(ii) quality audits;

10 “(iii) personnel;

11 “(iv) design controls;

12 “(v) document controls;

13 “(vi) purchasing controls;

14 “(vii) identification and traceability;

15 “(viii) production and process con-  
16 trols;

17 “(ix) acceptance activities;

18 “(x) nonconforming product;

19 “(xi) corrective and preventive action;

20 “(xii) labeling and packaging controls;

21 “(xiii) handling, storage, distribution,  
22 and installation;

23 “(xiv) records;

24 “(xv) servicing; and

25 “(xvi) statistical techniques.

1           “(2) QUALITY REQUIREMENTS FOR LABORA-  
2           TORIES CERTIFIED TO CONDUCT HIGH-COMPLEXITY  
3           TESTS.—Quality requirements applicable to the in  
4           vitro clinical tests and developers described in sub-  
5           section (a)(2) shall—

6                   “(A) avoid duplication of regulations under  
7                   section 353 of the Public Health Service Act;  
8                   and

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

11                           “(i) design controls;

12                           “(ii) purchasing controls;

13                           “(iii) acceptance activities;

14                           “(iv) corrective and preventative ac-  
15                           tion; and

16                           “(v) records.

17           “(3) QUALITY REQUIREMENTS FOR CERTAIN  
18           LABORATORIES DISTRIBUTING IN VITRO CLINICAL  
19           TESTS OR TEST PROTOCOLS WITHIN ORGANIZATIONS  
20           OR PUBLIC HEALTH NETWORKS.—

21                   “(A) IN GENERAL.—Quality requirements  
22                   applicable to the developer who is distributing  
23                   in vitro clinical test distributed as described in  
24                   subparagraph (B) shall consist of the following:

1 “(i) The requirements in paragraph  
2 (2).

3 “(ii) The labeling requirements in  
4 paragraph (1)(C)(xii).

5 “(iii) The requirement to maintain  
6 records of the laboratories to which the in  
7 vitro clinical test or test protocol is distrib-  
8 uted.

9 “(B) DISTRIBUTING LABORATORY.—Sub-  
10 paragraph (A) shall apply to developers that  
11 meet the following conditions:

12 “(i) The laboratory distributing the  
13 test protocol is certified by the Secretary  
14 under section 353 of the Public Health  
15 Service Act and meets the requirements for  
16 performing high-complexity testing.

17 “(ii) The laboratory develops its own  
18 in vitro clinical test or modifies another de-  
19 veloper’s in vitro clinical test in a manner  
20 described in section 587(6).

21 “(iii) The laboratory distributes the in  
22 vitro clinical test or test protocol for such  
23 test only to another laboratory that—

24 “(I) is certified by the Secretary  
25 under section 353 of the Public

1 Health Service Act and meets the re-  
2 quirements for performing high-com-  
3 plexity testing;

4 “(II) is within the same cor-  
5 porate organization and having com-  
6 mon ownership by the same parent  
7 corporation; or as applicable, is a lab-  
8 oratory within a public health labora-  
9 tory network coordinated or managed  
10 by the Centers for Disease Control  
11 and Prevention; and

12 “(III) implements the test pro-  
13 tocol without further modification.

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

17 “(1) for purposes of facilitating international  
18 harmonization, consider whether the developer par-  
19 ticipates in an audit program in which the United  
20 States participates or the United States recognizes  
21 or conforms with standards recognized by the Sec-  
22 retary; and

23 “(2) ensure a least burdensome approach de-  
24 scribed in section 587B(j) by leveraging, to the ex-  
25 tent applicable, the quality assurance requirements

1 applicable to developers certified by the Secretary  
2 under section 353 of the Public Health Service Act.

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

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

9 “(b) LABELS.—

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

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

15 “(B) is developed, manufactured, and used  
16 solely within a single laboratory certified by the  
17 Secretary under section 353 of the Public  
18 Health Service Act that meets the requirements  
19 for performing high-complexity testing.

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

24 “(c) LABELING.—

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

12           “(2) CONTENT.—

13           “(A) IN GENERAL.—Labeling accom-  
14          panying an in vitro clinical test that is in the  
15          form of a test report template or ordering infor-  
16          mation shall include—

17                   “(i) the test listing number that was  
18                   provided to the developer at the time of  
19                   listing;

20                   “(ii) instructions for how and where  
21                   to report an adverse event under section  
22                   587L;

23                   “(iii) instructions for how and where  
24                   to access the performance summary data



1 displayed in the listing database for the  
2 test;

3 “(iv) the intended use of the in vitro  
4 clinical test; and

5 “(v) any warnings, contraindications,  
6 or limitations.

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

14 “(i) trade secret or commercial con-  
15 fidential information; or

16 “(ii) national security or counter-  
17 measures or is restricted from disclosure  
18 pursuant to another provision of law.

19 “(3) ADDITIONAL REQUIREMENTS.—Labeling  
20 for an in vitro clinical test used for  
21 immunohematology testing shall meet the following  
22 applicable requirements set forth in part 660 of the  
23 Code of Federal Regulations (or any successor regu-  
24 lation), related to the labeling of blood grouping re-

1 agents, reagent red blood cells, and anti-human  
2 globulin.

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

5 “(1) IN GENERAL.—

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

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

18 “(i) designed and manufactured by a  
19 laboratory certified by the Secretary under  
20 section 353 of the Public Health Service  
21 Act that meets the requirements for per-  
22 forming high-complexity testing; and

23 “(ii) performed in the same laboratory  
24 in which it was developed or by another  
25 such laboratory certified by the Secretary

1 under section 353 Public Health Service  
2 Act that meets the requirements for per-  
3 forming high complexity testing and is  
4 under common ownership with the labora-  
5 tory that designed and manufactured the  
6 test.

7 “(2) TEST INSTRUMENT LABELING.—The label-  
8 ing for an instrument is not required to bear the in-  
9 formation indicated in paragraphs (3), (4), (5), (7),  
10 (8), (9), (10), (11), (12), and (13) of section  
11 809.10(b) of title 21 of the Code of Federal Regula-  
12 tions, as it appears on the date of enactment of this  
13 subchapter and amended thereafter.

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

20 “(4) LAB RESEARCH OR INVESTIGATIONAL  
21 USE.—A shipment or other delivery of an in vitro  
22 clinical test for research or investigational use pur-  
23 suant to section 587A(m) shall be exempt from the  
24 labeling requirements of subsection (b) and (c)(1)  
25 and from any standard promulgated through regula-

1 tions, except as required under section 353 of the  
2 Public Health Service Act or section 587R of this  
3 Act.

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

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

21 “(7) OVER-THE-COUNTER TEST SAMPLE COL-  
22 LECTION SYSTEMS LABELING.—The labeling for  
23 over-the-counter test sample collection systems for  
24 drugs of abuse testing shall bear the name and place  
25 of business of the developer included in the registra-

1       tion listing under section 587I, in language appro-  
2       priate for the intended users. If the labeling of such  
3       over-the-counter test sample collection system bears  
4       the information set forth in this paragraph (4)(G),  
5       it need not bear the information required by sub-  
6       section (c)(1).

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

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

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

24       “(f) GUIDANCE.—The Secretary may, in collabora-  
25       tion with developers, issue guidance on standardized, gen-

1 eral content and format for in vitro clinical test labeling  
2 to help ensure compliance with applicable requirements in  
3 this subsection.

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

5 “(a) APPLICABILITY.—

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

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

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

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

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

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

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

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

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

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

17                         “(A) means—

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

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

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

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

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

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

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

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

22           “(B) an injury that—

23           “(i) is life threatening;



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

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

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

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

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

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

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

22 “(B) to remedy a violation of this Act  
23 caused by the in vitro clinical test which may  
24 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 imposed under section 515 or section 520(e)  
6 until the effective date of restrictions issued under sub-  
7 section (a).

8       **“SEC. 5870. APPEALS.**

9       “(a) SIGNIFICANT DECISION.—

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

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

1           “(3) APPLICATION OF LEAST BURDENSOME RE-  
2           QUIREMENTS.—The substantive summary required  
3           under this subsection shall include a brief statement  
4           regarding how the least burdensome requirements  
5           were considered and applied consistent with section  
6           587B(j), as applicable.

7           “(b) REVIEW OF SIGNIFICANT DECISIONS.—

8           “(1) REQUEST FOR SUPERVISORY REVIEW OF  
9           SIGNIFICANT DECISION.—Any person may request a  
10          supervisory review of the significant decision de-  
11          scribed in subsection (a)(1). Such review may be  
12          conducted at the next supervisory level or higher  
13          above the agency official who made the significant  
14          decision.

15          “(2) SUBMISSION OF REQUEST.—A person re-  
16          questing a supervisory review under paragraph (1)  
17          shall submit such request to the Secretary not later  
18          than 30 days after the decision for which the review  
19          is requested and shall indicate in the request wheth-  
20          er such person seeks an in-person meeting or a tele-  
21          conference review.

22          “(3) TIMEFRAME.—The Secretary shall sched-  
23          ule an in-person or teleconference review, if so re-  
24          quested, not later than 30 days after such request  
25          is made. The Secretary shall issue a decision to the

1 person requesting a review under this subsection not  
2 later than 45 days after the request is made under  
3 paragraph (1), or, in the case of a person who re-  
4 quests an in-person meeting or teleconference, 30  
5 days after such meeting or teleconference.

6 “(c) **ADVISORY PANELS.**—The process established  
7 under subsection (a) shall permit the appellant to request  
8 review by an advisory committee established under section  
9 513 or 587G. The Secretary shall provide a response to  
10 an appellant under this subsection not later than 45 days  
11 after the requested advisory committee is convened.

12 **“SEC. 587P. ACCREDITED PERSONS.**

13 “(a) **IN GENERAL.**—

14 “(1) **REVIEW OF APPLICATIONS.**—

15 “(A) **ACCREDITATION FOR APPLICATION**  
16 **REVIEW.**—Subject to subparagraph (C), during  
17 the period beginning on the date of enactment  
18 of the Verifying Accurate Leading-edge IVCT  
19 Development Act of 2020 and ending 2 years  
20 after the date of enactment of such Act, the  
21 Secretary shall accredit persons for any of the  
22 following purposes:

23 “(i) Reviewing applications for pre-  
24 market approval under section 587B and

1 applications for technology certification  
2 under section 587D.

3 “(ii) Making recommendations to the  
4 Secretary with respect to an approval of an  
5 application under section 587B or issuance  
6 of a technology certification order under  
7 section 587D.

8 “(B) REQUIREMENT REGARDING REVIEW  
9 RECOMMENDATIONS.—

10 “(i) IN GENERAL.—In making a rec-  
11 ommendation to the Secretary under this  
12 section, an accredited person shall notify  
13 the Secretary in writing of the reasons for  
14 the recommendation concerning the appli-  
15 cation.

16 “(ii) TIME PERIOD FOR REVIEW.—  
17 Not later than 30 calendar days after the  
18 date on which the Secretary is notified of  
19 a recommendation under this section with  
20 respect to an application for premarket ap-  
21 proval or technology certification, the Sec-  
22 retary shall make a determination with re-  
23 spect to the application.

24 “(C) LACK OF APPLICATIONS WITHIN 2-  
25 YEAR TIMEFRAME.—If the Secretary does not



1 receive applications from persons that meet the  
2 criteria under subsection (c) within such period,  
3 the Secretary—

4 “(i) may accredit persons under this  
5 paragraph after the 2-year period de-  
6 scribed in subparagraph (A); and

7 “(ii) shall issue a public notice on the  
8 internet website of the Food and Drug Ad-  
9 ministration calling for applications for  
10 such accreditation.

11 “(2) INSPECTIONS.—

12 “(A) ACCREDITATION FOR INSPECTIONS.—

13 Subject to subparagraph (B), during the period  
14 beginning on the date of enactment of the  
15 Verifying Accurate Leading-edge IVCT Devel-  
16 opment Act of 2020 and ending 2 years after  
17 the date of enactment of such Act, the Sec-  
18 retary shall accredit persons for the purpose of  
19 conducting inspections of in vitro clinical test  
20 developers and other persons required to reg-  
21 ister pursuant to section 587L.

22 “(B) LACK OF APPLICATIONS WITHIN 2-  
23 YEAR TIMEFRAME.—If no persons who meet the  
24 criteria for such accreditation apply during the

1 2-year period described in subparagraph (A),  
2 the Secretary—

3 “(i) may accredit persons under this  
4 subparagraph after such period; and

5 “(ii) shall issue a public notice on the  
6 internet website of the Food and Drug Ad-  
7 ministration calling for applications for  
8 such accreditation.

9 “(C) EFFECT OF ACCREDITATION.—

10 “(i) IN GENERAL.—Persons accredited  
11 under subparagraph (A) to conduct inspec-  
12 tions, when conducting such inspections,  
13 shall record in writing their specific obser-  
14 vations and shall present their observations  
15 to the designated representative of the in-  
16 spected establishment.

17 “(ii) INSPECTION REPORT REQUIRE-  
18 MENTS.—Each person accredited under  
19 this paragraph shall prepare and submit to  
20 the Secretary an inspection report in a  
21 form and manner designated by the Sec-  
22 retary for conducting inspections, taking  
23 into consideration the goals of inter-  
24 national harmonization of quality systems  
25 standards. Any official classification of the

1 inspection shall be determined by the Sec-  
2 retary. Any statement or representation  
3 made by an employee or agent of an estab-  
4 lishment to a person accredited to conduct  
5 inspections shall be subject to section 1001  
6 of title 18, United States Code.

7 “(D) SAVINGS CLAUSE.—Nothing in this  
8 section affects the authority of the Secretary to  
9 inspect any in vitro clinical test developer or  
10 other person registered under section 587I.

11 “(E) INSPECTION LIMITATIONS.—The Sec-  
12 retary shall ensure that inspections carried out  
13 under this section are not duplicative of inspec-  
14 tions carried out under section 353 of the Pub-  
15 lic Health Service Act. Inspections under this  
16 section shall be limited to the data and informa-  
17 tion necessary—

18 “(i) for routine surveillance activities  
19 associated with applications under sections  
20 587B and 587D; or

21 “(ii) to meet the requirements to re-  
22 ceive premarket approval under section  
23 587B or a technology certification order  
24 under section 587D, as applicable.

25 “(b) ACCREDITATION.—

1 “(1) ACCREDITATION PROGRAM.—

2 “(A) IN GENERAL.—The Secretary may  
3 provide for accreditation under this section  
4 through programs administered by the Food  
5 and Drug Administration, by other non-Federal  
6 government agencies, or by qualified nongovern-  
7 mental organizations. A person may be accred-  
8 ited for the review of both applications sub-  
9 mitted under sections 587B and 587D as de-  
10 scribed in subsection (a)(1)(A) and to conduct  
11 inspection activities under subsection (a)(2)(A),  
12 or for a subset of such review or activities.

13 “(B) ELIGIBLE PERSONS.—Not later than  
14 180 days after the date of enactment of the  
15 Verifying Accurate Leading-edge IVCT Devel-  
16 opment Act of 2020, the Secretary shall issue  
17 draft guidance on the criteria that the Sec-  
18 retary will use to accredit or deny accreditation  
19 to a person who requests such accreditation  
20 under subsection (a), and not later than one  
21 year after the close of the comment period for  
22 the draft guidance issued in this section, issue  
23 final guidance.

24 “(C) REQUIREMENTS.—

1                   “(i) IN GENERAL.—The Secretary  
2                   shall not accredit or maintain accreditation  
3                   for a person unless such person meets the  
4                   minimum qualifications required under  
5                   subsection (c).

6                   “(ii) SCOPE OF ACCREDITATION.—  
7                   The accreditation of a person under this  
8                   section shall specify the particular activi-  
9                   ties under subsection (a) for which such  
10                  person is accredited.

11                  “(D) PUBLIC LIST.—The Secretary shall  
12                  publish on the internet website of the Food and  
13                  Drug Administration a list of persons who are  
14                  accredited under this section. Such list shall be  
15                  updated on at least a monthly basis. The list  
16                  shall specify the particular activity or activities  
17                  under this section for which the person is ac-  
18                  credited.

19                  “(2) ACCREDITATION PROCESS.—

20                  “(A) ACCREDITATION PROCESS GUID-  
21                  ANCE.—The Secretary shall—

22                  “(i) not later than 180 days after the  
23                  date of enactment of the Verifying Accu-  
24                  rate Leading-edge IVCT Development Act  
25                  of 2020, issue draft guidance specifying

1 the process for submitting a request for  
2 each type of accreditation and reaccredita-  
3 tion under this section, including the form  
4 and content of information to be submitted  
5 in such a request; and

6 “(ii) not later than 1 year after the  
7 close of the comment period for the draft  
8 guidance, issue final guidance.

9 “(B) RESPONSE TO REQUEST.—The Sec-  
10 retary shall respond to a request for accredita-  
11 tion or reaccreditation within 60 calendar days  
12 of the receipt of the request. The Secretary’s  
13 response may be to accredit or reaccredit the  
14 person, to deny accreditation, or to request ad-  
15 ditional information in support of the request.  
16 If the Secretary requests additional informa-  
17 tion, the Secretary shall respond within 60 cal-  
18 endar days of receipt of such additional infor-  
19 mation to accredit or deny the accreditation.

20 “(C) TYPE OF ACCREDITATION.—The ac-  
21 creditation or reaccreditation of a person shall  
22 specify the particular activity or activities under  
23 subsection (a) for which such person is accred-  
24 ited, and shall include any limitation to certain  
25 eligible in vitro clinical tests.

1           “(D) AUDIT.—The Secretary may audit  
2 the performance of persons accredited under  
3 this section for purposes of ensuring that such  
4 persons continue to meet the published criteria  
5 for accreditation, and may modify the scope or  
6 particular activities for which a person is ac-  
7 credited if the Secretary determines that such  
8 person fails to meet one or more criteria for ac-  
9 creditation.

10           “(E) SUSPENSION OR WITHDRAWAL.—The  
11 Secretary may suspend or withdraw accredita-  
12 tion of any person accredited under this section,  
13 after providing notice and an opportunity for an  
14 informal hearing, when such person is substan-  
15 tially not in compliance with the requirements  
16 of this section or the published criteria for ac-  
17 creditation, or poses a threat to public health,  
18 or fails to act in a manner that is consistent  
19 with the purposes of this section.

20           “(F) REACCREDITATION.—Accredited per-  
21 sons may be initially accredited for up to 4  
22 years. After expiration of such initial period,  
23 persons may be reaccredited for unlimited addi-  
24 tional 4-year periods, as determined by the Sec-  
25 retary.

1 “(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

2 “(1) ELIGIBILITY.—An accredited person, at a  
3 minimum, shall—

4 “(A) not be an employee of the Federal  
5 Government;

6 “(B) not engage in the activities of a de-  
7 veloper, as defined in section 587(7);

8 “(C) not be a person required to register  
9 under section 587I, unless such person has es-  
10 tablished sufficient processes and protocols to  
11 separate activities to develop in vitro clinical  
12 tests and the activities for which such person  
13 would be accredited under subsection (a) and  
14 discloses applicable information under this sec-  
15 tion;

16 “(D) not be owned or controlled by, and  
17 shall have no organizational, material or finan-  
18 cial affiliation with, an in vitro clinical test de-  
19 veloper or other person required to register  
20 under section 587I;

21 “(E) be a legally constituted entity per-  
22 mitted to conduct the activities for which it  
23 seeks accreditation;

24 “(F) ensure that the operations of such  
25 person are in accordance with generally accept-



1 ed professional and ethical business practices;  
2 and

3 “(G) include in its request for accredita-  
4 tion a commitment to, at the time of accredita-  
5 tion and at any time it is performing activities  
6 pursuant to this section—

7 “(i) certify that the information re-  
8 ported to the Secretary accurately reflects  
9 the data or protocol reviewed, and the doc-  
10 umented inspection findings, as applicable;

11 “(ii) limit work to that for which com-  
12 petence and capacity are available;

13 “(iii) treat information received or  
14 learned, records, reports, and recommenda-  
15 tions as proprietary information of the per-  
16 son submitting such information; and

17 “(iv) in conducting the activities for  
18 which the person is accredited in respect to  
19 a particular in vitro clinical test, protect  
20 against the use of any employee or consult-  
21 ant who has a financial conflict of interest  
22 regarding that in vitro clinical test.

23 “(2) WAIVER.—The Secretary may waive any  
24 requirements in subparagraphs (A), (B), (C), or (D)  
25 of paragraph (1) upon making a determination that

1 such person has implemented other appropriate con-  
2 trols sufficient to ensure a competent and impartial  
3 review.

4 “(d) COMPENSATION OF ACCREDITED PERSONS.—

5 “(1) IN GENERAL.—Compensation of an ac-  
6 credited person who reviews an application for pre-  
7 market approval submitted under section 587B or  
8 an application for technical certification submitted  
9 under section 587D shall be determined by agree-  
10 ment between the accredited person and the person  
11 who engages the services of the accredited person,  
12 and shall be paid by the person who engages such  
13 services.

14 “(2) INSPECTION ACCREDITATION.—Compensa-  
15 tion of an accredited person who is conducting an  
16 inspection under section 704 shall be determined by  
17 agreement between the accredited person and the  
18 person who engages the services of the accredited  
19 person, and shall be paid by the person who engages  
20 such services.

21 “(e) COOPERATIVE AGREEMENTS.—The Secretary is  
22 authorized to enter into cooperative arrangements with of-  
23 ficials of foreign countries to ensure that adequate and  
24 effective means are available for purposes of determining,  
25 from time to time, whether in vitro clinical tests intended

1 for use in the United States by a person whose facility  
2 is located outside the United States shall be refused ad-  
3 mission on any of the grounds set forth in section 801(a).

4 “(f) INFORMATION SHARING AGREEMENTS.—An ac-  
5 credited person may enter into an agreement with a test  
6 developer to provide information to the comprehensive test  
7 information system under section 587T, including any re-  
8 quirements under section 587I.

9 **“SEC. 587Q. RECOGNIZED STANDARDS.**

10 “(a) IN GENERAL.—The Secretary may by order es-  
11 tablish performance standards for an in vitro clinical test  
12 or tests with the same indication for use to provide reason-  
13 able assurance of the analytical validity, clinical validity,  
14 or as applicable safety, of that in vitro clinical test or tests  
15 with the same indications for use.

16 “(b) OTHER STANDARDS.—The Secretary may recog-  
17 nize all or part of appropriate standards established by  
18 nationally or internationally recognized standard develop-  
19 ment organizations for which a person may submit a dec-  
20 laration of conformity in order to meet a requirement  
21 under this subchapter to which that standard is applicable.  
22 In recognizing a standard, any person requesting recogni-  
23 tion of a standard or seeking to use a recognized standard,  
24 the Secretary shall follow the processes and requirements,  
25 in accordance with section 514(c). Standards for in vitro

1 diagnostic devices previously recognized under section  
2 514(c) shall be considered recognized standards under this  
3 section. The application of any such consensus standard  
4 shall only apply prospectively. The Secretary shall issue  
5 guidance establishing the criteria and process for such rec-  
6 ognition and adoption.

7 “(c) ORDER PROCESS.—In establishing a standard  
8 under subsection (a), the Secretary shall issue a draft  
9 order proposing to establish a standard and shall provide  
10 for a comment period of not less than 60 calendar days.  
11 The Secretary may choose to seek the recommendation of  
12 an advisory committee under section 587G concerning a  
13 proposed standard either prior to or after issuance of a  
14 proposed order. After considering the comments and with-  
15 in 90 days of the close of the comment period, the Sec-  
16 retary shall issue a final order adopting the proposed  
17 standard, adopting a modification of the proposed stand-  
18 ard or terminating the proceeding.

19 “(d) AMENDMENT PROCESS.—The procedures estab-  
20 lished in this section or in guidance issued under this sec-  
21 tion shall apply to amendment of an existing standard.

22 **“SEC. 587R. INVESTIGATIONAL USE.**

23 “(a) IN GENERAL.—Except as provided in subsection  
24 (c), an in vitro clinical test for investigational use shall

1 be exempt from the requirements of this subchapter other  
2 than sections 587A, 587O, and 587U.

3 “(b) REGULATIONS.—Not later than 2 years after  
4 the date of enactment of the Verifying Accurate Leading-  
5 edge IVCT Development Act of 2020, the Secretary shall  
6 promulgate regulations to implement this section.

7 “(c) APPLICATION FOR INVESTIGATIONAL USE.—

8 “(1) IN GENERAL.—The following shall apply  
9 with respect to in vitro clinical tests for investiga-  
10 tional use:

11 “(A) STREAMLINING APPLICATIONS SUB-  
12 MITTED UNDER THIS SECTION.—Requirements  
13 with respect to such tests shall be completed in  
14 accordance with current investigational use re-  
15 quirements for institutional review boards and  
16 current processes for any analytical or clinical  
17 validation.

18 “(B) VARIATION.—The requirements in  
19 the regulations promulgated under this section  
20 shall take into account variations based on—

21 “(i) the scope and duration of clinical  
22 testing to be conducted under investigation  
23 that is the subject of such application;

24 “(ii) the number of human subjects  
25 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 approval specified in para-  
5 graph (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 OF APPROVAL.—

11 “(A) IN GENERAL.—An investigational use  
12 application with respect to significant risk tests  
13 shall only be approved if each of the following  
14 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 of approval under this paragraph, the  
12          Secretary shall not impose a limit on the sam-  
13          ple size for a significant risk in vitro clinical  
14          test that meets the requirements of section  
15          587C, as long as such test is developed within  
16          a laboratory that is certified to conduct high-  
17          complexity testing under section 353 of the  
18          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 an investigational new drug application involving  
23          an in vitro clinical test shall supersede the reporting  
24          requirement in paragraph (2)(B), but only to the ex-  
25          tent the requirement with respect to the investiga-

1           tional new drug application is duplicative of the re-  
2           porting requirement under such paragraph.

3           “(5) INVESTIGATION PLAN REQUIREMENTS.—

4                   “(A) IN GENERAL.—With respect to an in-  
5           vestigational plan submitted under paragraph  
6           (2)(A), the sponsor submitting such plan  
7           shall—

8                           “(i) in the case of such a plan sub-  
9                           mitted to an institutional review com-  
10                          mittee, promptly notify the Secretary of  
11                          the approval or the suspension or termi-  
12                          nation of the approval of such plan by an  
13                          institutional review committee;

14                           “(ii) in the case of an in vitro clinical  
15                          test made available to investigators for  
16                          clinical testing, assurance that all inves-  
17                          tigators will comply with this section, regu-  
18                          lations promulgated or revised under this  
19                          section, and applicable human subjects reg-  
20                          ulations;

21                           “(iii) submit an assurance to the Sec-  
22                          retary that informed consent will be ob-  
23                          tained from each human subject (or the  
24                          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 application that meets the requirements of sub-  
5           section (c)(2), issues an order under subsection  
6           (d)(1) and notifies the sponsor submitting the appli-  
7           cation, the application shall be treated as approved  
8           as of such date without further action by the Sec-  
9           retary.

10           “(3) DISAPPROVAL.—The Secretary may dis-  
11           approve an investigational use application submitted  
12           under this subsection if the Secretary determines  
13           that the investigation with respect to which the ap-  
14           plication is submitted does not conform to the re-  
15           quirements of subsection (c)(3). A listing of such  
16           disapproval submitted to the sponsor with respect to  
17           such an application shall contain the order of dis-  
18           approval and a complete statement of the reasons  
19           for the Secretary’s disapproval of the application.

20           “(e) WITHDRAWAL OF APPROVAL.—

21           “(1) IN GENERAL.—The Secretary may, by ad-  
22           ministrative order, withdraw the approval of an ex-  
23           emption granted under this section with respect to  
24           an in vitro clinical test, including an exemption  
25           granted based on the Secretary’s failure to act pur-

1 suant to subsection (d)(2), if the Secretary deter-  
2 mines that the test does not meet the applicable con-  
3 ditions under subsection (c)(3) for such approval.

4 “(2) OPPORTUNITY TO BE HEARD.—

5 “(A) IN GENERAL.—Subject to subpara-  
6 graph (B), an order withdrawing the approval  
7 of an exemption granted under this section may  
8 be issued only after the Secretary provides the  
9 applicant or sponsor of the test with an oppor-  
10 tunity for an 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 approval of an ap-  
4       plication for an exemption or the approval of a sup-  
5       plement to such an application. Such regulations  
6       shall 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 represents 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          healthcare professionals, healthcare systems, payers,  
18          Federal and State agencies, entities responsible for  
19          accrediting clinical laboratories, international regu-  
20          latory bodies, test developers, or other interested en-  
21          tities 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 2020, 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 prin-  
21 cipals under this Act.

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 internet website of the Food  
8 and Drug Administration matters for which it is  
9 seeking comments or recommendations, in a timely  
10 manner;

11 “(2) maintain a list of all collaborative commu-  
12 nities in which the Secretary participates and make  
13 such list available on the internet website of the  
14 Food and Drug Administration; and

15 “(3) post on the internet website of the Food  
16 and Drug Administration at least once every year a  
17 report on the recommendations it has adopted and  
18 recommendations it has not adopted from collabo-  
19 rative communities.

20 “(f) PARTICIPATION.—The Secretary may participate  
21 in a collaborative community only if such community re-  
22 quires members to disclose conflicts of interest and has  
23 established a process to address conflicts of interest.

24 “(g) EXCEPTION.—The Federal Advisory Committee  
25 Act in the appendix to title 5 shall not apply to collabo-

1 rative communities established and used in accordance  
2 with this section.

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 2020, 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 internet website of the Food and Drug Administra-  
16 tion for stakeholders, to the extent permitted by ap-  
17 plicable 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 587B and 587D.

15          **“SEC. 587U. PREEMPTION.**

16          “(a) IN GENERAL.—No State, tribal, or local govern-  
17          ment (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  
22          postmarket surveillance, unless the Secretary deter-  
23          mines 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 subsections (a) or  
3           (b); 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 sections  
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)”; and

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”; and

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;

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 proc-  
2 essing,” 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) IN GENERAL.—Except as otherwise pro-  
25 vided in this section, the amendments made by this

1 Act apply beginning on the first day of the fourth  
2 fiscal year that begins after the date of enactment  
3 of this Act (in this section and in subchapter J of  
4 chapter V of the Federal Food, Drug, and Cosmetic  
5 Act, as added by this Act, referred to in this section  
6 as the “effective date of this Act”), except that the  
7 Secretary of Health and Human Services (in this  
8 section referred to as the “Secretary”) may take the  
9 actions described in paragraph (2) as described in  
10 such paragraph, and may take such other actions,  
11 and expend such funds, as the Secretary determines  
12 necessary to ensure an orderly transition.

13 (2) ACTIONS.—The Secretary shall, prior to the  
14 date on which the amendments made by this Act  
15 generally apply pursuant to paragraph (1)—

16 (A) within 2 years of the date of enact-  
17 ment of this Act hold the public meetings de-  
18 scribed in subchapter J of chapter V of the  
19 Federal Food, Drug, and Cosmetic Act, as  
20 added by section 3;

21 (B) within 2 years of the date of enact-  
22 ment of this Act promulgate regulations re-  
23 quired under sections 587L, 587M, 587V, and  
24 587W;



1 (C) issue final guidance on premarket re-  
2 view requirements under section 587B, tech-  
3 nology certification review requirements under  
4 section 587D, and applicability under section  
5 587A; and

6 (D) promulgate additional regulations re-  
7 quired by such amendments made by this Act.

8 (3) APPLICABILITY OF REGULATIONS.—Not-  
9 withstanding the date on which guidance or regula-  
10 tions are issued under paragraph (2), no guidance or  
11 regulations issued pursuant to the amendments  
12 made by this Act shall take effect until the effective  
13 date of this Act, as described in paragraph (1), ex-  
14 cept as otherwise provided for transitional tests.

15 (b) APPLICATION OF AUTHORITIES TO IN VITRO  
16 CLINICAL TESTS UNTIL AND AFTER EFFECTIVE DATE  
17 OF THIS ACT.—Except as provided in subsection (d), for  
18 any product or test that is an in vitro clinical test as de-  
19 fined in section 201(ss) of the Federal Food, Drug, and  
20 Cosmetic Act, as added by this Act, the following authori-  
21 ties shall apply:

22 (1) TESTS OFFERED PRIOR TO ENACTMENT.—  
23 An in vitro clinical test that meets the criteria for  
24 a grandfathered test as set forth in section  
25 587A(c)(2) of the Federal Food, Drug, and Cos-

1        metric Act, as added by section 3, may continue to  
2        be offered for clinical use and shall be subject only  
3        to applicable provisions of section 353 of the Public  
4        Health Service Act and section 587A(a)(4) of the  
5        Federal Food, Drug, and Cosmetic Act, as added by  
6        section 3.

7            (2) TESTS OFFERED ON OR AFTER ENACTMENT  
8        BUT BEFORE IMPLEMENTATION.—Before any prod-  
9        uct or test that is an in vitro clinical test as defined  
10       in section 201(ss) of the Federal Food, Drug, and  
11       Cosmetic Act, as added by this Act, is first offered,  
12       sold, or distributed after the date of enactment of  
13       this Act, but prior to 90 days before the effective  
14       date of this Act, such product or test shall be con-  
15       sidered a transitional test as described under sub-  
16       section (d) and comply with the applicable device  
17       provisions of the Federal Food, Drug, and Cosmetic  
18       Act (21 U.S.C. 301 et seq.) and the Public Health  
19       Service Act (42 U.S.C. 201 et seq.).

20            (3) TESTS UNDER REVIEW BEGINNING ON OR  
21        AFTER THE DATE OF ENACTMENT OF THIS ACT BUT  
22        PRIOR TO IMPLEMENTATION.—For any product or  
23        test that is an in vitro clinical test as defined in sec-  
24        tion 201(ss) of the Federal Food, Drug, and Cos-  
25        metic Act, as added by this Act, for which a submis-

1 sion for marketing authorization under section 515,  
2 clearance under section 510(k), authorization under  
3 section 513(f)(2), approval under section 520(m), or  
4 emergency use authorization under section 564 of  
5 the Federal Food, Drug, and Cosmetic Act (21  
6 U.S.C. 360e, 360(k), 360c(f)(2), 360j(m), 360bbb–  
7 3) or approval under the Public Health Service Act  
8 (42 U.S.C. 201 et seq.) is pending on the effective  
9 date of this Act, the Secretary may review and take  
10 action on such submission after the effective date of  
11 this Act according to the statutory provision under  
12 which such submission was submitted.

13 (c) APPLICATION OF AUTHORITIES TO TRANSI-  
14 TIONAL AND GRANDFATHERED IN VITRO CLINICAL  
15 TESTS.—

16 (1) DEFINITION.—For purposes of this para-  
17 graph, the term “transitional in vitro clinical test”  
18 means an in vitro clinical test, as defined in section  
19 201(ss) of the Federal Food, Drug, and Cosmetic  
20 Act, as added by this Act, that—

21 (A) was developed by a clinical laboratory  
22 certified by the Secretary under section 353 of  
23 the Public Health Service Act (42 U.S.C. 263a)  
24 that meets the requirements for performing  
25 high-complexity testing for use only within that

1 certified laboratory or another laboratory within  
2 the organization under common ownership;

3 (B) does not have an approval under sec-  
4 tion 515, a clearance under section 510(k), an  
5 authorization under 513(f)(2), an approval  
6 under section 520(m), or an emergency use au-  
7 thorization under section 564 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C.  
9 360e, 360(k), 360c(f)(2), 360j(m), 360bbb-3)  
10 or approval under the Public Health Service  
11 Act (42 U.S.C. 201 et seq.); and

12 (C) is first offered for clinical use during  
13 the period beginning on the date of enactment  
14 of this Act and ending on the implementation  
15 date of this Act.

16 (2) CONTINUED OFFERING.—Notwithstanding  
17 subsection (c), a transitional in vitro clinical test  
18 may continue to be offered for clinical use until the  
19 effective date of this Act, as described in subsection  
20 (b)(1), except that the Secretary retains authority to  
21 enforce the device provisions of the Federal Food,  
22 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and  
23 the Public Health Service Act (42 U.S.C. 201 et  
24 seq.) for any specific transitional in vitro clinical  
25 test, or any type of transitional in vitro clinical test,

1 as the Secretary determines necessary to protect the  
2 public from a serious risk to health.

3 (3) PREMARKET REVIEW OR TECHNOLOGY CER-  
4 TIFICATION.—A transitional in vitro clinical test  
5 that is the subject of an application for premarket  
6 review under section 587B of the Federal Food,  
7 Drug, and Cosmetic Act or technology certification  
8 application under section 587D of such Act, as  
9 added by this Act, that is submitted within 90 days  
10 of the effective date of this Act may continue to be  
11 offered, sold, or distributed until completion of the  
12 Secretary's review of the premarket application or  
13 technology certification application.

14 (d) CONVERSION.—

15 (1) DEEMED PREMARKET APPROVAL.—Any in  
16 vitro clinical test (as defined in section 201(ss) of  
17 the Federal Food, Drug, and Cosmetic Act, as  
18 added by this Act) with a premarket approval under  
19 section 515, a clearance under section 510(k), an  
20 authorization under section 513(f), or a licensure  
21 under section 351 of the Public Health Service Act  
22 (42 U.S.C. 262) is deemed to have an approved ap-  
23 plication under section 587B of the Federal Food,  
24 Drug, and Cosmetic Act, as added by this Act, be-  
25 ginning on the later of—

1 (A) the effective date of this Act; or

2 (B) such other date, not later than 3 years  
3 after such effective date, as the person respon-  
4 sible for the device selects.

5 (2) DEEMED INVESTIGATIONAL USE AP-  
6 PROVAL.—Any in vitro clinical test (as defined in  
7 section 201(ss) of the Federal Food, Drug, and Cos-  
8 metic Act, as added by this Act) that has an ap-  
9 proved investigational device exemption under sec-  
10 tion 520(g) of the Federal Food, Drug, and Cos-  
11 metic Act (21 U.S.C. 360j(g)) is deemed to have an  
12 approved investigational use under section 587Q of  
13 such Act, as added by this Act, beginning on the ef-  
14 fective date of this Act.

15 (e) INSTRUMENTS.—An instrument (as defined in  
16 section 587 of the Federal Food, Drug, and Cosmetic Act,  
17 as added by this Act) that was purchased prior to the date  
18 of enactment of this Act and was not cleared, authorized,  
19 or approved by the Food and Drug Administration or part  
20 of an instrument family that was cleared, authorized, or  
21 approved by the Food and Drug Administration at the  
22 time of purchase may continue to be used by the purchaser  
23 to develop and introduce into interstate commerce an in  
24 vitro clinical test during the period beginning on the date  
25 of enactment of this Act and ending 5 years after such

1 date of enactment. Beginning at the end of such period,  
2 any new in vitro clinical test that is developed and intro-  
3 duced into interstate commerce shall be based on an in-  
4 strument (as defined in section 587(11) of the Federal  
5 Food, Drug, and Cosmetic Act, as added by section 3)  
6 that complies with the requirements of the Federal Food,  
7 Drug, and Cosmetic Act, as amended by this Act.

8 (f) RELATION TO IN VITRO CLINICAL TEST PROVI-  
9 SION.—This section applies notwithstanding section  
10 587A(a)(1)(C) of the Federal Food, Drug, and Cosmetic  
11 Act, as added by this Act.

12 **SEC. 6. EMERGENCY USE AUTHORIZATION.**

13 Section 564 of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 360bbb–3) is amended—

15 (1) in paragraphs (1) and (4)(C) of subsection  
16 (a), by inserting “in vitro clinical test,” before “or  
17 biological product” each place such term appears;  
18 and

19 (2) in subsection (e)(3)—

20 (A) in subparagraph (B), by striking  
21 “and” at the end;

22 (B) in subparagraph (C), by striking the  
23 period and inserting “; and”; and

24 (C) by adding at the end the following:

1                   “(D) quality system requirements (with re-  
2                   spect to in vitro clinical tests) under section  
3                   587J.”.

4 **SEC. 7. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

5           Section 511A of the Federal Food, Drug, and Cos-  
6           metic Act (21 U.S.C. 360a-2) is amended—

7                   (1) in subsection (a)(1)(C)—

8                           (A) by striking “or approve under section  
9                           515” and inserting “approve under section 515,  
10                           or approve, exempt, or issue a technology cer-  
11                           tification order under subchapter J”; and

12                           (B) by striking “testing devices” and in-  
13                           serting “tests”;

14                   (2) in subsection (c)(5), by striking “drug or  
15                   device” each place it appears and inserting “drug,  
16                   device, or in vitro clinical test”;

17                   (3) in subsection (e)—

18                           (A) in the heading, by striking “TESTING  
19                           DEVICES” and inserting “IN VITRO CLINICAL  
20                           TESTS”

21                           (B) in paragraph (1)—

22                                   (i) by striking “and 515,” and insert-  
23                                   ing “515, 587B, and 587D”;

24                                   (ii) by striking “antimicrobial suscep-  
25                                   tibility testing device” and inserting “anti-



1 microbial susceptibility in vitro clinical  
2 test”; and

3 (iii) by striking “such device” and in-  
4 sserting “such test”

5 (C) in paragraph (2)—

6 (i) in the heading, by striking “TEST-  
7 ING DEVICES” and inserting “IN VITRO  
8 CLINICAL TESTS”; and

9 (ii) by amending subparagraph (C) to  
10 read as follows:

11 “(C) The antimicrobial susceptibility in  
12 vitro clinical test meets all other requirements  
13 to be approved under section 587B or exempted  
14 from premarket review under section 587D.”.

15 (D) after making the amendments in sub-  
16 paragraph (B)(ii), (B)(iii), and (C)(ii), by strik-  
17 ing “device” each place it appears and inserting  
18 “in vitro clinical test”; and

19 (4) in subsection (f), by amending paragraph  
20 (1) to read as follows:

21 “(1) The term ‘antimicrobial susceptibility in  
22 vitro clinical test’ means an in vitro clinical test that  
23 utilizes susceptibility test interpretive criteria to de-  
24 termine and report the in vitro susceptibility of cer-  
25 tain microorganisms to a drug (or drugs).”; and

1 (5) in subsection (g)(2)—

2 (A) by amending the matter preceding sub-  
3 paragraph (A) to read as follows:

4 “(2) with respect to clearing under section  
5 510(k), classifying under section 513(f)(2), approv-  
6 ing under section 515 or section 587B, or exempting  
7 from approval requirements under section 587D—”;  
8 and

9 (B) in subparagraph (A)—

10 (i) by striking “device” and inserting  
11 “in vitro clinical test”; and

12 (ii) by striking “antimicrobial suscep-  
13 tibility testing device” and inserting “anti-  
14 microbial susceptibility in vitro clinical  
15 test”.

16 **SEC. 8. COMBINATION PRODUCTS.**

17 (a) IN GENERAL.—Section 503(g) of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is  
19 amended—

20 (1) in paragraph (1)—

21 (A) in subparagraph (A)—

22 (i) by inserting “(except for a com-  
23 bination product constituted of a device  
24 and an in vitro clinical test)” after “agency  
25 center,”; and

1 (ii) by inserting “in vitro clinical  
2 test,” before “or biological product”; and

3 (B) in subparagraph (D)—

4 (i) in the matter preceding clause (i),  
5 by striking “. If the Secretary determines”  
6 and inserting “, except for a combination  
7 product constituted of a device and an in  
8 vitro clinical test. For other combination  
9 products, if the Secretary determines”; and

10 (ii) in clause (ii)—

11 (I) by inserting “or in vitro clin-  
12 ical test” after “device”; and

13 (II) by inserting “and in vitro  
14 clinical tests” before “shall”;

15 (2) in paragraph (3), by striking “safety and  
16 effectiveness or substantial equivalence” and insert-  
17 ing “safety and effectiveness, substantial equiva-  
18 lence, or analytical validity and clinical validity” be-  
19 fore “for the approved constituent part”;

20 (3) in paragraph (4)—

21 (A) in subparagraph (A), by striking “or  
22 513(f)(2) (submitted in accordance with para-  
23 graph (5))” and inserting “513(f)(2) (sub-  
24 mitted in accordance with paragraph (5)),

1           587B, or an exempt test under section 587A, as  
2           applicable”; and

3                   (B) in subparagraph (B), by inserting “or  
4           587B” after “section 515”;

5           (4) in paragraph (5)(A), by striking “or  
6           510(k)” and inserting “, 510(k), or 587B”;

7           (5) in paragraph (7), by striking “or substan-  
8           tial equivalence” and inserting “, substantial equiva-  
9           lence, or analytical validity and clinical validity”;

10           (6) in paragraph (8), by adding at the end the  
11           following:

12                   “(I) This paragraph shall not apply to a  
13           combination product constituted of a device and  
14           an in vitro clinical test.”; and

15           (7) in paragraph (9)—

16                   (A) in subparagraph (C)(i), by striking “or  
17           520(g)” and inserting “520(g), or 587B”; and

18                   (B) in subparagraph (D), by striking “or  
19           520” and inserting “520, or 587B”.

20           (b) CLASSIFICATION OF PRODUCTS.—Section 563 of  
21           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22           360bbb–2) is amended by adding at the end the following:

23                   “(d) EXEMPTION.—This section shall not apply to a  
24           combination product constituted of a device and an in  
25           vitro clinical test.”.

1 **SEC. 9. RESOURCES.**

2 (a) FINDINGS.—Congress finds that the fees author-  
3 ized by this section will be dedicated to meeting the goals  
4 identified in the letters from the Secretary of Health and  
5 Human Services to the Committee on Health, Education,  
6 Labor, and Pensions of the Senate and the Committee on  
7 Energy and Commerce of the House of Representatives,  
8 as set forth in the Congressional Record.

9 (b) ESTABLISHMENT OF USER FEE PROGRAM.—

10 (1) DEVELOPMENT OF USER FEES FOR IN  
11 VITRO CLINICAL TESTS.—

12 (A) IN GENERAL.—Beginning not later  
13 than October 1, 2020, the Secretary of Health  
14 and Human Services (in this section referred to  
15 as the “Secretary”) shall develop recommenda-  
16 tions to present to Congress with respect to the  
17 goals, and plans for meeting the goals, for the  
18 process of the review of in vitro clinical test ap-  
19 plications submitted under subchapter J of  
20 chapter V of the Federal Food, Drug, and Cos-  
21 metic Act, as added by this Act, for the first 5  
22 fiscal years after fiscal year 2021. In developing  
23 such recommendations, the Secretary shall con-  
24 sult with—

- 1 (i) the Committee on Energy and  
2 Commerce of the House of Representa-  
3 tives;
- 4 (ii) the Committee on Health, Edu-  
5 cation, Labor, and Pensions of the Senate;
- 6 (iii) scientific and academic experts;
- 7 (iv) health care professionals;
- 8 (v) representatives of patient and con-  
9 sumer advocacy groups; and
- 10 (vi) the regulated industry.
- 11 (B) PRIOR PUBLIC INPUT.—Prior to begin-  
12 ning negotiations with the regulated industry  
13 on the authorization of such subchapter J, the  
14 Secretary shall—
- 15 (i) publish a notice in the Federal  
16 Register requesting public input on the au-  
17 thorization of user fees;
- 18 (ii) hold a public meeting at which the  
19 public may present its views on the author-  
20 ization, including specific suggestions for  
21 the recommendations submitted under sub-  
22 paragraph (E);
- 23 (iii) provide a period of 30 days after  
24 the public meeting to obtain written com-

1                   ments from the public suggesting changes  
2                   to such subchapter J; and

3                   (iv) publish any comments received  
4                   under clause (iii) on the internet website of  
5                   the Food and Drug Administration.

6                   (C) PERIODIC CONSULTATION.—Not less  
7                   frequently than once every month during nego-  
8                   tiations with the regulated industry, the Sec-  
9                   retary shall hold discussions with representa-  
10                  tives of patient and consumer advocacy groups  
11                  to continue discussions of the authorization  
12                  under such subchapter J and to solicit sugges-  
13                  tions to be included in the recommendations  
14                  transmitted to Congress under subparagraph  
15                  (E).

16                  (D) PUBLIC REVIEW OF RECOMMENDA-  
17                  TIONS.—After negotiations with the regulated  
18                  industry, the Secretary shall—

19                  (i) present the recommendations de-  
20                  veloped under subparagraph (A) to the  
21                  Committee on Health, Education, Labor,  
22                  and Pensions of the Senate and the Com-  
23                  mittee on Energy and Commerce of the  
24                  House of Representatives;

1 (ii) publish such recommendations in  
2 the Federal Register;

3 (iii) provide for a period of 30 days  
4 for the public to provide written comments  
5 on such recommendations;

6 (iv) hold a meeting at which the pub-  
7 lic may present its views on such rec-  
8 ommendations; and

9 (v) after consideration of such public  
10 views and comments, revise such rec-  
11 ommendations as necessary.

12 (E) TRANSMITTAL OF RECOMMENDA-  
13 TIONS.—

14 (i) IN GENERAL.—Not later than  
15 June 1, 2021, the Secretary shall transmit  
16 to Congress the revised recommendations  
17 under subparagraph (A), a summary of the  
18 views and comments received under such  
19 subparagraph, and any changes made to  
20 the recommendations in response to such  
21 views and comments.

22 (ii) RECOMMENDATION REQUIRE-  
23 MENTS.—The recommendations trans-  
24 mitted under this subparagraph shall—



1 (I) include the number of full-  
2 time equivalent employees per fiscal  
3 year that are agreed to be hired to  
4 carry out the goals included in such  
5 recommendations for each year of the  
6 5-year period;

7 (II) provide that the amount of  
8 operating reserve balance in the user  
9 fee program established under this  
10 section is not more than the equiva-  
11 lent of 10 weeks of operating reserve;

12 (III) require the development of  
13 a strategic plan for any surplus within  
14 the operating reserve account above  
15 the 10-week operating reserve within  
16 2 years of the establishment of the  
17 program;

18 (IV) include an operating reserve  
19 adjustment such that, if the Secretary  
20 has an operating reserve balance in  
21 excess of 10 weeks of such operating  
22 reserves, the Secretary shall decrease  
23 such fee revenue and fees to provide  
24 for not more than 10 weeks of such  
25 operating reserves;

1 (V) if an adjustment is made as  
2 described in subclause (IV), provide  
3 the rationale for the amount of the  
4 decrease in fee revenue and fees shall  
5 be contained in the Federal Register;  
6 and

7 (VI) provide that the fees as-  
8 sessed and collected for the full-time  
9 equivalent employees at the Center for  
10 Devices and Radiological Health, with  
11 respect to which the majority of time  
12 reporting data indicates are dedicated  
13 to the review of in vitro clinical tests,  
14 are not supported by the funds au-  
15 thorized to be collected and assessed  
16 under section 738 of the Federal  
17 Food Drug and Cosmetic Act (21  
18 U.S.C. 379j).

19 (F) PUBLICATION OF RECOMMENDA-  
20 TIONS.—The Secretary shall publish on the  
21 internet website of the Food and Drug Admin-  
22 istration the revised recommendations under  
23 subparagraph (A), a summary of the views and  
24 comments received under subparagraphs (B)  
25 through (D), and any changes made to the rec-

1           ommendations originally proposed by the Sec-  
2           retary in response to such views and comments.

3           (G) MINUTES OF NEGOTIATION MEET-  
4           INGS.—

5           (i) PUBLIC AVAILABILITY.—Before  
6           transmitting the recommendations devel-  
7           oped under subparagraphs (A) through (F)  
8           to Congress, the Secretary shall make pub-  
9           licly available, on the internet website of  
10          the Food and Drug Administration, min-  
11          utes of all negotiation meetings conducted  
12          under this subsection between the Food  
13          and Drug Administration and the regu-  
14          lated industry.

15          (ii) CONTENT.—The minutes de-  
16          scribed under clause (i) shall summarize  
17          any substantive proposal made by any  
18          party to the negotiations, any significant  
19          controversies or differences of opinion dur-  
20          ing the negotiations, and the resolution of  
21          any such controversy or difference of opin-  
22          ion.

23          (2) ESTABLISHMENT OF USER FEE PRO-  
24          GRAM.—Effective on October 1, 2021, provided that  
25          the Secretary transmits the recommendations under

1 paragraph (1)(E), the Secretary is authorized to col-  
2 lect user fees relating to the submission of in vitro  
3 clinical test applications submitted under subchapter  
4 J of chapter V of the Federal Food, Drug, and Cos-  
5 metic Act, as added by this Act. Fees under such  
6 program shall be assessed and collected only if the  
7 requirements under paragraph (4) are met.

8 (3) AUDIT.—

9 (A) IN GENERAL.—On the date that is 2  
10 years after first receiving a user fee applicable  
11 to submission of an in vitro clinical test applica-  
12 tion submitted under subchapter J of chapter V  
13 of the Federal Food, Drug, and Cosmetic Act,  
14 as added by this Act, and on a biennial basis  
15 thereafter until October 1, 2027, the Secretary  
16 shall perform an audit of the costs of reviewing  
17 such applications under such subchapter J.  
18 Such an audit shall compare the costs of re-  
19 viewing such applications under such sub-  
20 chapter J to the amount of the user fee applica-  
21 ble to such applications.

22 (B) ALTERATION OF USER FEE.—If the  
23 audit performed under subparagraph (A) indi-  
24 cates that the user fees applicable to applica-  
25 tions submitted under such subchapter J exceed

1           30 percent of the costs of reviewing such appli-  
2           cations, the Secretary shall alter the user fees  
3           applicable to applications submitted under such  
4           subchapter J such that the user fees do not ex-  
5           ceed such percentage.

6           (C) ACCOUNTING STANDARDS.—The Sec-  
7           retary shall perform an audit under subpara-  
8           graph (A) in conformance with the accounting  
9           principles, standards, and requirements pre-  
10          scribed by the Comptroller General of the  
11          United States under section 3511 of title 31,  
12          United State Code, to ensure the validity of any  
13          potential variability.

14          (4) CONDITIONS.—The user fee program de-  
15          scribed in this subsection shall take effect only if the  
16          Food and Drug Administration issues draft guidance  
17          related to the review requirements for in vitro diag-  
18          nostic tests that would be subject to premarket re-  
19          view under section 587B of the Federal Food, Drug,  
20          and Cosmetic Act, as added by section 3, the review  
21          requirements for test categories eligible for tech-  
22          nology certification under section 587D of such Act,  
23          as added by section 3, and the parameters for the  
24          test categories that would be exempt from any re-  
25          view under subchapter J of chapter V of such Act.

1           (5) USER FEE PROGRAM DEFINITIONS AND RE-  
2           SOURCE REQUIREMENTS.—

3           (A) IN GENERAL.—The term “process for  
4           the review of in vitro clinical test applications”  
5           means the following activities of the Secretary  
6           with respect to the review of premarket applica-  
7           tions under section 587B of the Federal Food,  
8           Drug, and Cosmetic Act (as added by section  
9           3), technology certification applications under  
10          section 587D of such Act (as added by section  
11          3), and supplements for such applications:

12                   (i) The activities necessary for the re-  
13                   view of premarket applications, premarket  
14                   reports, and supplements to such applica-  
15                   tions.

16                   (ii) The issuance of action letters that  
17                   allow the marketing of in vitro clinical  
18                   tests or which set forth in detail the spe-  
19                   cific deficiencies in such applications, re-  
20                   ports, supplements, or submissions and,  
21                   where appropriate, the actions necessary to  
22                   place them in condition for approval.

23                   (iii) The inspection of manufacturing  
24                   establishments and other facilities under-  
25                   taken as part of the Secretary’s review of

1 pending premarket applications, technology  
2 certifications, and supplements.

3 (iv) Monitoring of research conducted  
4 in connection with the review of such appli-  
5 cations, supplements, and submissions.

6 (v) Review of in vitro clinical test ap-  
7 plications subject to section 351 of the  
8 Public Health Service Act (42 U.S.C.  
9 262), investigational new drug applications  
10 under section 505(i) of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C.  
12 355(i)), or investigational test exemptions  
13 under section 587A(m) of the Federal  
14 Food, Drug, and Cosmetic Act (as added  
15 by section 3), and activities conducted in  
16 anticipation of the submission of such ap-  
17 plications under section 505(i) of the Fed-  
18 eral Food, Drug, and Cosmetic Act or in-  
19 vestigational use under section 587R of the  
20 Federal Food, Drug, and Cosmetic Act (as  
21 added by section 3).

22 (vi) The development of guidance, pol-  
23 icy documents, or regulations to improve  
24 the process for the review of premarket ap-

1 applications, technology certification applica-  
2 tions, and supplements.

3 (vii) The development of voluntary  
4 test methods, consensus standards, or  
5 mandatory performance standards in con-  
6 nection with the review of such applica-  
7 tions, supplements, or submissions and re-  
8 lated activities.

9 (viii) The provision of technical assist-  
10 ance to in vitro clinical test developers in  
11 connection with the submission of such ap-  
12 plications, reports, supplements, or submis-  
13 sions.

14 (ix) Any activity undertaken in con-  
15 nection with the initial classification or re-  
16 classification of an in vitro clinical test in  
17 connection with any requirement for ap-  
18 proval of an in vitro clinical test.

19 (x) Evaluation of postmarket studies  
20 required as a condition of an approval of  
21 a premarket application of an in vitro clin-  
22 ical test.

23 (xi) Compiling, developing, and re-  
24 viewing information on relevant in vitro  
25 clinical tests to identify issues with the ap-



1           pllicable standard for premarket applica-  
2           tions, technology certification applications,  
3           and supplements.

4           (B) RESOURCE REQUIREMENTS.—Fees col-  
5           lected and assessed under this section shall be  
6           used for the process for the review of in vitro  
7           clinical test applications, as described in sub-  
8           paragraph (A), and shall—

9                   (i) be subject to the limitation under  
10                  section 738(g)(3) of the Federal Food,  
11                  Drug, and Cosmetic Act (21 U.S.C.  
12                  379j(g)(3)), in the same manner that fees  
13                  collected and assessed under section  
14                  737(9)(C) of such Act (21 U.S.C.  
15                  379i(9)(C)) are subject to such limitation;

16                   (ii) include travel expenses for officers  
17                  and employees of the Food and Drug Ad-  
18                  ministration only if the Secretary deter-  
19                  mines that such travel is directly related to  
20                  an activity described in subparagraph (A);  
21                  and

22                   (iii) not be allocated to purposes de-  
23                  scribed under section 722(a) of the Con-  
24                  solidated Appropriations Act, 2018 (Public  
25                  Law 115–141).

1 (c) REPORTS.—

2 (1) PERFORMANCE REPORT.—

3 (A) IN GENERAL.—

4 (i) GENERAL REQUIREMENTS.—Be-  
5 ginning with fiscal year 2021, for each fis-  
6 cal year for which fees are collected under  
7 this section, the Secretary shall prepare  
8 and submit to the Committee on Health,  
9 Education, Labor, and Pensions of the  
10 Senate and the Committee on Energy and  
11 Commerce of the House of Representatives  
12 annual reports concerning the progress of  
13 the Food and Drug Administration in  
14 achieving the goals identified in the rec-  
15 ommendations transmitted to Congress by  
16 the Secretary pursuant to subsection  
17 (b)(1)(E) during such fiscal year and the  
18 future plans of the Food and Drug Admin-  
19 istration for meeting the goals.

20 (ii) ADDITIONAL INFORMATION.—Be-  
21 ginning with fiscal year 2021, the annual  
22 report under this subparagraph shall in-  
23 clude the progress of the Food and Drug  
24 Administration in achieving the goals, and

1 future plans for meeting the goals, includ-  
2 ing—

3 (I) the number of premarket ap-  
4 plications filed under section 587B of  
5 the Federal Food, Drug, and Cos-  
6 metic Act during the applicable fiscal  
7 year;

8 (II) the number of technology  
9 certification applications submitted  
10 under section 587D of the Federal  
11 Food, Drug, and Cosmetic Act during  
12 the applicable fiscal year for each re-  
13 view division; and

14 (III) the number of breakthrough  
15 designations under section 587C of  
16 the Federal Food, Drug, and Cos-  
17 metic Act during the applicable fiscal  
18 year.

19 (iii) REAL-TIME REPORTING.—

20 (I) IN GENERAL.—Not later than  
21 30 calendar days after the end of the  
22 second quarter of fiscal year 2021,  
23 and not later than 30 calendar days  
24 after the end of each quarter of each  
25 fiscal year thereafter, the Secretary

1 shall post the data described in sub-  
2 clause (II) on the internet website of  
3 the Food and Drug Administration  
4 for such quarter and on a cumulative  
5 basis for such fiscal year, and may re-  
6 move duplicative data from the annual  
7 report under this subparagraph.

8 (II) DATA.—The Secretary shall  
9 post the following data in accordance  
10 with subclause (I):

11 (aa) The number and titles  
12 of draft and final guidance on  
13 topics related to the process for  
14 the review of in vitro clinical  
15 tests, and whether such guid-  
16 ances were issued as required by  
17 statute or pursuant to the rec-  
18 ommendations transmitted to  
19 Congress by the Secretary pursu-  
20 ant to subsection (b)(1)(E).

21 (bb) The number and titles  
22 of public meetings held on topics  
23 related to the process for the re-  
24 view of in vitro clinical tests, and  
25 if such meetings were required by

1 statute or pursuant to the rec-  
2 ommendations transmitted to  
3 Congress by the Secretary pursu-  
4 ant to subsection (b)(1)(E).

5 (iv) RATIONALE FOR IVCT USER FEE  
6 PROGRAM CHANGES.—Beginning with fis-  
7 cal year 2022, the Secretary shall include  
8 in the annual performance report under  
9 paragraph (1)—

10 (I) data, analysis, and discussion  
11 of the changes in the number of full-  
12 time equivalents hired as agreed upon  
13 in the recommendations transmitted  
14 to Congress by the Secretary pursuant  
15 to subsection (b)(1)(E) and the num-  
16 ber of full-time equivalents funded by  
17 budget authority at the Food and  
18 Drug Administration by each division  
19 within the Center for Devices and Ra-  
20 diological Health, the Center for Bio-  
21 logics Evaluation and Research, the  
22 Office of Regulatory Affairs, and the  
23 Office of the Commissioner;

24 (II) data, analysis, and discus-  
25 sion of the changes in the fee revenue

1 amounts and costs for the process for  
2 the review of in vitro clinical tests, in-  
3 cluding identifying drivers of such  
4 changes; and

5 (III) for each of the Center for  
6 Devices and Radiological Health, the  
7 Center for Biologics Evaluation and  
8 Research, the Office of Regulatory Af-  
9 fairs, and the Office of the Commis-  
10 sioner, the number of employees for  
11 whom time reporting is required and  
12 the number of employees for whom  
13 time reporting is not required.

14 (v) ANALYSIS.—For each fiscal year,  
15 the Secretary shall include in the report  
16 under clause (i) an analysis of the fol-  
17 lowing:

18 (I) The difference between the  
19 aggregate number of premarket appli-  
20 cations filed under section 587B or  
21 section 587D of the Federal Food,  
22 Drug, and Cosmetic Act and the ag-  
23 gregate number of major deficiency  
24 letters, not approvable letters, and de-

1 nials for such applications issued by  
2 the agency, accounting for—

3 (aa) the number of applica-  
4 tions filed under each of sections  
5 587B and 587D of the Federal  
6 Food, Drug, and Cosmetic Act  
7 during one fiscal year for which a  
8 decision is not scheduled to be  
9 made until the following fiscal  
10 year; and

11 (bb) the aggregate number  
12 of applications under each of sec-  
13 tions 587B and 587D of the  
14 Federal Food, Drug, and Cos-  
15 metic Act for each fiscal year  
16 that did not meet the goals as  
17 identified by the recommenda-  
18 tions transmitted to Congress by  
19 the Secretary pursuant to sub-  
20 section (b)(1)(E).

21 (II) Relevant data to determine  
22 whether the Center for Devices and  
23 Radiological Health has met perform-  
24 ance enhancement goals identified by  
25 the recommendations transmitted to

1 Congress by the Secretary pursuant to  
2 subsection (b)(1)(E).

3 (III) The most common causes  
4 and trends for external or other cir-  
5 cumstances affecting the ability of the  
6 Food and Drug Administration to  
7 meet review time and performance en-  
8 hancement goals identified by the rec-  
9 ommendations transmitted to Con-  
10 gress by the Secretary pursuant to  
11 subsection (b)(1)(E) .

12 (B) PUBLICATION.—With regard to infor-  
13 mation to be reported by the Food and Drug  
14 Administration to industry on a quarterly and  
15 annual basis pursuant to recommendations  
16 transmitted to Congress by the Secretary pur-  
17 suant to subsection (b)(1)(E), the Secretary  
18 shall make such information publicly available  
19 on the internet website of the Food and Drug  
20 Administration not later than 60 days after the  
21 end of each quarter or 120 days after the end  
22 of each fiscal year, respectively, to which such  
23 information applies.

24 (C) UPDATES.—The Secretary shall in-  
25 clude in each report under subparagraph (A)



1 information on all previous cohorts for which  
2 the Secretary has not given a complete response  
3 on all in vitro clinical test premarket applica-  
4 tions and technology certification orders and  
5 supplements, premarket, and technology certifi-  
6 cation notifications in the cohort.

7 (2) CORRECTIVE ACTION REPORT.—Beginning  
8 with fiscal year 2022, for each fiscal year for which  
9 fees are collected under this section, the Secretary  
10 shall prepare and submit a corrective action report  
11 to the Committee on Health, Education, Labor, and  
12 Pensions and the Committee on Appropriations of  
13 the Senate and the Committee on Energy and Com-  
14 merce and the Committee on Appropriations of the  
15 House of Representatives. The report shall include  
16 the following information, as applicable:

17 (A) GOALS MET.—For each fiscal year, if  
18 the Secretary determines, based on the analysis  
19 under paragraph (1)(A)(v), that each of the  
20 goals identified by the recommendations trans-  
21 mitted to Congress by the Secretary pursuant  
22 to subsection (b)(1)(E) for the applicable fiscal  
23 year have been met, the corrective action report  
24 shall include recommendations on ways in which  
25 the Secretary can improve and streamline the in

1 vitro clinical test premarket application and  
2 technology certification review process.

3 (B) GOALS MISSED.—For each of the goals  
4 identified by the letters described in rec-  
5 ommendations transmitted to Congress by the  
6 Secretary pursuant to subsection (b)(1)(E) for  
7 the applicable fiscal year that the Secretary de-  
8 termines to not have been met, the corrective  
9 action report shall include—

10 (i) a justification for such determina-  
11 tion;

12 (ii) a description of the types of cir-  
13 cumstances, in the aggregate, under which  
14 applications or reports submitted under  
15 sections 587B and 587D of the Federal  
16 Food, Drug, and Cosmetic Act missed the  
17 review goal times but were approved dur-  
18 ing the first cycle review, as applicable;

19 (iii) a summary and any trends with  
20 regard to the circumstances for which a re-  
21 view goal was missed; and

22 (iv) the performance enhancement  
23 goals that were not achieved during the  
24 previous fiscal year and a description of ef-  
25 forts the Food and Drug Administration

1           has put in place for the fiscal year in  
2           which the report is submitted to improve  
3           the ability of such agency to meet each  
4           such goal for the such fiscal year.

5           (3) FISCAL REPORT.—For fiscal years 2021  
6           and annually thereafter, not later than 120 days  
7           after the end of each fiscal year during which fees  
8           are collected under this subpart, the Secretary shall  
9           prepare and submit to the Committee on Health,  
10          Education, Labor, and Pensions of the Senate and  
11          the Committee on Energy and Commerce of the  
12          House of Representatives, a report on the implemen-  
13          tation of the authority for such fees during such fis-  
14          cal year and the use, by the Food and Drug Admin-  
15          istration, of the fees collected during such fiscal year  
16          for which the report is made.

17           (A) CONTENTS.—Such report shall include  
18           expenditures delineated by budget authority and  
19           user fee dollars related to administrative ex-  
20           penses and information technology infrastruc-  
21           ture contracts and expenditures.

22           (B) OPERATING RESERVE.—Such report  
23           shall provide the amount of operating reserve  
24           balance available each year, and any planned al-  
25           locations or obligations of such balance that is

1           above 10 weeks of operating reserve for the pro-  
2           gram.

3           (4) PUBLIC AVAILABILITY.—The Secretary  
4           shall make the reports required under paragraphs  
5           (1) through (3) available to the public on the inter-  
6           net website of the Food and Drug Administration.

7           (5) ENHANCED COMMUNICATION.—

8           (A) COMMUNICATIONS WITH CONGRESS.—  
9           Each fiscal year, as applicable and requested,  
10          representatives from the Centers with expertise  
11          in the review of in vitro clinical tests shall meet  
12          with representatives from the Committee on  
13          Health, Education, Labor, and Pensions of the  
14          Senate and the Committee on Energy and Com-  
15          merce of the House of Representatives to report  
16          on the contents described in the reports under  
17          this section.

18          (B) PARTICIPATION IN CONGRESSIONAL  
19          HEARING.—Each fiscal year, as applicable and  
20          requested, representatives from the Food and  
21          Drug Administration shall participate in a pub-  
22          lic hearing before the Committee on Health,  
23          Education, Labor, and Pensions of the Senate  
24          and the Committee on Energy and Commerce  
25          of the House of Representatives, to report on

## 245

1           the contents described in the reports under this  
2           section. Such hearing shall occur not later than  
3           120 days after the end of each fiscal year for  
4           which fees are collected under this section.