

[PRELIMINARY DISCUSSION DRAFT]115TH CONGRESS
2^D SESSION**H. R.** _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON (for himself and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on _____

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 2018” or the “VALID Act of 2018”.

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

- Sec. 1. Short title; table of contents.
Sec. 2. Definitions.
Sec. 3. Regulation of in vitro clinical tests.

“SUBCHAPTER J—IN VITRO CLINICAL TESTS

- “Sec. 587. Definitions.
“Sec. 587A. Applicability.
“Sec. 587B. Premarket review.
“Sec. 587C. Priority review.
“Sec. 587D. Precertification.
“Sec. 587E. Mitigating measures.
“Sec. 587F. Regulatory pathway designation.
“Sec. 587G. Advisory committees.
“Sec. 587H. Request for informal feedback.
“Sec. 587I. Registration and notification.
“Sec. 587J. Quality system 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. Standards.
“Sec. 587R. Investigational use.
“Sec. 587S. Emergency use authorization.
“Sec. 587T. Collaborative communities for in vitro clinical tests.
“Sec. 587U. Comprehensive test information system.
“Sec. 587V. Preemption.
“Sec. 587W. Adulteration.
“Sec. 587X. Misbranding.
“Sec. 587Y. Postmarket surveillance.
“Sec. 587Z. Electronic format for submissions.
“Sec. 587AA. Postmarket remedies.

- Sec. 4. Prohibited acts, enforcement, and other provisions.
Sec. 5. Transition.
Sec. 6. Antimicrobial susceptibility tests.
Sec. 7. Combination products.
Sec. 8. User fees.

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’ means—

6 “(A) a test intended to be used in the collec-
7 tion, preparation, analysis, or in vitro clinical exam-

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

3 “(i) identifying, diagnosing, screening,
4 measuring, detecting, predicting, prognosing,
5 analyzing, or monitoring a disease or condition,
6 including by making a determination of an indi-
7 vidual’s state of health; or

8 “(ii) selecting, monitoring, or informing
9 therapy or treatment for a disease or condition;

10 “(B) a test protocol intended to be used as de-
11 scribed in clause (A);

12 “(C) a test platform (as defined in section 587)
13 for use in or with a test described in clause (A);

14 “(D) an article for taking or deriving specimens
15 from the human body for a purpose described in
16 clause (A);

17 “(E) software for a purpose described in clause
18 (A), excluding software that is excluded by section
19 520(o) from the definition of a device under section
20 201(h); or

21 “(F) subject to subparagraph (2), a component
22 or part of a test, a test protocol, a test platform, an
23 article, or software described in any of clause (A)
24 through (E), whether alone or in combination, in-
25 cluding reagents, calibrators, and controls.

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

6 “(A) Blood, blood components, or human cells
7 or tissues, from the time of donation or recovery of
8 such article, including determination of donor eligi-
9 bility, as applicable, until such time as the article is
10 released into interstate commerce as a component or
11 part of an in vitro clinical test by the establishment
12 that collected such article.

13 “(B) An article used for invasive sampling.

14 “(C) General purpose laboratory equipment.

15 “(D) An article used solely for personal protec-
16 tion during the administering, conducting, or other-
17 wise performing test activities.”;

18 (2) by adding at the end of section 201(g) the
19 following:

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

22 (3) in section 201(h), by striking “section
23 520(o)” and inserting “section 520(o) or an in vitro
24 clinical test”.

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

4 (1) by striking “(1) The term ‘biological prod-
5 uct’ means” and inserting “(1)(A) The term ‘biologi-
6 cal product’ means”; and

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

8 “(B) The term ‘biological product’ does not in-
9 clude an in vitro clinical test as defined in section
10 201(ss) of the Federal Food, Drug, and Cosmetic
11 Act.”.

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

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

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

18 (2) by adding at the end of chapter V the fol-
19 lowing:

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

21 **“SEC. 587. DEFINITIONS.**

22 “In this subchapter:

23 “(1) ANALYTICAL VALIDITY.—

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

4 “(i) identify, measure, detect, cal-
5 culate, or analyze one or more analytes,
6 biomarkers, substances, or other targets
7 intended to be identified, measured, de-
8 tected, calculated, or analyzed by the test;
9 or

10 “(ii) as applicable, assist in such iden-
11 tification, measurement, detection, calcula-
12 tion, or analysis.

13 “(B) For an article for taking or deriving
14 specimens from the human body described in
15 section 201(ss)(1)(DD), the term ‘analytical va-
16 lidity’ means that such article performs as in-
17 tended and will support the analytical validity
18 of an in vitro clinical test with which it is used.

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

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

5 “(4) COMPREHENSIVE TEST INFORMATION SYS-
6 TEM.—The term ‘comprehensive test information
7 system’ means an online database that the Secretary
8 may use to store and provide information about in
9 vitro clinical tests to developers and the general pub-
10 lic, as described in section 587U.

11 “(5) CROSS-REFERENCED TEST.— The term
12 ‘cross-referenced test’ means an in vitro clinical test
13 that—

14 “(A) references in its labeling the trade
15 name or intended use of another medical prod-
16 uct that is not an in vitro clinical test; or

17 “(B) is referenced by trade name or in-
18 tended use in the labeling of another medical
19 product that is not an in vitro clinical test.

20 “(6) DEVELOPER.—The term ‘developer’ means
21 a person who—

22 “(A) develops an in vitro clinical test, in-
23 cluding by designing, validating, producing,
24 manufacturing, remanufacturing, propagating,
25 or assembling the kit of an in vitro clinical test;

1 “(B) imports an in vitro clinical test; or

2 “(C) modifies an in vitro clinical test ini-
3 tially developed by a different person in a man-
4 ner that—

5 “(i) changes any of the notification
6 elements specified in paragraph (11) that
7 define a test group, performance claims,
8 or, as applicable, the safety of such in vitro
9 clinical test; or

10 “(ii) adversely affects the performance
11 of the in vitro clinical test.

12 “(7) HIGH-RISK.—

13 “(A) Subject to subparagraph (B), the
14 term ‘high-risk’, with respect to an in vitro clin-
15 ical test or category of in vitro clinical tests,
16 means that an undetected inaccurate result
17 from such test or category—

18 “(i) when used as intended, would
19 likely cause serious or irreversible harm or
20 death to a patient or patients, or would
21 otherwise cause serious harm to the public
22 health; and

23 “(ii) would pose a likelihood of ad-
24 verse patient impact or adverse public

1 health impact caused by such an inaccurate
2 result that is not remote.

3 “(B) Such term does not include an in
4 vitro clinical test if mitigating measures are es-
5 tablished and applied to sufficiently mitigate
6 the risk of inaccurate results as described in
7 subparagraph (A), taking into account—

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

14 “(ii) the clinical circumstances (in-
15 cluding clinical presentation) under which
16 the in vitro clinical test is used, and the
17 availability of other tests (such as confirm-
18 atory or adjunctive tests) or relevant mate-
19 rial standards.

20 “(8) LOW-RISK.—

21 “(A) Subject to subparagraph (B), the
22 term ‘low-risk’, with respect to an in vitro clin-
23 ical test or category of in vitro clinical tests,
24 means that an undetected inaccurate result
25 from such in vitro clinical test, or such category

1 of in vitro clinical tests, when used as in-
2 tended—

3 “(i) would cause minimal or no harm
4 or disability, or immediately reversible
5 harm, or would lead to only a remote risk
6 of adverse patient impact or adverse public
7 health impact; or

8 “(ii) could cause non-life threatening
9 injury or injury that is medically revers-
10 ible, or delay necessary treatment.

11 “(B) Such term does not include an in
12 vitro clinical test if mitigating measures are
13 sufficient to prevent such inaccurate result, de-
14 tect such inaccurate result prior to any adverse
15 patient impact or adverse public health impact,
16 or otherwise sufficiently mitigate the risk asso-
17 ciated with such inaccurate result.

18 “(9) MITIGATING MEASURES.—The term ‘miti-
19 gating measures’—

20 “(A) means requirements that the Sec-
21 retary determines, based on available evidence,
22 are necessary—

23 “(i) for an in vitro clinical test, or a
24 category of in vitro clinical tests, to meet

1 the relevant standard for its intended use
2 as defined in paragraph (10); or

3 “(ii) to mitigate the risk of harm en-
4 suing from a false result or misinterpreta-
5 tion of any result; and

6 “(B) includes applicable requirements re-
7 garding labeling, advertising, website posting of
8 information, testing, clinical studies, postmarket
9 surveillance, user comprehension studies, train-
10 ing, conformance to standards, and perform-
11 ance criteria.

12 “(10) RELEVANT STANDARD.— The term ‘rel-
13 evant standard’, with respect to an in vitro clinical
14 test, means a reasonable assurance of adequate ana-
15 lytical and clinical validity, except that such term—

16 “(A) with respect to test platforms, means
17 a reasonable assurance of adequate analytical
18 validity; and

19 “(B) with respect to articles for taking or
20 deriving specimens from the human body for
21 purposes described in clause (i) or (ii) of section
22 201(ss)(1)(A) means a reasonable assurance of
23 adequate analytical validity and, where applica-
24 ble, safety.

1 “(11) TEST GROUP.—The term ‘test group’
2 means one or more in vitro clinical tests that have
3 all of the following notification elements in common:

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

7 “(B) Type or types of specimen or sample.

8 “(C) Test method.

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

11 “(E) Diseases or conditions for which the
12 in vitro clinical test is intended for use.

13 “(F) Intended patient populations.

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

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

24 “(13) VALID SCIENTIFIC EVIDENCE.—

1 “(A) VALID SCIENTIFIC EVIDENCE.—The
2 term ‘valid scientific evidence’ means, with re-
3 spect to an in vitro clinical test, evidence—

4 “(i) which has been generated and
5 evaluated by persons qualified by training
6 or experience to do so, using procedures
7 generally accepted by other persons so
8 qualified; and

9 “(ii) from which it can be fairly and
10 responsibly concluded by qualified experts
11 whether the relevant standard has been
12 met by the in vitro clinical test for its in-
13 tended use.

14 “(B) VALID SCIENTIFIC EVIDENCE.—The
15 term ‘valid scientific evidence’ may include evi-
16 dence described in subparagraph (A) consisting
17 of—

18 “(i) peer-reviewed literature;

19 “(ii) clinical guidelines;

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

22 “(iv) bench studies;

23 “(v) case studies or histories;

24 “(vi) clinical data;

25 “(vii) consensus standards;

1 “(viii) reference standards;
2 “(ix) data registries;
3 “(x) postmarket data;
4 “(xi) clinical trials; and
5 “(xii) data collected in countries other
6 than the United States if such data are
7 demonstrated to be adequate for the pur-
8 pose of making a regulatory determination
9 under the relevant standard in the United
10 States.

11 “(14) FIRST-OF-A-KIND.—The term ‘first-of-a-
12 kind’ means, with respect to an in vitro clinical test,
13 a test that has a combination of the notification ele-
14 ments specified in paragraph (11) that constitutes a
15 test group that differs from the combination of any
16 such elements in any test group that is legally avail-
17 able in the United States.

18 “(15) WELL-CHARACTERIZED.—The term ‘well-
19 characterized’ means well-established and well-recog-
20 nized by the scientific or clinical community, if ade-
21 quately evidenced by one or more of the following:

22 “(A) Literature.

23 “(B) Practice guidelines.

24 “(C) Consensus standards.

25 “(D) Recognized standards of care.

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

2 “(F) Scientific publication by multiple
3 sites.

4 “(G) Wide recognition or adoption by the
5 scientific or clinical community.

6 “(H) Real world data.

7 **“SEC. 587A. APPLICABILITY.**

8 “(a) IN GENERAL.—

9 “(1) SCOPE.—An in vitro clinical test—

10 “(A) shall be subject to the requirements
11 of this subchapter, except as set forth in this
12 section;

13 “(B) that is offered for clinical use in the
14 United States is deemed to be introduced into
15 interstate commerce for purposes of enforcing
16 the requirements of this Act; and

17 “(C) subject to any exemption or exclusion
18 in this section, shall not be subject to any provi-
19 sion or requirement of this Act other than this
20 subchapter unless such other provision or re-
21 quirement—

22 “(i) applies expressly to in vitro clin-
23 ical tests; or

1 “(ii) describes the authority of the
2 Secretary when regulating such articles or
3 subset of articles, with respect to—

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

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

8 “(2) LABORATORIES AND BLOOD AND TISSUE
9 ESTABLISHMENTS.—

10 “(A) RELATION TO CLIA.—Nothing in this
11 subchapter shall be construed to modify the au-
12 thority of the Secretary with respect to labora-
13 tories or clinical laboratories under section 353
14 of the Public Health Service Act.

15 “(B) AVOIDING DUPLICATION.—In imple-
16 menting this subchapter, the Secretary shall, to
17 the greatest extent possible, unless necessary to
18 protect public health, avoid issuing or enforcing
19 regulations that are duplicative of regulations
20 under section 353 of the Public Health Service
21 Act.

22 “(C) BLOOD AND TISSUE.—Nothing in
23 this subchapter shall be construed to modify the
24 authority of the Secretary with respect to lab-
25 oratories, establishments, or other facilities to

1 the extent they are engaged in the propagation,
2 manufacture, or preparation, including filling,
3 testing, labeling, packaging, and storage, of
4 blood, blood components, human cells, tissues,
5 or tissue products under this Act or section 351
6 of the Public Health Service Act.

7 “(3) PRACTICE OF MEDICINE.—

8 “(A) IN GENERAL.—Nothing in this sub-
9 chapter shall be construed to limit or interfere
10 with the authority of a health care practitioner
11 to prescribe or administer any legally marketed
12 in vitro clinical test for any condition or disease
13 within a legitimate health care practitioner-pa-
14 tient relationship.

15 “(B) SALE, DISTRIBUTION, LABELING.—
16 Nothing in this paragraph shall be construed to
17 limit any authority of the Secretary to establish
18 and enforce restrictions on the sale, distribu-
19 tion, or labeling of an in vitro clinical test
20 under this Act.

21 “(C) PROMOTION OF UNAPPROVED
22 USES.—Nothing in this paragraph shall be con-
23 strued to alter any prohibition on the promotion
24 of unapproved uses of legally marketed in vitro
25 clinical tests.

1 “(4) SPECIAL RULE.—

2 “(A) PREMARKET REVIEW APPLICABLE.—

3 Notwithstanding the exemptions from pre-
4 market review under section 587B set forth in
5 subsections (b), (c), (d), (e), (f), (g), (h), and
6 (k), an in vitro clinical test shall be subject to
7 the requirements of section 587B if the Sec-
8 retary determines, in accordance with subpara-
9 graph (B), that—

10 “(i) there is insufficient valid sci-
11 entific evidence that an article for taking
12 or deriving specimens from the human
13 body for the purposes specified in section
14 201(ss)—

15 “(I) performs as intended;

16 “(II) will support the analytical
17 validity of tests with which it is used;
18 or

19 “(III) where applicable, is safe
20 for use;

21 “(ii) there is insufficient valid sci-
22 entific evidence to support the analytical
23 validity or the clinical validity of such in
24 vitro clinical test;

1 “(iii) such in vitro clinical test is
2 being offered by its developer with materi-
3 ally deceptive or fraudulent analytical or
4 clinical claims; or

5 “(iv) there is a reasonable potential
6 that such in vitro clinical test will cause
7 death or serious adverse health con-
8 sequences, including by causing the ab-
9 sence, delay, or discontinuation of appro-
10 priate medical treatment.

11 “(B) PROCESS.—

12 “(i) REQUEST FOR INFORMATION.—If
13 the Secretary has reason to believe that
14 one or more of the criteria listed in sub-
15 paragraph (A) apply to an in vitro clinical
16 test, the Secretary may request that the
17 developer of the test submit information—

18 “(I) pertaining to such criteria;

19 and

20 “(II) establishing the basis for
21 any claimed exemption from pre-
22 market review.

23 “(ii) DEADLINE FOR SUBMITTING IN-
24 FORMATION.—Upon receiving a request for
25 information under clause (i), the developer

1 of an in vitro clinical test shall submit the
2 information within 30 days of such receipt.

3 “(iii) REVIEW DEADLINE.—Upon re-
4 ceiving a submission under clause (ii), the
5 Secretary shall—

6 “(I) review the submitted infor-
7 mation within 30 days of such receipt;
8 and

9 “(II) determine whether one of
10 more of the criteria listed in subpara-
11 graph (A) apply to the in vitro clinical
12 test.

13 “(iv) PREMARKET REVIEW RE-
14 QUIRED.—If the Secretary finds one or
15 more of the criteria listed in subparagraph
16 (A) apply to the in vitro clinical test, the
17 developer shall—

18 “(I) promptly, and not later than
19 90 days after the date of receipt of
20 such information, submit an applica-
21 tion for premarket review of the test
22 under section 587B; or

23 “(II) cease to market the test.

24 “(v) CONTINUED MARKETING.—Dur-
25 ing the period beginning on the date of a

1 submission under clause (ii) and ending on
2 the date of the disposition of an applica-
3 tion for premarket review of the in vitro
4 clinical test under section 587B, the devel-
5 oper of the test may continue to market
6 the test for clinical use, unless the Sec-
7 retary issues an order to the developer
8 under clause (vi) to immediately cease dis-
9 tribution of the test.

10 “(vi) ORDER TO CEASE DISTRIBUTION.—If the developer of an in vitro clin-
11 ical test fails to submit an application for
12 premarket review of the test by the dead-
13 line applicable under clause (iv), if the Sec-
14 retary finds that one of more of the cri-
15 teria listed in subparagraph (A) apply to
16 an in vitro clinical test, or if the Secretary
17 finds that it is in the best interest of the
18 public health, the Secretary may issue an
19 order requiring the developer of such in
20 vitro clinical test, and any other appro-
21 priate person (including a distributor or
22 retailer of the in vitro clinical test)—

24 “(I) to immediately cease dis-
25 tribution of the test pending approval

1 of an application for premarket review
2 of the test under section 587B; and

3 “(II) to immediately notify health
4 professionals and other user facilities
5 of the order and to instruct such pro-
6 fessionals and facilities to cease use of
7 such in vitro clinical test.

8 An order under this clause shall provide
9 the person subject to the order with an op-
10 portunity for an informal hearing, to be
11 held not later than 10 days after the date
12 of the issuance of the order, on the actions
13 required by the order and on whether the
14 order should be amended to require a re-
15 call of such in vitro clinical test. If, after
16 providing an opportunity for such a hear-
17 ing, the Secretary determines that inad-
18 equate grounds exist to support the actions
19 required by the order, the Secretary shall
20 vacate the order.

21 “(vii) AMENDMENT TO REQUIRE RE-
22 CALL.—If the Secretary determines that
23 an order issued under clause (vi) should be
24 amended to include a recall of the in vitro
25 clinical test with respect to which the order

1 was issued, the Secretary shall amend the
2 order to require a recall. In such amended
3 order, the Secretary shall specify a time-
4 table in which the in vitro clinical test re-
5 call will occur and shall require periodic re-
6 ports to the Secretary describing the
7 progress of the recall.

8 **[(viii) EFFECT OF TEST AP-**
9 **PROVAL.—[Any order issued under this**
10 **paragraph with respect to an in vitro clin-**
11 **ical test shall cease to be in effect if such**
12 **test is granted approval under section**
13 **587B, provided that the in vitro clinical**
14 **test is developed and offered for clinical**
15 **use in accordance with such approval.]]**

16 **“(5) EMERGENCY USE.—**

17 **“(A) IN GENERAL.—The exemptions from**
18 **premarket review under subsections (b), (c),**
19 **(d), (e), (f), (g), (h), and (k) of section 587B**
20 **shall not apply to any in vitro clinical test that**
21 **is eligible for an emergency use authorization**
22 **under section 564(a).**

23 **“(B) TESTS OFFERED FOR CLINICAL USE**
24 **UNDER AN EXEMPTION PRIOR TO A DECLARA-**
25 **TION.—**

1 “(i) CONTINUED MARKETING.—If the
2 Secretary makes a declaration under sec-
3 tion 564(b) for an in vitro clinical test that
4 was offered for clinical use under an ex-
5 emption under subsection (b), (c), (d), (e),
6 (f), (g), (h), or (k) of section 587B prior
7 to the declaration, such test may continue
8 to be offered for clinical use after such
9 declaration only if—

10 “(I) the developer of the test sub-
11 mits to the Secretary, not later than
12 5 days after the date of issuance of
13 the declaration, a request for an
14 emergency use authorization for the
15 test under section 564(a) and the re-
16 quest remains pending;

17 “(II) the Secretary grants an
18 emergency use authorization for the
19 test under section 564(a); or

20 “(III) the Secretary approves the
21 test for marketing under section
22 587B.

23 “(ii) NECESSARY ACTIONS.—The Sec-
24 retary, in collaboration with the developers
25 of in vitro clinical tests and other affected

1 entities, as appropriate, shall take such ac-
2 tions as the Secretary determines to be
3 necessary actions to ensure such tests are
4 no longer distributed or offered for clinical
5 use until they receive the required approval
6 or authorization.

7 “(b) COMPONENTS AND PARTS.—

8 “(1) EXEMPTION.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (B), an in vitro clinical test that is a
11 component or part described in section
12 201(ss)(1)(F) is exempt from the requirements
13 of this Act if it is intended for further develop-
14 ment as described in paragraph (2).

15 “(B) INAPPLICABILITY TO OTHER
16 TESTS.—Notwithstanding subparagraph (A), an
17 in vitro clinical test that is described in sub-
18 paragraph (A), (B), (C), (D), or (E) of section
19 201(ss)(1) and that uses a component or part
20 described in such subparagraph shall be subject
21 to the requirements of this Act, including re-
22 quirements relating to the establishment and
23 use of supplier controls, unless the test is other-
24 wise exempted under this section.

1 “(2) FURTHER DEVELOPMENT.—An in vitro
2 clinical test that is a component or part (as de-
3 scribed in paragraph (1)(A)) is intended for further
4 development (for purposes of such paragraph) if—

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

7 “(B) if introduced or delivered for intro-
8 duction into interstate commerce after the date
9 of enactment of the Verifying Accurate Lead-
10 ing-edge IVCT Development Act of 2018, the
11 labeling of such test bears the following state-
12 ment: ‘This product is intended solely for fur-
13 ther development of an in vitro clinical test and
14 is exempt from FDA regulation. This product
15 must be evaluated by the in vitro clinical test
16 developer in accordance with supplier controls if
17 it is used with or in the development of an in
18 vitro clinical test.’.

19 “(c) GRANDFATHERED TESTS.—

20 “(1) EXEMPTION.—An in vitro clinical test that
21 meets the criteria set forth in paragraph (2) is ex-
22 empt from premarket review under section 587B,
23 the quality system requirements under section 587J,
24 and the labeling requirements under section 587K,

1 and may be lawfully marketed subject to the other
2 applicable requirements of this Act, if—

3 “(A) each test report template under sec-
4 tion 587K for the test bears a statement of
5 adequate prominence that reads as follows:
6 ‘This in vitro clinical test was developed and
7 first introduced prior to 90 days prior to date
8 of enactment of the Verifying Accurate Lead-
9 ing-edge IVCT Development Act of 2018 and
10 has not been reviewed by the Food and Drug
11 Administration.’; and

12 “(B) the developer of the test—

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

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

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

22 “(A)(i) was first offered for clinical use or
23 otherwise introduced or delivered for introduc-
24 tion into interstate commerce by such labora-
25 tory 90 days or more before the date of enact-

1 ment of the Verifying Accurate Leading-edge
2 IVCT Development Act of 2018;

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

9 “(iii) is performed in the same laboratory
10 in which it was developed or by another such
11 laboratory for which a certificate is in effect
12 under section 353 within the same corporate or-
13 ganization and having common ownership by
14 the same parent corporation;

15 “(B) does not have in effect an approval
16 under section 515, a clearance under section
17 510(k), an authorization under section
18 513(f)(2), or an approval under section 520(m);
19 and

20 “(C) is not modified on or after the date
21 that is 90 days before the date of enactment of
22 the Verifying Accurate Leading-edge IVCT De-
23 velopment Act of 2018 by its initial developer
24 (or another person) in a manner such that the

1 test is a new in vitro clinical test under sub-
2 section (l).

3 “(3) MODIFICATIONS.—When a person modifies
4 the person’s own or another person’s in vitro clinical
5 test that is exempt as specified in paragraph (1) and
6 determines that the modified test is not a new in
7 vitro clinical test under subsection (l), such person
8 shall—

9 “(A) document each such modification and
10 the basis for such determination; and

11 “(B) provide such documentation to the
12 Secretary upon request or inspection.

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

14 “(1) EXEMPTION.—An in vitro clinical test is
15 exempt from premarket review under section 587B
16 and may be lawfully marketed subject to the other
17 applicable requirements of this Act, if it meets the
18 criteria described in paragraph (2).

19 “(2) CRITERIA FOR EXEMPTION.—The criteria
20 described in this paragraph are that—

21 “(A) the in vitro clinical test—

22 “(i) was offered for clinical use prior
23 to the date of enactment of the Verifying
24 Accurate Leading-edge IVCT Development
25 Act of 2018; and

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

6 “(B) the test—

7 “(i) was not offered for clinical use
8 prior to such date of enactment;

9 “(ii) is not a test platform (as defined
10 in section 587); and

11 “(iii) falls within a category of tests
12 that was exempt from the requirements for
13 submission of a report under section
14 510(k) as of such date of enactment **[(in-**
15 **cluding class II 510(k)-exempt devices and**
16 **excluding class I reserved devices)]**.

17 “(3) EFFECT ON SPECIAL CONTROLS.—For any
18 in vitro clinical test, or category of in vitro clinical
19 tests, that is exempted from premarket review based
20 on the criteria in paragraph (2), any special control
21 that applied to a device within a predecessor cat-
22 egory immediately prior to the date of enactment of
23 Verifying Accurate Leading-edge IVCT Development
24 Act of 2018 shall be deemed a mitigating measure
25 applicable under section 587E to an in vitro clinical

1 test within the successor category, except to the ex-
2 tent such mitigating measure is withdrawn or
3 changed in accordance with section 587E.

4 “(4) NEAR-PATIENT TESTING.—The Secretary
5 shall issue guidance indicating categories of tests
6 that shall be exempt from premarket review under
7 section 587B when offered for near-patient testing
8 (point of care), which were not exempt from submis-
9 sion of a report under section 510(k) pursuant to
10 subsection (l) or (m)(2) of section 510 and regula-
11 tions imposing limitations on exemption for in vitro
12 devices intended for near-patient testing (point of
13 care).

14 “(e) LOW-RISK TESTS.—

15 “(1) EXEMPTION.—An in vitro clinical test is
16 exempt from premarket review under section 587B
17 and may be lawfully marketed subject to the other
18 applicable requirements of this Act, if such test is
19 included in, or falls within a category of tests that
20 is included in, the list of low-risk in vitro clinical
21 tests in effect under paragraph (2).

22 “(2) LIST OF LOW-RISK TESTS.—

23 “(A) IN GENERAL.—The Secretary shall
24 maintain, and make publicly available on the
25 website of the Food and Drug Administration,

1 a list of in vitro clinical tests, and categories of
2 in vitro clinical tests, that are low-risk in vitro
3 clinical tests for purposes of the exemption
4 under this subsection.

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

7 “(i) all in vitro clinical tests and cat-
8 egories of in vitro clinical tests that are ex-
9 empt from premarket review pursuant to
10 subsection (d)(1) or (d)(4); and

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

16 “(C) DESIGNATION OF TESTS AND CAT-
17 EGORIES.—Without regard to subchapter II of
18 chapter 5 of title 5, United States Code, the
19 Secretary may designate, in addition to the
20 tests and categories described in subparagraph
21 (B)(i), additional in vitro clinical tests, and cat-
22 egories of in vitro clinical tests, as low-risk in
23 vitro clinical tests for purposes of the exemption
24 under this subsection. The Secretary may make
25 such a designation on the Secretary’s own ini-

1 tiative or in response to a request by any per-
2 son. In making such a designation for a test or
3 category of tests, the Secretary shall consider—

4 “(i) whether the test, or category of
5 tests, is low-risk (as defined in section
6 587); and

7 “(ii) such other factors as the Sec-
8 retary deems to be relevant.

9 “(f) MANUAL TESTS.—

10 “(1) EXEMPTION.—An in vitro clinical test that
11 is designed, manufactured, and used within a single
12 laboratory for which a certificate is in effect under
13 section 353 of the Public Health Service Act that
14 meets the requirements under section 353 for per-
15 forming high-complexity testing, is exempt from the
16 requirements of this Act, if the test—

17 “(A) meets the criteria described in para-
18 graph (2); and

19 “(B) is not intended—

20 “(i) for detecting human immuno-
21 deficiency virus (HIV) , or for measuring
22 an analyte that serves as a surrogate
23 marker for screening, diagnosis, moni-
24 toring, or monitoring therapy for acquired
25 immunodeficiency syndrome (AIDS);

1 “(ii) for testing donors, donations,
2 and recipients of blood, blood components,
3 human cells, tissues, cellular-based prod-
4 ucts, or tissue-based products; or

5 “(iii) for testing maternal or fetal
6 specimens for hemolytic disease of the
7 fetus or newborn.

8 “(2) CRITERIA FOR EXEMPTION.—The criteria
9 described in this paragraph are that—

10 “(A) the output of the in vitro clinical test
11 is the result of manual interpretation (meaning
12 direct observation) by a qualified laboratory
13 professional, without the use of automated in-
14 strumentation or software for intermediate or
15 final interpretation; and

16 “(B) the test—

17 “(i) is not a high-risk test; or

18 “(ii) is a high-risk test for which the
19 Secretary publishes in the Federal Register
20 a notice determining that the test is appro-
21 priate to be exempted pursuant to para-
22 graph (1) and that the test meets at least
23 one of the following conditions:

24 “(I) No component or part of
25 such test, including any reagent, is in-

1 introduced into interstate commerce
2 under the exemption under subsection
3 (b)(1) (relating to components or
4 parts intended for further develop-
5 ment), and [any article for taking or
6 deriving specimens from the human
7 body used in conjunction with the test
8 remains subject to] the requirements
9 of this Act.

10 “(II) The test has been developed
11 in accordance with the quality system
12 requirements under section 587J.

13 “(g) TESTS FOR RARE DISEASES.—

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

18 “(A) the test meets the criteria described
19 in paragraph (2); and

20 “(B) the developer of the test—

21 “(i) maintains documentation (which
22 may include literature citations in special-
23 ized medical journals, textbooks, special-
24 ized medical society proceedings, govern-
25 mental statistics publications, or, if no

1 such studies or literature citations exist,
2 credible conclusions from appropriate re-
3 search or surveys) demonstrating that such
4 test meets and continues to meet the cri-
5 teria described in paragraph (2); and

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

8 “(2) CRITERIA.—The criteria described in this
9 paragraph are that—

10 “(A) fewer than 8,000 individuals per year
11 in the United States would be subject to testing
12 using the in vitro clinical test;

13 “(B) the test is not a cross-referenced test;
14 and

15 “(C) the test is not for a communicable
16 disease.

17 “(h) CUSTOM TESTS AND LOW-VOLUME TESTS.—

18 “(1) EXEMPTION.—An in vitro clinical test that
19 meets the criteria described in paragraph (2) is ex-
20 empt from premarket review under section 587B,
21 the quality system requirements under section 587J,
22 and the notification requirements under section
23 587I, and may be lawfully marketed subject to the
24 other applicable requirements of this Act, if—

25 “(A) the developer of the test—

1 “(i) maintains documentation dem-
2 onstrating that such test meets and con-
3 tinues to meet the applicable criteria de-
4 scribed in paragraph (2); and

5 “(ii) makes such documentation avail-
6 able to the Secretary upon request; and

7 “(B) the developer of the test informs the
8 Secretary, on an annual basis, in a manner pre-
9 scribed by the Secretary by guidance, that such
10 test was introduced into interstate commerce.

11 “(2) CRITERIA FOR EXEMPTION.—The criteria
12 described in this paragraph are that the test—

13 “(A) is a low-volume test offered to no
14 more than 5 patients per year; or

15 “(B) is a custom test to diagnose a unique
16 pathology or physical condition of a specific pa-
17 tient named in an order of a physician, dentist,
18 or other health professional (or any other spe-
19 cially qualified person designated under regula-
20 tions promulgated by the Secretary for pur-
21 poses of this subparagraph) for which no other
22 in vitro clinical test is commercially available in
23 the United States, and is—

24 “(i) not used for other patients;

1 “(ii) developed or modified to comply
2 with such order; and

3 “(iii) not included in any test menu,
4 template test report, or other promotional
5 materials, and not otherwise advertised.

6 “(i) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

7 “(1) IN GENERAL.—The provisions of this sub-
8 chapter shall not apply to a test intended to be used
9 solely for public health surveillance.

10 “(2) DEFINITION.—In this subsection, the term
11 ‘public health surveillance’ means ongoing systematic
12 activities, including collection, analysis, and interpre-
13 tation of health-related data, essential to planning,
14 implementing, and evaluating public health practice.

15 “(3) EXCLUSION.—An in vitro clinical test that
16 is either intended for use in making clinical decisions
17 for individual patients or other purposes not de-
18 scribed in paragraph (2) or whose individually iden-
19 tifiable results may be reported back to an individual
20 patient or the patient’s health care provider, even if
21 also intended for public health surveillance, is not in-
22 tended solely for use in public health surveillance for
23 purposes of this subsection.

24 “(j) LAW ENFORCEMENT.—An in vitro clinical test
25 that is intended solely for use in forensic analysis or other

1 law enforcement activity is exempt from the requirements
2 of this Act. An in vitro clinical test that is intended for
3 use in making clinical decisions for individual patients, or
4 whose individually identifiable results may be reported
5 back to an individual patient or the patient's health care
6 provider, even if also intended for law enforcement pur-
7 poses, is not intended solely for use in law enforcement
8 for purposes of this subsection.

9 **[(k) PRECERTIFIED TESTS.—[An in vitro clinical**
10 test that is subject to a precertification order, as described
11 in section 587D(a)(2), is exempt from premarket review
12 under section 587B.]]

13 **“(l) MODIFIED TESTS.—**

14 **“(1) IN GENERAL.—**An in vitro clinical test
15 that is modified, by the initial developer of the test
16 or a different person, is a new in vitro clinical test
17 subject to this Act if the modification—

18 **“(A) changes any of the elements specified**
19 in section 587(11) that define a test group;

20 **“(B) changes performance claims made**
21 with respect to the test;

22 **“(C) causes the test to no longer comply**
23 with applicable mitigating measures or restric-
24 tions;

1 “(D) adversely affects performance of the
2 test; or

3 “(E) as applicable, affects the safety of an
4 article for taking or deriving specimens from
5 the human body for a purpose described in sec-
6 tion 201(ss)(1).

7 “(2) DOCUMENTATION.—When a person modi-
8 fies an in vitro clinical test that was developed by
9 another person, such modified test is exempt from
10 the requirements of this Act provided that such per-
11 son shall—

12 “(A) document the modification that was
13 made and the basis for determining that the
14 modification, considering the changes individ-
15 ually and collectively, was not a type of modi-
16 fication described in paragraph (1); and

17 “(B) provide such documentation to the
18 Secretary upon request or inspection.

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

22 “(n) TRANSFER OR SALE OF AN IN VITRO CLINICAL
23 TEST.—

24 “(1) TRANSFER AND ASSUMPTION OF REGU-
25 LATORY OBLIGATIONS.—If ownership of an in vitro

1 clinical test is sold or transferred in such manner
2 that the developer transfers the regulatory submis-
3 sions and obligations applicable under this sub-
4 chapter with respect to the test, the transferee or
5 purchaser becomes the developer of the test and
6 shall have all regulatory obligations applicable to
7 such a test under this subchapter. The transferee or
8 purchaser shall update the registration and notifica-
9 tion information under section 587I for the in vitro
10 clinical test.

11 **【“(2) TRANSFER OR SALE OF PREMARKET AP-
12 PROVAL.—】**

13 **【“(A) NOTICE REQUIRED.—If a developer
14 of an in vitro clinical test transfers or sells the
15 approval of the in vitro clinical test, the trans-
16 feror or seller shall—】**

17 **【“(i) submit a notice of the transfer
18 or sale to the Secretary and update the
19 registration and notification information
20 under section 587I for the in vitro clinical
21 test; and】**

22 **【“(ii) submit a supplemental applica-
23 tion if required under subsection (f).】**

24 **【“(B) EFFECTIVE DATE OF APPROVAL
25 TRANSFER.—A transfer or sale described in**

1 subparagraph (A) shall become effective upon
2 completion of a transfer or sale described in
3 paragraph (1) or the approval of a supple-
4 mental application under subsection (f) if re-
5 quired, whichever is later. The transferee or
6 purchaser shall update the registration and no-
7 tification information under section 587I for
8 the in vitro clinical test within 15 calendar days
9 of the effective date of the transfer or sale.】

10 【“(3) TRANSFER OR SALE OF
11 PRECERTIFICATION.—】

12 【“(A) REQUIREMENTS FOR TRANSFER OR
13 SALE OF PRECERTIFICATION.—A
14 precertification can be transferred or sold if the
15 transferee or purchaser—】

16 【“(i) is an eligible person under sec-
17 tion 587D(b)(1); and】

18 【“(ii) maintains, upon such transfer
19 or sale, the site, quality system, processes
20 and procedures, and scope of
21 precertification identified in the applicable
22 precertification submission.】

23 【“(B) NOTICE REQUIRED.—If a developer
24 of an in vitro clinical test transfers or sells an
25 approved precertification, the transferor or sell-

1 er shall submit a notice of the transfer or sale
2 to the Secretary and shall update the registra-
3 tion and notification information under section
4 587I for all in vitro clinical tests covered by the
5 precertification.】

6 【“(C) EFFECTIVE DATE OF
7 PRECERTIFICATION TRANSFER.—The transfer
8 of a precertification shall become effective upon
9 completion of a transfer or sale described in
10 subparagraph (A). The transferee or purchaser
11 shall update the registration and notification in-
12 formation under section 587I for the in vitro
13 clinical test within 30 calendar days of the ef-
14 fective date of the precertification transfer.】

15 【“(D) NEW PRECERTIFICATION RE-
16 QUIRED.—If the requirements of subclause
17 (A)(ii) are not met, then the approved
18 precertification cannot be transferred and the
19 transferee or purchaser of an in vitro clinical
20 test must submit an application for
21 precertification and obtain approval of such ap-
22 plication prior to offering the test for clinical
23 use.】

24 “(o) GENERAL EXEMPTION AUTHORITY.—The Sec-
25 retary may, by order published in the Federal Register

1 following notice and an opportunity for comment, exempt
2 a class of persons from any section under this subchapter
3 upon a finding that such exemption is appropriate in light
4 of public health and other relevant considerations.

5 “(p) REGULATIONS.—The Secretary may issue regu-
6 lations to implement this subchapter.

7 **“SEC. 587B. PREMARKET REVIEW.**

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

11 “(1) an approval of an application filed pursu-
12 ant to subsection (b) [or pursuant to priority review
13 under section 587C] is effective with respect to test;
14 or

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

17 “(b) APPLICATION.—

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

21 “(2) CONTENTS.—An application submitted
22 under paragraph (1) with respect to an in vitro clin-
23 ical test shall include the following:

24 “(A) The information required in para-
25 graphs (a), (b)(1), (b)(2), (b)(3)(iii), (b)(3)(iv),

1 (b)(3)(v), (b)(3)(vi), (b) (8), (b)(10), and
2 (b)(12) of section 814.20 of title 21 of the Code
3 of Federal Regulations (or successor regula-
4 tions) until such time as the Secretary promul-
5 gates final regulations requiring comparable in-
6 formation with respect to in vitro clinical tests
7 and such regulations are in effect.

8 “(B) General information regarding the
9 test, including—

10 “(i) a description of its intended use;

11 “(ii) an explanation regarding how the
12 test functions and significant performance
13 characteristics;

14 “(iii) a risk assessment of the test;
15 and

16 “(iv) a statement attesting to the
17 truthfulness and accuracy of the informa-
18 tion submitted in the application.

19 “(C) Except for test platforms, collection
20 articles, and [in vitro clinical tests eligible for
21 precertification], information regarding the
22 methods used in, or the facilities or controls
23 used for, the development of the test to dem-
24 onstrate compliance with the applicable quality
25 system requirements under section 587J.

1 “(D) Information demonstrating compli-
2 ance with—

3 “(i) any applicable mitigating meas-
4 ures under section 587E; and

5 “(ii) standards established or recog-
6 nized under section 514 prior to the date
7 of enactment of the Verifying Accurate
8 Leading-edge IVCT Development Act of
9 2018, or, after applicable standards are es-
10 tablished or recognized under section
11 587Q, with such standards.

12 “(E) Valid scientific evidence to support
13 analytical and clinical validity of the test, which
14 shall include—

15 “(i) summary information for all sup-
16 porting validation studies performed; and

17 “(ii) raw data for—

18 “(I) tests that are high-risk,
19 cross-referenced, or first-of-a-kind,
20 unless the Secretary determines other-
21 wise; and

22 “(II) all other types of in vitro
23 clinical tests, available upon the Sec-
24 retary’s request;

1 “(iii) in the case of a test platform or
2 article for taking or deriving specimens
3 from the human body, information con-
4 cerning a representative test or tests cov-
5 ering all intended test methodologies using
6 the test platform or article;

7 “(iv) for nonclinical laboratory studies
8 involving the test, a statement that studies
9 were conducted in compliance with applica-
10 ble good laboratory practices under part 58
11 of title 21 of the Code of Federal Regula-
12 tions (or successor regulations) **【**which
13 shall be interpreted to apply to in vitro
14 clinical tests**】**; and

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

19 “(I) institutional review board
20 regulations in part 56 of title 21 of
21 the Code of Federal Regulations (or
22 successor regulations)**【**, which shall be
23 interpreted to apply to in vitro clinical
24 tests**】**;

1 “(II) informed consent regula-
2 tions in part 50 of title 21 of the
3 Code of Federal Regulations (or suc-
4 cessor regulations)【, which shall be
5 interpreted to apply to in vitro clinical
6 tests】; and

7 “(III) investigational use require-
8 ments in section 587R, as applicable.

9 “(F) To the extent the application seeks
10 authorization to make modifications to the test
11 within the scope of the approval, a change pro-
12 tocol that includes validation procedures and
13 acceptance criteria for specific types of antici-
14 pated modifications that could be made to the
15 test within the scope of the approval.

16 “(G) For an article for taking or deriving
17 specimens from the human body, and for any in
18 vitro clinical test that includes such article,
19 safety information, as applicable, including bio-
20 compatibility, sterility, human factors, and user
21 studies, and information regarding the types of
22 tests that could be used with the article【; how-
23 ever, collection articles shall not be subject to
24 premarket review of quality systems documenta-
25 tion or preapproval inspection, and the devel-

1 oper shall not be required to provide raw data
2 by default】.

3 “(H) For a test platform that has not been
4 previously approved by the Food and Drug Ad-
5 ministration, and for any in vitro clinical test
6 that includes such test platform, data, as appli-
7 cable, to support software validation, electro-
8 magnetic compatibility, and electrical safety, or
9 information demonstrating compliance with ap-
10 plicable recognized standards addressing these
11 areas. 【These platforms shall not be subject to
12 premarket review of quality systems documenta-
13 tion and preapproval inspection, and the devel-
14 oper shall not be required to provide raw data
15 by default.】

16 “(I) Proposed labeling, in accordance with
17 the requirements of section 587K.

18 “(J) Such other information as the Sec-
19 retary may require through guidance 【or regu-
20 lation】.

21 【“(3) PRECERTIFICATION ELIGIBLE TESTS.—
22 【For an in vitro clinical test eligible for
23 precertification under section 587D, unless re-
24 quested by the Secretary—】】

1 【“(A) an application under paragraph (2)
2 need not include quality systems documentation
3 or raw data; and】

4 【“(B) a preapproval inspection need not
5 occur.】

6 “(4) REFERRAL TO PANEL.—Upon receipt of
7 an application meeting the requirements set forth in
8 paragraph (2) or (3), the Secretary may refer such
9 application to 【the appropriate panel under section
10 513】 for study and for submission to the Secretary
11 (within such period as the Secretary may establish)
12 of a report and recommendation respecting approval
13 of the application, together with all underlying data
14 and the reasons or basis for the recommendation.
15 Such referral may be—

16 “(A) on the Secretary’s own initiative; or

17 “(B) on the request of an applicant 【un-
18 less the Secretary finds that the information in
19 the application requested to be reviewed by a
20 panel substantially duplicates information which
21 has previously been reviewed by a panel under
22 section 513】.

23 “(5) DEFICIENT APPLICATION.—If, after 【re-
24 ceipt】 of an application under this section, the Sec-
25 retary determines that any portion of such applica-

1 tion is deficient, the Secretary shall provide to the
2 applicant a description of such deficiencies and iden-
3 tify the information required to correct such defi-
4 ciencies.

5 “(c) AMENDMENTS TO AN APPLICATION.—

6 “(1) IN GENERAL.—An applicant may amend
7 or supplement an application under subsection (b).

8 “(2) REQUIRED AMENDMENT OR SUPPLE-
9 MENT.—An applicant shall amend or supplement an
10 application under subsection (b) if the applicant be-
11 comes aware of information that—

12 “(A) could reasonably affect an evaluation
13 of whether the relevant standard has been met;
14 or

15 “(B) could reasonably affect the statement
16 of contraindications, warnings, precautions, and
17 adverse reactions in the proposed labeling.

18 “(3) REQUEST FOR AMENDMENT OR SUPPLE-
19 MENT.—The Secretary may request that an appli-
20 cant amend or supplement an application under sub-
21 section (b) with any information necessary for review
22 under this section.

23 “(d) ACTION ON AN APPLICATION FOR PREMARKET
24 APPROVAL.—

25 “(1) REVIEW.—

1 “(A) DISPOSITION.—As promptly as pos-
2 sible, but not later than [_____] days after
3 an application under subsection (b) is accepted
4 for submission, unless the Secretary determines
5 that an extension is necessary to review one or
6 more major amendments to the application
7 under subsection (c), the Secretary, after con-
8 sidering any applicable report and recommenda-
9 tion by a panel pursuant to subsection (b)(4),
10 shall issue an order—

11 “(i) approving the application if the
12 Secretary finds that all of the grounds for
13 approval in paragraph (2) are met; or

14 “(ii) denying approval of the applica-
15 tion if the Secretary finds that one or more
16 grounds for approval in paragraph (2) are
17 not met.

18 “(B) RELIANCE ON PROPOSED LABEL-
19 ING.—In determining whether to approve or
20 deny an application under paragraph (1), the
21 Secretary shall rely on the intended use in-
22 cluded in the proposed labeling, if such labeling
23 is not false or misleading based on a fair eval-
24 uation of all material facts.

1 “(2) APPROVAL OR DENIAL OF AN APPLICA-
2 TION.—

3 “(A) IN GENERAL.—The Secretary shall
4 approve an application submitted under sub-
5 section (b) with respect to an in vitro clinical
6 test if the Secretary finds that there has been
7 an adequate showing that—

8 “(i) the relevant standard is met;

9 “(ii) the applicant is in compliance
10 with applicable quality system require-
11 ments in section 587J **【**or as otherwise
12 specified in a condition of approval**】**;

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

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

19 “(v) the applicant **【**permits/permitted,
20 if requested,**】** authorized employees of the
21 Food and Drug Administration and per-
22 sons accredited under section 587P an op-
23 portunity—

24 “(I) to inspect at a reasonable
25 time and in a reasonable manner the

1 facilities and all pertinent equipment,
2 finished and unfinished materials,
3 containers, and labeling therein, in-
4 cluding all things (including records,
5 files, papers, and controls) bearing on
6 whether an in vitro clinical test is
7 adulterated, misbranded, or otherwise
8 in violation of this Act; and

9 “(II) to view and to copy and
10 verify all records pertinent to the ap-
11 plication and the in vitro clinical test;

12 “(vi) the test conforms in all respects
13 with any applicable performance standards
14 under section 587Q and any applicable
15 mitigating measures under section 587E;

16 “(vii) all nonclinical laboratory studies
17 that are described in the application, and
18 that are essential to show, with respect to
19 the test, analytical validity and clinical va-
20 lidity, were conducted in compliance with
21 the good laboratory practice regulations in
22 part 58 of title 21 of the Code of Federal
23 Regulations (or successor regulations)
24 **【which shall be interpreted to apply to in**
25 **vitro clinical tests】;**

1 “(viii) all clinical investigations involv-
2 ing human subjects described in the appli-
3 cation subject to the institutional review
4 board regulations in part 56 of title 21 of
5 the Code of Federal Regulations and in-
6 formed consent regulations in part 50 of
7 title 21 of the Code of Federal Regulations
8 (or successor regulations) [each of which
9 shall be interpreted to apply to in vitro
10 clinical tests,] were conducted in compli-
11 ance with those regulations; and

12 “(ix) such other showings as the Sec-
13 retary may require.

14 “(B) CONDITIONS OF APPROVAL.—An
15 order approving an application pursuant to this
16 paragraph may require conditions of approval
17 for the in vitro clinical test, including conform-
18 ance with performance standards under section
19 587Q and restrictions under section 587N.

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

23 “(i) may impose requirements for the
24 test group, including conformance with
25 performance standards under section

1 587Q, restrictions under section 587N,
2 and mitigating measures under section
3 587E; and

4 “(ii) shall indicate whether subsequent
5 in vitro clinical tests in that test group
6 may meet an exemption set forth in section
7 587A.

8 “(D) PUBLICATION.—The Secretary shall
9 publish each order approving an application
10 pursuant to this paragraph on the public
11 website of the Food and Drug Administration
12 and make publicly available a summary of the
13 data used to grant the approval, except to the
14 extent that such order or data is restricted from
15 disclosure pursuant to statutory provisions
16 other than this section.

17 “(3) REVIEW OF DENIALS.—[An applicant
18 whose application submitted under subsection (b)
19 has been denied approval may, by petition filed not
20 more than [____ days] after the date on which the
21 applicant receives notice of such denial, obtain re-
22 view of the denial in accordance with section 587O,
23 and any interested person may obtain review, in ac-
24 cordance with section 587O].

25 “(e) BREAKTHROUGH.—[*to be supplied*]

1 “(f) SUPPLEMENTS TO AN APPLICATION.—

2 “(1) RISK ANALYSIS.—Prior to implementing
3 any modification to an in vitro clinical test, the hold-
4 er of the application approved under subsection (d)
5 for such test shall perform a risk analysis in accord-
6 ance with section 587J.

7 “(2) SUPPLEMENT REQUIREMENT.—

8 “(A) IN GENERAL.—Except as provided in
9 subparagraph (B), or otherwise specified by the
10 Secretary, the holder of the application ap-
11 proved under subsection (d) for an in vitro clin-
12 ical test shall submit to the Secretary and re-
13 ceive approval of a supplement before imple-
14 menting a modification to the test.

15 “(B) EXCEPTIONS.—Subject to subpara-
16 graphs (C) and (D), and so long as the holder
17 of an application approved under subsection (d)
18 for an in vitro clinical test does not add a man-
19 ufacturing site, or change activities at an exist-
20 ing manufacturing site, with respect to the test,
21 the holder may, without prior approval of a
22 supplement, implement the following modifica-
23 tions to the test:

1 “(i) Modifications included in and im-
2 plemented in accordance with an approved
3 change protocol.

4 “(ii) Modifications that—

5 “(I) do not change any of the ele-
6 ments listed in section 587(11) with
7 respect to the test group involved;

8 “(II) do not change performance
9 claims for the test;

10 “(III) do not change, as applica-
11 ble, the safety of the test;

12 “(IV) do not adversely affect the
13 performance of the test; and

14 “(V) do not cause the test to no
15 longer comply with applicable miti-
16 gating measures under section 587E
17 or restrictions under section 587N.

18 “(iii) Labeling changes that are ap-
19 propriate to address a safety concern.

20 “(C) REPORTING FOR FIRST CATEGORIES
21 OF EXCEPTIONS.—The holder of the application
22 approved under subsection (d) for an in vitro
23 clinical test shall—

24 “(i) report any modification to the
25 test described in clause (i) or (ii) of sub-

1 paragraph (B) in the next annual report
2 for the test under subsection (h) following
3 the date on which the test, with the modi-
4 fication, is introduced into interstate com-
5 merce; and

6 “(ii) include in such report—

7 “(I) a description of the modi-
8 fication; and

9 “(II) as applicable, a summary of
10 the analytical validity and clinical va-
11 lidity of the test, as modified, and ac-
12 ceptance criteria.

13 “(D) REPORTING FOR OTHER CATEGORY
14 OF EXCEPTIONS.—The holder of the application
15 approved under subsection (d) for an in vitro
16 clinical test shall—

17 “(i) report to the Secretary any modi-
18 fication to the test described in clause (iii)
19 of subparagraph (B) not more than 30
20 days after the date on which the test, with
21 the modification, is introduced into inter-
22 state commerce; and

23 “(ii) include in the report—

24 “(I) a summary of the relevant
25 change or changes;

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

3 “(III) a description of how the
4 change or changes were evaluated.

5 Upon review of such report and a finding that
6 the relevant modification is inconsistent with
7 the standard specified under clause (iii) of sub-
8 paragraph (B), the Secretary may require a
9 supplement under subparagraph (A).

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

13 “(A) for modifications other than manufac-
14 turing site changes—

15 “(i) a description of the modification;

16 “(ii) summary or raw data, as appli-
17 cable, to demonstrate that the relevant
18 standard is met;

19 “(iii) acceptance criteria; and

20 “(iv) any revised labeling; and

21 “(B) for manufacturing site changes—

22 “(i) the matter listed in subparagraph
23 (A); and

24 “(ii) information regarding the meth-
25 ods used in, or the facilities or controls

1 used for, the development of the test to
2 demonstrate compliance with the applicable
3 quality system requirements under section
4 587J.

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

7 “(A) the data, if applicable, demonstrate
8 that the modified in vitro clinical test meets the
9 relevant standard; and

10 “(B) the holder of the application approved
11 under subsection (d) for the test has dem-
12 onstrated compliance with applicable quality
13 system and inspection requirements, where ap-
14 propriate.

15 “(5) ADDITIONAL DATA.—The Secretary may
16 require, when necessary, data to evaluate a modifica-
17 tion to an in vitro clinical test that is in addition to
18 the data otherwise required under the preceding
19 paragraphs.

20 “(6) CONDITIONS OF APPROVAL.—In an order
21 approving a supplement under this subsection, the
22 Secretary may require conditions of approval for the
23 in vitro clinical test, including conformance with per-
24 formance standards under section 587Q and compli-
25 ance with restrictions under section 587N.

1 “(7) PUBLICATION.—The Secretary shall pub-
2 lish on the public website of the Food and Drug Ad-
3 ministration notice of any order approving a supple-
4 ment under this subsection.

5 “(8) REVIEW OF DENIAL.—An applicant whose
6 supplement under this subsection has been denied
7 approval may, by petition filed on or before the
8 【____】 day after the date upon which the applicant
9 receives notice of such denial, obtain review of the
10 denial in accordance with section 587O, 【and any
11 interested person may obtain review, in accordance
12 with section 587O, of an order of the Secretary ap-
13 proving a supplement】.

14 “(g) WITHDRAWAL AND TEMPORARY SUSPENSION
15 OF APPROVAL.—

16 “(1) ORDER WITHDRAWING APPROVAL.—

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

24 “(i) the grounds for approval in sub-
25 section (d)(2) 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 appropriate medical treatment.

6 “(B) CONTENTS.—An order under sub-
7 paragraph (A) withdrawing approval of an ap-
8 plication shall state each ground for withdrawal
9 and shall notify the holder of such application.

10 “(C) PUBLICATION.—The Secretary shall
11 publish any order under subparagraph (A) on
12 the public website of the Food and Drug Ad-
13 ministration.

14 “(2) ORDER OF TEMPORARY SUSPENSION.—If,
15 after providing due notice and an opportunity for an
16 informal hearing to the holder of an approved appli-
17 cation for an in vitro clinical test under this section,
18 the Secretary determines there is a reasonable likeli-
19 hood that the in vitro clinical test would cause death
20 or serious adverse health consequences, including by
21 causing the absence, delay, or discontinuation of ap-
22 propriate medical treatment, the Secretary shall by
23 order temporarily suspend the approval of the appli-
24 cation. If the Secretary issues such an order, the

1 Secretary shall proceed expeditiously under para-
2 graph (1) to withdraw approval of such application.

3 **【“(h) LEAST BURDENSOME REQUIREMENTS.—】**

4 **【“(1) IN GENERAL.—**In carrying out this sub-
5 chapter, the Secretary shall consider the **【least bur-**
6 **densome】** appropriate means necessary to dem-
7 onstrate that an in vitro clinical test has met the rel-
8 evant standard and other regulatory requirements.**】**

9 **【“(2) NECESSARY DEFINED.—**For purposes of
10 paragraph (1) and paragraph (3), the term ‘nec-
11 essary’ means the minimum required information
12 that would support a determination by the Secretary
13 that the relevant standard or other regulatory re-
14 quirement has been met.**】**

15 **【“(3) CONSIDERATION OF ROLE OF**
16 **POSTMARKET INFORMATION.—**For purposes of this
17 subsection, the Secretary shall consider the role of
18 postmarket information in determining the **【least**
19 **burdensome】** appropriate means necessary to dem-
20 onstrate that the relevant standard and other regu-
21 latory requirements have been met.**】**

22 **【“(4) RULE OF CONSTRUCTION.—**Nothing in
23 this subsection alters the relevant standard as de-
24 fined in section 587.**】**

25 **“(i) ANNUAL REPORT.—**

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

6 “(A) identify all modifications that an ap-
7 proved application holder has made to any test
8 that is covered by the approval order, including
9 any modification that requires a supplement
10 under subsection (f); and

11 “(B) include any other information re-
12 quired by the Secretary.

13 “(2) EXCEPTION.—This annual reporting re-
14 quirement in paragraph (1) shall not apply to in
15 vitro clinical tests that are deemed to have a pre-
16 market approval based on a prior clearance under
17 section 510(k) or prior authorization under section
18 513(f).

19 “(j) SERVICE OF ORDERS.—Orders of the Secretary
20 under this section with respect to applications under sub-
21 section (b) or supplements under subsection (f) shall be
22 served—

23 “(1) in person by any officer or employee of the
24 Department of Health and Human Services des-
25 ignated by the Secretary; or

1 “(2) by mailing the order by registered mail or
2 certified mail or electronic equivalent addressed to
3 the applicant at the last known address in the
4 records of the Secretary.

5 **【“SEC. 587C. PRIORITY REVIEW.**

6 **【“(a) IN GENERAL.—】**

7 【“(1) An in vitro clinical test that is otherwise
8 required to have approval under section 587B may
9 be designated by the Secretary for priority review in
10 accordance with this section. An application for in
11 vitro clinical test that has been so designated may
12 be granted approval under subsection (f), in accord-
13 ance with the requirements of this section.】

14 【“(2) An in vitro clinical test for which ap-
15 proval has been granted under this section, and for
16 which such approval is in effect, is exempt from the
17 requirement to obtain premarket approval under sec-
18 tion 587B.】

19 【“(b) ELIGIBILITY.—An in vitro clinical test is eligi-
20 ble for designation, review, or approval under this section
21 if—】

22 【“(1) the test provides or enables more effec-
23 tive treatment or diagnosis of life-threatening or ir-
24 reversibly debilitating human disease or conditions

1 compared to existing approved or precertified alter-
2 natives; and】

3 【“(2) it is a test—】

4 【“(A) that represents a breakthrough tech-
5 nology;】

6 【“(B) for which no approved or
7 precertified alternative exists;】

8 【“(C) that offers a clinically meaningful
9 advantage over existing approved or precertified
10 alternatives, including the potential, compared
11 to existing approved or precertified alternatives,
12 to reduce or eliminate the need for hospitaliza-
13 tion, improve patient quality of life, facilitate
14 patients’ ability to manage their own care (such
15 as through self-directed personal assistance), or
16 establish long-term clinical efficiencies; or】

17 【“(D) the availability of which is in the
18 best interest of patients or public health.】

19 【“(c) DESIGNATION.—】

20 【“(1) REQUEST.—Except as provided in section
21 587(e), to receive breakthrough approval or approval
22 under this section, an applicant must first request
23 that the Secretary designate the in vitro clinical test
24 for priority review. Such a request shall include in-

1 formation demonstrating that the test is eligible for
2 designation under subsection (b).】

3 【“(2) DETERMINATION.—Not later than 60
4 calendar days after the receipt of a request under
5 paragraph (1), and prior to acceptance of an appli-
6 cation for approval, the Secretary shall determine
7 whether the in vitro clinical test that is the subject
8 of the request meets the criteria described in sub-
9 section (b). If the Secretary determines that the test
10 meets the criteria, the Secretary shall designate the
11 test for priority review.】

12 【“(3) REVIEW.—Review of a request under
13 paragraph (1) shall be undertaken by a team that is
14 composed of experienced staff and senior managers
15 of the Food and Drug Administration.】

16 【“(4) WITHDRAWAL.—】

17 【“(A) The designation of an in vitro clin-
18 ical test under this subsection is deemed to be
19 withdrawn, and such in vitro clinical test shall
20 no longer be eligible for review and approval
21 under this section, if an application for ap-
22 proval under subsection (f) for the test is de-
23 nied.】

24 【“(B) The Secretary may not withdraw a
25 designation granted under this subsection based

1 on the subsequent approval or
2 **【precertification】** of another test that—**】**

3 **【“(i) is designated under this section;**
4 **or】**

5 **【“(ii) was given priority review under**
6 **section 515C.】**

7 **【“(d) EXPEDITED DEVELOPMENT AND PRIORITY**
8 **REVIEW.—】**

9 **【“(1) For purposes of expediting the develop-**
10 **ment and review of in vitro clinical tests under this**
11 **section, the Secretary may take the actions and ad-**
12 **ditional actions set forth in section 515B(e) when**
13 **reviewing such tests under subsection (e) or (f).】**

14 **【“(2) Any reference or authorization in section**
15 **515B(e) with respect to a device shall be deemed a**
16 **reference or authorization with respect to an in vitro**
17 **clinical test for purposes of this section.】**

18 **【“(e) BREAKTHROUGH IN VITRO CLINICAL**
19 **TESTS.—【*To be supplied*】】**

20 **【“(f) ANNUAL REPORT.—Unless otherwise specified**
21 **by the Secretary, section 587B, requiring annual reports**
22 **applies to in vitro clinical tests approved under this sub-**
23 **section.】**

24 **【“(g) SERVICE OF ORDERS.—Orders of the Sec-**
25 **retary under this section shall be served—】**

1 【“(1) in person by any officer or employee of
2 the Department of Health and Human Services des-
3 ignated by the Secretary; or】

4 【“(2) by mailing the order by registered mail or
5 certified mail or electronic equivalent addressed to
6 the applicant at his last known address in the
7 records of the Secretary.】

8 **【“SEC. 587D. PRECERTIFICATION.**

9 **【“(a) IN GENERAL.—】**

10 【“(1) Any eligible person may seek
11 precertification in accordance with this section.】

12 【“(2) An in vitro clinical test is exempt from
13 premarket review under section 587A if its developer
14 is eligible under this section and the in vitro clinical
15 test—】

16 【“(A) is an eligible in vitro clinical test
17 under subsection (b)(2); and】

18 【“(B) falls within the scope of a
19 precertification order issued under this section,
20 and such order is in effect.】

21 **【“(b) ELIGIBILITY.—】**

22 【“(1) ELIGIBLE PERSON.—As used in this sec-
23 tion, the term ‘eligible person’ means an in vitro
24 clinical test developer unless, at the time such per-

1 son seeks or would seek precertification, the per-
2 son—】

3 【“(A) has been found to have committed a
4 significant violation of this Act or the Public
5 Health Service Act, except that this subpara-
6 graph shall not apply if—】

7 【“(i) such violation occurred more
8 than 5 years prior to the date on which
9 such precertification is or would be
10 sought;】

11 【“(ii) such violation has been re-
12 solved; or】

13 【“(iii) such violation is not pertinent
14 to any in vitro clinical test within the scope
15 of the precertification that such person
16 seeks or would seek; or】

17 【“(B) has been disqualified by the Sec-
18 retary on the basis of actions or omissions that
19 raise serious questions regarding whether the
20 eligibility of such person would be in the inter-
21 est of public health, such as—】

22 【“(i) making false or misleading
23 statements about matters relevant under
24 this subchapter;】

1 【“(ii) failing to maintain required cer-
2 tifications under section 353 of the Public
3 Health Service Act (42 U.S.C. 263a); or】

4 【“(iii) violating any requirement of
5 this Act or the Public Health Service Act,
6 where such violation exposes persons to se-
7 rious risk of illness, injury, or death.】

8 【“(2) ELIGIBLE IN VITRO CLINICAL TEST.—An
9 in vitro clinical test is eligible under subsection
10 (a)(2) for exemption from premarket review under
11 section 587A except as provided in this paragraph.】

12 【“(A) An in vitro clinical test is not eligi-
13 ble under subsection (a)(2) for an exemption
14 from premarket review if it is—】

15 【“(i) a component or part of an in
16 vitro clinical test as described under sec-
17 tion 201(ss)(1)(E);】

18 【“(ii) a test platform under section
19 201(ss)(1)(B);】

20 【“(iii) an article for taking or deriv-
21 ing specimens from the human body under
22 section 201(ss)(1)(C);】

23 【“(iv) software under section
24 201(ss)(1)(D), unless such software itself
25 identifies, diagnoses, screens, measures,

1 detects, predicts, prognoses, analyzes, or
2 monitors a disease or condition, including
3 a determination of the state of health, or
4 itself selects, monitors, or informs therapy
5 or treatment for a disease or condition; or】

6 【“(v) an in vitro clinical test, includ-
7 ing reagents used in such tests, intended
8 for use—】

9 【“(I) in the collection, manufac-
10 ture, or use of blood and blood compo-
11 nents intended for transfusion or fur-
12 ther manufacturing use or the recov-
13 ery, manufacture, or use of human
14 cells, tissues, and cellular and tissue-
15 based products intended for implanta-
16 tion, transplantation, infusion, or
17 transfer into a human recipient, in-
18 cluding tests intended for use in de-
19 termination of donor eligibility, dona-
20 tion suitability, and compatibility be-
21 tween donor and recipient;】

22 【“(II) in the diagnosis, moni-
23 toring, or treatment of hemolytic dis-
24 ease of the newborn, including tests
25 intended for use in ?determination of

1 compatibility between mother and
2 newborn; or】

3 【“(III) in the diagnosis or moni-
4 toring of human retroviruses or
5 human retrovirus infection.】

6 【“(B) An in vitro clinical test that is a
7 first-of-a-kind in vitro clinical test, test system
8 for home use, high risk in vitro clinical test,
9 cross-referenced in vitro clinical test, or a di-
10 rect-to-consumer in vitro clinical test is not eli-
11 gible under subsection (a)(2) for an exemption
12 from premarket review unless the Secretary
13 makes a determination pursuant to section
14 587F.】

15 【“(c) APPLICATION FOR PRECERTIFICATION.—】

16 【“(1) IN GENERAL.—A person seeking
17 precertification shall submit an application under
18 this subsection, which shall contain the information
19 specified under paragraph (2).】

20 【“(2) CONTENTS OF APPLICATION.—An appli-
21 cation for precertification shall contain—】

22 【“(A) a statement identifying the scope of
23 the proposed precertification, which shall be no
24 broader than a single technology (i.e., test
25 method) and shall specify medical subspecialties

1 (such as would be described by the combination
2 of a test purpose and disease or condition) in-
3 tended to be offered under the application, con-
4 sistent with the procedures for analytical valida-
5 tion and clinical validation included in the ap-
6 plication;】

7 【“(B) information showing that the person
8 seeking precertification is an eligible person
9 under subsection (b)(1);】

10 【“(C) information showing that the meth-
11 ods used in, and the facilities and controls used
12 for, the development of all eligible in vitro clin-
13 ical tests within the proposed scope of
14 precertification conform to the quality system
15 requirements of section 587J;】

16 【“(D) procedures for analytical validation,
17 including all procedures for validation,
18 verification, and acceptance criteria, and an ex-
19 planation as to how such procedures, when
20 used, provide a reasonable assurance of analyt-
21 ical validity of all eligible in vitro clinical tests
22 within the proposed scope of precertification;】

23 【“(E) procedures for clinical validation, in-
24 cluding all procedures for validation,
25 verification, and acceptance criteria, and an ex-

1 planation as to how such procedures, when
2 used, provide a reasonable assurance of clinical
3 validity of all eligible in vitro clinical tests with-
4 in the proposed scope of precertification;】

5 【“(F) a notification under section 587I for
6 each in vitro clinical test that would be
7 precertified under the application for
8 precertification and would be introduced or de-
9 livered for introduction into interstate com-
10 merce upon the issuance of the precertification
11 order;】

12 【“(G) information concerning one or more
13 representative in vitro clinical tests, including—
14 】

15 【“(i) the highest complexity test to
16 validate and run within the developer’s
17 stated scope, and a rationale for such se-
18 lection;】

19 【“(ii) the information specified in sec-
20 tion 587B(b) for the representative in vitro
21 clinical test or tests, except that raw data
22 shall be provided for any such in vitro clin-
23 ical test unless the Secretary determines
24 otherwise;】

1 【“(iii) an explanation of how the rep-
2 representative in vitro clinical test or tests
3 adequately represent the range of proce-
4 dures included in the application under
5 subparagraphs (C), (D), (E), and (F);
6 and】

7 【“(iv) a narrative description of how
8 the procedures included in the application
9 under subparagraphs (C), (D), (E), and
10 (F) have been applied to the representative
11 in vitro clinical test or tests;】

12 【“(H) such other information relevant to
13 the subject matter of the application as the Sec-
14 retary may require; and】

15 【“(I) a certification, in the opinion of the
16 developer and to the best of his knowledge, that
17 all information submitted in the application is
18 truthful and accurate and that no material fact
19 has been omitted.】

20 【“(d) ACTION ON AN APPLICATION FOR
21 PRECERTIFICATION.—】

22 【“(1) As promptly as possible, but no later
23 than 【X days】 after receipt of an application under
24 subsection (c), the Secretary shall—】

1 【“(A) issue a precertification order grant-
2 ing the application, which shall specify the
3 scope of the precertification, if the Secretary
4 finds that all of the grounds in paragraph (3)
5 are met; or】

6 【“(B) deny the application if the Secretary
7 finds (and sets forth the basis of such finding
8 as part of or accompanying such denial) that
9 one or more grounds for granting the applica-
10 tion specified in paragraph (3) are not met.】

11 【“(2) If, after receipt of an application under
12 this section, the Secretary determines that any por-
13 tion of such application is deficient, the Secretary
14 shall provide to the applicant a description of such
15 deficiencies and identify the information required to
16 correct such deficiencies.】

17 【“(3) The Secretary shall grant an application
18 under this section if, on the basis of the information
19 submitted to the Secretary as part of the application
20 and any other information before him or her with re-
21 spect to such applicant, the Secretary finds that—
22 】

23 【“(A) there is a showing of reasonable as-
24 surance of adequate analytical validity for all el-
25 igible in vitro clinical tests within the proposed

1 scope of the precertification, as evidenced by
2 the procedures for analytical validation;】

3 【“(B) there is a showing of reasonable as-
4 surance of adequate clinical validity for all eligi-
5 ble in vitro clinical tests within the proposed
6 scope of the precertification, as evidenced by
7 the procedures for clinical validation;】

8 【“(C) the methods used in, or the facilities
9 or controls used for, the development of all eli-
10 gible in vitro clinical tests within the proposed
11 scope of the precertification conform to the re-
12 quirements of section 587J;】

13 【“(D) based on a fair evaluation of all ma-
14 terial facts, the applicant’s labeling and adver-
15 tising is not false or misleading in any par-
16 ticular;】

17 【“(E) the application does not contain a
18 false statement of material fact;】

19 【“(F) there is a showing that the rep-
20 resentative in vitro clinical test or tests—】

21 【“(i) meets the standard for approval
22 under section 587B; and】

23 【“(ii) adequately represent the range
24 of procedures for analytical validation and

1 clinical validation included in the applica-
2 tion; and】

3 【“(G) the applicant permits authorized
4 employees of the Food and Drug Administra-
5 tion or persons accredited under this Act an op-
6 portunity to inspect at a reasonable time and in
7 a reasonable manner the facilities and all perti-
8 nent equipment, finished and unfinished mate-
9 rials, containers, and labeling therein, including
10 all things (including records, files, papers, and
11 controls) bearing on whether an in vitro clinical
12 test is adulterated, misbranded, or otherwise in
13 violation of this Act, and permits such author-
14 ized employees or persons accredited under this
15 Act to view and to copy and verify all records
16 pertinent to the application and the in vitro
17 clinical test.】

18 【“(4) An applicant whose application has been
19 denied may, by petition filed on or before the date
20 that is 30 calendar days after the date upon which
21 such applicant receives notice of such denial, obtain
22 review thereof in accordance with section 5870.】

23 【“(e) DURATION; SUBSEQUENT SUBMISSIONS.—】

1 **【“(1) ORDER DURATION.—A precertification**
2 order under subsection (d)(1)(A) shall remain in ef-
3 fect until the earliest of—**】**

4 **【“(A) the expiration of such**
5 precertification order under paragraph (2); or**】**

6 **【“(B) the withdrawal of such**
7 precertification order under subsection (h).**】**

8 **【“(2) EXPIRATION.—An initial precertification**
9 order under subsection (d)(1)(A) shall expire on the
10 date that is two years after the date that such order
11 is issued, except that if an application for renewal
12 under paragraph (3) has been received not later
13 than 30 days prior to the expiration of such order
14 under this paragraph, such order shall expire on the
15 date on which the Secretary has granted or denied
16 the application for renewal. Any such subsequent re-
17 newal of precertification shall expire on the date that
18 is four years after the date that such precertification
19 order is issued.**】**

20 **【“(3) RENEWAL.—(A) Any person with a**
21 precertification order in effect with respect to devel-
22 opment of in vitro clinical tests may seek renewal of
23 such order provided that—**】**

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

1 【“(ii) none of the information specified in
2 subsection (c)(2) has changed.】

3 【“(B) An application for renewal under this
4 paragraph shall include information concerning one
5 or more representative in vitro clinical tests in ac-
6 cordance with subsection (c)(2)(G), except that such
7 representative test or tests shall be different from
8 the representative test or tests included in any prior
9 application and shall represent a medical subspe-
10 ciality that has not yet been reviewed, if applicable.】

11 【“(C) The Secretary’s action on an application
12 for renewal of precertification under this paragraph
13 shall be conducted in accordance with subsection (d),
14 and any order resulting from such application shall
15 be treated as a precertification order for purposes of
16 this subchapter.】

17 【“(4) SUPPLEMENTS; REPORTS.—】

18 【“(A) SUPPLEMENTS.—Except as provided
19 in subparagraph (B), any person with a
20 precertification order in effect may seek a sup-
21 plement to such order upon a change or
22 changes to the information provided in the ap-
23 plication for precertification under subpara-
24 graphs (C), (D), and (E) of subsection (c)(2),
25 provided that such person is an eligible person

1 under subsection (b)(1) and that such change
2 does not expand the scope of the
3 precertification. A supplement may contain only
4 information relevant to the change or changes.
5 The Secretary’s action on a supplement shall be
6 in accordance with subsection (d), and any
7 order resulting from such supplement shall be
8 treated as an amendment to a precertification
9 order that is in effect.】

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

17 【“(i) Any report to the Secretary
18 under this subparagraph shall include—】

19 【“(I) a summary of the relevant
20 change or changes;】

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

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

1 【“(ii) Upon review of such report and
2 a finding that the relevant change or
3 changes are inconsistent with the standard
4 specified under this subparagraph, the Sec-
5 retary may require a supplement under
6 subparagraph (A).】

7 【“(f) MAINTENANCE REQUIREMENTS.—For the du-
8 ration of a precertification under subsection (e)(1), a hold-
9 er of a precertification order shall—】

10 【“(1) use the procedures included in the rel-
11 evant application, supplement, or report under sub-
12 sections (b) and (e);】

13 【“(2) ensure compliance with any applicable
14 mitigating measures;】

15 【“(3) maintain, and provide to the Secretary
16 upon request, records related to any in vitro clinical
17 test offered without premarket review under the
18 precertification order, where those records are nec-
19 essary to demonstrate compliance with applicable
20 provisions of this Act; and】

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

25 【“(g) TEMPORARY HOLD.—】

1 【“(1) IN GENERAL.—Upon one or more find-
2 ings under paragraph (3), the Secretary may issue
3 a temporary hold prohibiting any holder of a
4 precertification order from introducing into inter-
5 state commerce an in vitro clinical test that was not
6 previously the subject of a notification under section
7 587I. The temporary hold must identify the grounds
8 for the temporary hold under paragraph (3) and the
9 rationale for such finding.】

10 【“(2) WRITTEN REQUESTS.—Any written re-
11 quest to the Secretary from the holder of a
12 precertification order that a temporary hold under
13 paragraph (1) be removed shall receive a decision, in
14 writing and specifying the reasons therefore, within
15 【180】 days after receipt of such request. Any such
16 request shall include information to support the re-
17 moval of the temporary hold.】

18 【“(3) GROUNDS FOR TEMPORARY HOLD.—A
19 temporary hold under this subsection may be
20 instated upon a finding or findings that the holder
21 of a precertification order—】

22 【“(A) is not in compliance with any main-
23 tenance requirements under subsection (f);】

1 【“(B) labels or advertises one or more in
2 vitro clinical tests with false or misleading
3 claims; or】

4 【“(C) is no longer an eligible person under
5 subsection (b)(1).】

6 【“(h) WITHDRAWAL.—】(1) The Secretary may, after
7 due notice and opportunity for informal hearing, issue an
8 order withdrawing a precertification order if the Secretary
9 finds that—】

10 【“(A) the application, supplement, or report
11 under subsections (b) or (e) contains false or mis-
12 leading information or fails to reveal a material fact;
13 or】

14 【“(B) such holder fails to correct false or mis-
15 leading labeling or advertising upon the request of
16 the Secretary;】

17 【“(C) in connection with a precertification, the
18 holder provides false or misleading information to
19 the Secretary; or】

20 【“(D) the holder of such precertification order
21 fails to correct the grounds for temporary hold with-
22 in a timeframe specified in the temporary hold
23 order.】

1 【“(2) Paragraph (1) shall not apply to any person
2 who violates the requirements of subsections (b) or (e) un-
3 less such violation constitutes—】

4 【“(A) a significant or knowing departure, as
5 defined in parts 17.3 (A)(1) and (2) of title 21 of
6 the Code of Federal Regulations, from such require-
7 ments; or】

8 【“(B) a risk to public health.】

9 【“(i) REPORTS TO CONGRESS.—】

10 【“(1) Not later than one year after the effec-
11 tive date, and annually thereafter, for a total of five
12 years, the Secretary shall prepare and submit to the
13 Committee on Energy and Commerce of the House
14 of Representatives and the Committee on Health,
15 Education, Labor, and Pensions of the Senate, and
16 make publicly available, including through posting
17 on the Internet website of the Food and Drug Ad-
18 ministration, a report containing the information re-
19 quired under paragraph (2).】

20 【“(2) The report shall at a minimum address—
21 】

22 【“(A) the number and type of applications
23 for precertification filed, granted, withdrawn or
24 denied;】

1 【“(B) the number of precertifications put
2 on temporary hold under subsection (g) and the
3 number of precertifications withdrawn under
4 subsection (h);】

5 【“(C) the technologies and medical sub-
6 specialties for which precertification orders were
7 granted;】

8 【“(D) the number of high-risk in vitro
9 clinical tests offered without premarket review
10 pursuant to precertification orders according to
11 technology and medical subspecialty; or】

12 【“(E) the number of laboratories and
13 manufacturers with precertification orders in
14 effect.】

15 【“(3) No later than 【two months】 after sub-
16 mission of the fourth report under subsection (i)(1),
17 the Secretary of Health and Human Services shall
18 convene a public meeting on the program being con-
19 ducted under this section. The Secretary shall invite
20 to such meeting representatives from the in vitro
21 clinical test industry and organizations representing
22 patients and consumers. The public meeting shall be
23 assigned a docket number by the Commissioner of
24 Food and Drugs and made available for the submis-
25 sion of public comments.】

1 【“(4) The fifth report submitted under sub-
2 section (i)(1) shall include a summary of, and re-
3 sponses to, comments raised in the meeting and
4 docket described in subsection (i)(3).】

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

6 “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

7 “(1) ESTABLISHING, CHANGING, OR WITH-
8 DRAWING.—

9 “(A) ESTABLISHMENT.—If the Secretary
10 determines that the establishment of mitigating
11 measures is necessary for any of the reasons
12 identified in section 587(9)(A) for any test
13 group or test groups, the Secretary may require
14 that in vitro clinical tests in such group or
15 groups comply with such mitigating measures.

16 “(B) PROCESS.—Notwithstanding sub-
17 chapter II of chapter 5 of title 5, United States
18 Code, the Secretary may establish, change, or
19 withdraw a requirement for compliance with
20 mitigating measures under subparagraph (A)
21 by—

22 “(i) publishing a proposed administra-
23 tive order in the Federal Register;

24 “(ii) providing an opportunity for
25 public comments; and

1 “(iii) after consideration of such com-
2 ments, publishing a final administrative
3 order in the Federal Register.

4 “(2) IN VITRO CLINICAL TESTS PREVIOUSLY
5 REGULATED AS DEVICES.—

6 “(A) IN GENERAL.—Any special controls
7 or restrictions applicable to an in vitro clinical
8 test or test group based on prior regulation as
9 a device, including any such special controls or
10 restrictions established during the period begin-
11 ning on the date of enactment of the Verifying
12 Accurate Leading-edge IVCT Development Act
13 of 2018 and ending on the effective date of
14 such Act (as described in section 5(b) of such
15 Act)—

16 “(i) shall continue to apply to such
17 test or test group after such effective date;
18 and

19 “(ii) are deemed to be mitigating
20 measures as of such effective date.

21 “(B) CHANGES.—The Secretary may es-
22 tablish, change, or withdraw mitigating meas-
23 ures for such a test or test group using the pro-
24 cedures under paragraph (1).

25 “(b) DOCUMENTATION.—

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

5 “(A) in accordance with section
6 587B(b)(2)(D), submit documentation to the
7 Secretary as part of the application for the test
8 under section 587B(b) demonstrating that such
9 mitigating measures have been met;

10 “(B) if such application is approved, main-
11 tain documentation demonstrating that such
12 mitigating measures continue to be met; and

13 “(C) make such documentation available to
14 the Secretary upon request or inspection.

15 “(2) OTHER TESTS.—The developer of an in
16 vitro clinical test that is marketed within the scope
17 of a **[precertification]** or other exemption from pre-
18 market review under section 587B and to which
19 mitigating measures apply shall—

20 “(A) maintain documentation in accord-
21 ance with the quality systems requirements in
22 section 587J demonstrating that such miti-
23 gating measures continue to be met;

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

1 “(C) include in the performance summary
2 for such test a description of how such miti-
3 gating measures are met, if applicable.

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

5 “(a) IN GENERAL.—Based on new information, in-
6 cluding the establishment of mitigating measures under
7 section 587E, and after considering all available evidence
8 respecting a test group, the Secretary may, upon the ini-
9 tiative of the Secretary or upon petition of an interested
10 person—

11 “(1) revoke any exemption or requirement in ef-
12 fect under this subchapter with respect to such test
13 group; or

14 “(2) determine that the test group is subject to
15 premarket review under section 587B, is eligible for
16 【precertification in accordance with section
17 587D(b)(2)(B)】, or is exempt from premarket re-
18 view under section 587B or other requirements of
19 this subchapter.

20 “(b) PROCESS.—Any action under subsection (a), in-
21 cluding any revocation, shall be made by publication of
22 a 【notice】 of such proposed action in the Federal Reg-
23 ister, consideration of comments to a public docket on
24 such proposal, and publication of a final 【notice】 in the

1 Federal Register, notwithstanding subchapter II of chap-
2 ter 5 of title 5, United States Code.

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

4 “(a) IN GENERAL.—The Secretary may establish ad-
5 visory committees to make recommendations to the Sec-
6 retary regarding in vitro clinical tests for the purposes
7 of—

8 “(1) determining whether to approve an appli-
9 cation for an in vitro clinical test submitted under
10 this subchapter, including for evaluating the analyt-
11 ical validity, clinical validity, and as applicable safe-
12 ty, of in vitro clinical tests;

13 “(2) evaluating the potential effectiveness of
14 mitigating measures for a determination on the ap-
15 plicable regulatory pathway under section 587 or
16 risk evaluation for an in vitro clinical test or test
17 group;

18 “(3) establishing quality system requirements
19 under section 587J or applying such requirements to
20 in vitro clinical tests developed or imported by devel-
21 opers; and

22 “(4) such other purposes as the Secretary de-
23 termines appropriate.

24 “(b) APPOINTMENTS.—

1 “(1) VOTING MEMBERS.—The Secretary shall
2 appoint to each committee established under sub-
3 section (a), as voting members, individuals who are
4 qualified by training and experience to evaluate in
5 vitro clinical tests for the purposes specified in sub-
6 section (a), including individuals with knowledge of
7 in vitro clinical tests, laboratory operations, and the
8 use of in vitro clinical tests. The Secretary shall des-
9 ignate one member of each committee to serve as
10 chair thereof.

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

15 “(A) a representative of consumer inter-
16 ests; and

17 “(B) a representative of interests of the in
18 vitro clinical test industry.

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

24 “(4) COMPENSATION.—Members of an advisory
25 committee established under subsection (a), while at-

1 tending meetings or conferences or otherwise en-
2 gaged in the business of the advisory committee—

3 “(A) shall receive compensation [at rates
4 to be fixed by the Secretary]; and

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

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

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

13 “Before submitting a premarket application or
14 [precertification package] for an in vitro clinical test—

15 “(1) the developer of the test may submit to the
16 Secretary a written request for a meeting or con-
17 ference to discuss and provide information relating
18 to—

19 “(A) the submission process and the type
20 and amount of evidence expected to dem-
21 onstrate the relevant standard;

22 “(B) [which regulatory pathway is appro-
23 priate for an in vitro clinical test; or]

24 “(C) [an investigation plan for an in vitro
25 clinical test, including a clinical protocol; and]

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

3 “(A) within **[X]** calendar days after such
4 receipt, or within such time period as may be
5 agreed to by the developer, meet or confer with
6 the developer submitting the request; and

7 “(B) within **[X]** calendar days after such
8 meeting or conference, provide to the developer
9 a written record or response describing the
10 issues discussed and conclusions reached in the
11 meeting or conference.

12 **“SEC. 587I. REGISTRATION AND NOTIFICATION.**

13 “(a) REGISTRATION OF ESTABLISHMENTS FOR IN
14 VITRO CLINICAL TESTS.—

15 “(1) Each person who is an in vitro clinical test
16 developer— or a contract manufacturer (including
17 contract packaging), contract sterilizer, repackager,
18 relabeler, distributor, or a person who introduces or
19 proposes to begin the introduction or delivery for in-
20 troduction into interstate commerce any in vitro clin-
21 ical test shall—

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

1 establishments engaged in the activities specified
2 under this paragraph, the unique facility identi-
3 fier of each such establishment, and a point of
4 contact for each such establishment, including
5 an electronic point of contact; and

6 “(B) Submit an initial registration con-
7 taining the information required under subpara-
8 graph (A) not later than—

9 “(i) the date of implementation of this
10 section if such establishment is engaged in
11 any activity described in this paragraph on
12 the date of enactment of this section, un-
13 less the Secretary establishes by guidance
14 a date later than such implementation date
15 for all or a category of such establish-
16 ments; or

17 “(ii) 30 days prior to engaging in any
18 activity described in this paragraph after
19 enactment of this section, if such establish-
20 ment is not engaged in any activity de-
21 scribed in this paragraph on the date of
22 enactment of this section.

23 “(2) The Secretary may assign a registration
24 number or unique facility identifier to any person or
25 any establishment registered in accordance with this

1 section. Registration information shall be made pub-
2 licly available by publication on the website main-
3 tained by the Food and Drug Administration.

4 “(3) Every person or establishment that is re-
5 quired to be registered with the Secretary under this
6 section shall be subject to inspection pursuant to
7 section 704.

8 “(b) NOTIFICATION INFORMATION FOR IN VITRO
9 CLINICAL TESTS.—

10 “(1) Each developer of an in vitro clinical test
11 shall submit a notification to the Secretary con-
12 taining the information described in this subsection
13 in accordance with the applicable schedule described
14 under subsection (c). Such notification shall be pre-
15 pared in such form and manner as the Secretary
16 may specify in guidance. Notification information
17 shall be submitted to the comprehensive test infor-
18 mation system in accordance with section 587U.

19 “(2) Each developer shall electronically submit
20 to the comprehensive test information system the
21 following information for each in vitro clinical test
22 for which such person is a developer in the form and
23 manner prescribed by the Secretary:

24 “(A) name of the establishment and its
25 unique facility identifier;

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

3 “(C) name (common name and trade
4 name, if applicable) of the in vitro clinical test;
5 and its test notification number (when avail-
6 able).

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

15 “(E) the appropriate category under this
16 subchapter under which the in vitro clinical test
17 is offered, introduced or marketed, such as —
18 **【precertification】**, low-risk exemption, pre-
19 market approval, grandfathering, or another
20 specified category;

21 “(F) brief narrative description of the in
22 vitro clinical test;

23 “(G) substance or substances measured by
24 the in vitro clinical test, such as analyte, pro-
25 tein, or pathogen;

1 “(H) type or types of specimen or sample;

2 “(I) test method;

3 “(J) test purpose, as described in section
4 201(ss)(1)(A), such as screening, predicting, or
5 monitoring;

6 “(K) disease or condition for which the in
7 vitro clinical test is intended for use;

8 “(L) intended patient population;

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

13 “(N) summary of in vitro clinical test ana-
14 lytical performance and clinical performance,
15 and as applicable lot release criteria;

16 “(O) statement describing conformance
17 with applicable mitigating measures, restric-
18 tions, and standards;

19 “(P) representative labeling for the in vitro
20 clinical test; and

21 “(Q) a certification that the information
22 submitted is truthful and accurate.

23 “(3) The Secretary may assign a test notifica-
24 tion number to each in vitro clinical test that is the
25 subject of a notification under this section. The

1 process for assigning test notification numbers may
2 be established through guidance, and may include
3 the recognition of standards, formats, or conventions
4 developed by a third-party organization.

5 “(4) A person who is not a developer but is oth-
6 erwise required to register pursuant to subsection
7 (a) shall submit an abbreviated notification to the
8 Secretary containing the information described in
9 subparagraphs (A) through (C) of paragraph (2),
10 the name of the developer, and any other informa-
11 tion described in paragraph (2) as may be specified
12 by the Secretary in guidance, as applicable to the ac-
13 tivities of each class of persons required to register.
14 The information shall be submitted in accordance
15 with the applicable schedule described under sub-
16 section (c). Such abbreviated notification shall be
17 prepared in such form and manner as the Secretary
18 may specify in guidance. Notification information
19 shall be submitted to the comprehensive test infor-
20 mation system in accordance with section 587U.

21 “(c) **TIMELINES FOR SUBMISSION.**—

22 “(1) For an in vitro clinical test that was listed
23 as a device under section 510(j) prior to the date of
24 enactment of this section, a person shall maintain a
25 device listing under section 510 until such time as

1 the system for submitting the notification informa-
2 tion required under subsection (b) becomes available
3 to in vitro clinical test developers, and thereafter
4 shall submit the notification information no later
5 than **[X]**.

6 “(2) For an in vitro clinical test that is subject
7 to the grandfathering provisions of section 587A(c),
8 a person shall submit the notification information
9 required under subsection (b) no later than **[X]**
10 months after the system for submitting the notifica-
11 tion becomes available.

12 “(3) For an in vitro clinical test that is not
13 subject to paragraph (1) or (2), a person shall sub-
14 mit the required notification information prior to of-
15 fering, introducing, or marketing the in vitro clinical
16 test as follows:

17 “(A) For an in vitro clinical test that is
18 not exempt from premarket approval, a person
19 shall submit the required notification informa-
20 tion no later than ten business days after the
21 date of approval of the premarket approval ap-
22 plication.

23 “(B) For an in vitro clinical test that is
24 exempt from premarket approval, a person shall
25 submit the required notification information at

1 least ten business days prior to offering the in
2 vitro test for clinical use or otherwise intro-
3 ducing the in vitro clinical test into interstate
4 commerce.

5 “(4) Each person required to submit notifica-
6 tion information under this section shall update such
7 information within ten business days of any change
8 that causes any previously notified information to be
9 inaccurate or incomplete.

10 “(5) Each person required to submit notifica-
11 tion information under this section shall update its
12 information annually during the period beginning on
13 October 1 and ending on December 31 of each year
14 and certify that the information contained in such
15 notification is truthful and accurate, and shall pay
16 the annual notification fee prescribed in section
17 587W.

18 “(d) PUBLIC AVAILABILITY OF NOTIFICATION IN-
19 FORMATION.—

20 “(1) Notification information submitted pursu-
21 ant to this section shall be made publicly available
22 by publication on the website of the Food and Drug
23 Administration after the in vitro clinical test devel-
24 oper has certified the information as truthful and
25 accurate.

1 “(2) Notification information for an in vitro
2 clinical test that is subject to premarket approval or
3 【precertification】 shall remain confidential until
4 such date as the in vitro clinical test receives the ap-
5 plicable premarket approval or 【precertification】.

6 “(3) The registration and notification informa-
7 tion requirements described in subsections (a) and
8 (b) shall not apply to the extent the Secretary deter-
9 mines that such information is restricted from dis-
10 closure pursuant to another statute, including infor-
11 mation relating to national security or counter-
12 measures.

13 **“SEC. 587J. QUALITY SYSTEM REQUIREMENTS.**

14 “(a) APPLICABILITY.—

15 “(1) Each developer and each other person re-
16 quired to register under section 587I(a)(1) shall es-
17 tablish and maintain a quality system in accordance
18 with the applicable requirements set forth in sub-
19 section (b), except as provided in section 587A.

20 “(2) A developer that operates its own clinical
21 laboratory certified by the Secretary under section
22 263a of title 42 of the United States Code that
23 meets the requirements for performing high-com-
24 plexity testing and develops its own in vitro clinical
25 test or tests or modifies another developer’s in vitro

1 clinical test in that certified laboratory in a manner
2 described in section 587(6), where such in vitro clin-
3 ical test or in vitro clinical tests are for use only
4 within that certified laboratory, shall establish and
5 maintain with respect to such test or tests a quality
6 system that complies with the requirements set forth
7 in subsection (b)(2). The applicable requirements set
8 forth in subsection (b)(1) shall apply to any test
9 platform, article for taking or deriving specimens
10 from the human body, component or part that is de-
11 veloped for use by a clinical laboratory to which the
12 first sentence of this paragraph applies.

13 “(3) A clinical laboratory certified by the Sec-
14 retary under section 263a of title 42 of the United
15 States Code that meets the requirements for per-
16 forming high-complexity testing must comply with
17 the applicable quality system requirements under
18 subsection (b) no later than the date of implementa-
19 tion of this subchapter.

20 “(4) As necessary, the Secretary shall amend
21 part 820 of title 21 of the Code of Federal Regula-
22 tions, or successor regulations, to implement the
23 provisions of this **[section]**. In considering such
24 amendment, the Secretary shall consider whether
25 and to what extent international harmonization

1 might be appropriate. Until such amendment takes
2 effect, such regulations shall be interpreted to apply
3 to in vitro clinical tests and developers.

4 “(5) The Secretary may establish such other
5 regulations under this section as are necessary to as-
6 sure the analytical and clinical validity of in vitro
7 clinical tests, or the safety of articles for taking or
8 deriving specimens from the human body.

9 “(6) In implementing quality system require-
10 ments for test developers under this section, the Sec-
11 retary shall—

12 “(A) for purposes of facilitating inter-
13 national harmonization, take into account
14 whether the developer participates in an audit
15 program in which the United States partici-
16 pates or the United States recognizes or con-
17 forms with standards recognized by the Sec-
18 retary; and

19 “(B) ensure a **[least burdensome]** ap-
20 proach by leveraging, to the extent applicable,
21 the quality assurance requirements applicable to
22 developers certified by the Secretary under sec-
23 tion 263a of title 42 of the United States Code.

24 “(b) QUALITY SYSTEM REQUIREMENTS.—

1 “(1) IN GENERAL.—The quality system require-
2 ments applicable under this section shall, including
3 applying or amending part 820 of title 21 of the
4 Code of Federal Regulations as provided in sub-
5 section (a)(4)—

6 “(A) apply only with respect to the design,
7 development, validation, production, manufac-
8 ture, preparation, propagation, or assembly of
9 an in vitro clinical test, offered under this sub-
10 chapter;

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

13 “(C) shall include each of the following,
14 subject to paragraphs (2) and (3):

15 “(i) Management responsibility.

16 “(ii) Quality audit.

17 “(iii) Personnel.

18 “(iv) Design controls.

19 “(v) Document controls.

20 “(vi) Purchasing controls, including
21 supplier controls.

22 “(vii) Identification and Traceability.

23 “(viii) Production and process con-
24 trols.

25 “(ix) Acceptance activities.

- 1 “(x) Nonconforming product.
- 2 “(xi) Corrective and preventive action.
- 3 “(xii) Labeling and packaging con-
4 trols.
- 5 “(xiii) Handling, storage, distribution,
6 and installation.
- 7 “(xiv) Records.
- 8 “(xv) Servicing.
- 9 “(xvi) Statistical techniques.

10 “(2) QUALITY SYSTEM REQUIREMENTS FOR
11 CERTAIN LABORATORIES.—With regard to estab-
12 lishing quality system requirements under this Act,
13 including applying or amending part 820 of title 21
14 of the Code of Federal Regulations as provided in
15 subsection (a)(4), quality system requirements appli-
16 cable to the in vitro clinical tests and developers de-
17 scribed in subsection (a)(2) shall consist of the fol-
18 lowing:

- 19 “(A) Design controls.
- 20 “(B) Purchasing controls, including sup-
21 plier controls.
- 22 “(C) Acceptance activities.
- 23 “(D) Corrective and preventative action.
- 24 “(E) Records.

1 “(3) QUALITY SYSTEM REQUIREMENTS FOR
2 CERTAIN LABORATORIES DISTRIBUTING PROTO-
3 COLS.—

4 “(A) With regard to establishing quality
5 system requirements under this Act, including
6 applying or amending part 820 of title 21 of
7 the Code of Federal Regulations as provided in
8 subsection (a)(4), quality system requirements
9 applicable to the developer and in vitro clinical
10 test distributed under subparagraph (B) shall
11 consist of the following provided that the condi-
12 tions of subparagraph (B) are met:

13 “(i) The requirements in paragraph
14 (2).

15 “(ii) The labeling requirements in
16 subparagraph (1)(L).

17 “(iii) The requirement to maintain
18 records of the laboratories to which the
19 test protocol is distributed.

20 “(B) To be eligible for subparagraph (A),
21 the following conditions must be met—

22 “(i) the laboratory distributing the
23 protocol is certified by the Secretary under
24 section 263a of title 42 of the United

1 States Code and meets the requirements
2 for performing high-complexity testing;

3 “(ii) the laboratory develops its own
4 in vitro clinical test or modifies another de-
5 veloper’s in vitro clinical test in a manner
6 described in section 587(6); and

7 “(iii) the laboratory distributes the
8 test protocol for such test only to another
9 laboratory that—

10 “(I) is certified by the Secretary
11 under section 263a of title 42 of the
12 United States Code and meets the re-
13 quirements for performing high-com-
14 plexity testing; and

15 “(II) is within the same cor-
16 porate organization and having com-
17 mon ownership by the same parent
18 corporation; or as applicable, is within
19 the Laboratory Response Network of
20 the Centers for Disease Control and
21 Prevention.

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

23 “(a) IN GENERAL.—An in vitro clinical test shall
24 bear or be accompanied by labeling, and a label as applica-
25 ble, that meet the requirements set forth in subsections

1 (b) and (c), and any other requirements established by the
2 Secretary by regulations, unless such test is exempt as
3 specified in subsection (d) or (e).

4 “(b) LABELS.—

5 “(1) The label of an in vitro clinical test shall
6 meet the requirements set forth in paragraph (2),
7 except this requirement shall not apply to an in vitro
8 clinical test that consists solely of a test protocol, or
9 that is designed, manufactured, and used solely
10 within a single laboratory certified by the Secretary
11 under section 263a of title 42 that meets the re-
12 quirements for performing high-complexity testing.

13 “(2) The label of an in vitro clinical test shall
14 state the name and place of business of its developer
15 and meet the requirements set forth in section
16 809.10(a) of title 21 of the Code of Federal Regula-
17 tions, or any successor regulation. The Secretary
18 shall amend such regulation, as necessary, to ensure
19 its applicability to in vitro clinical tests. Until such
20 amendment takes effect, such regulations shall be
21 interpreted to apply to in vitro clinical tests.

22 “(c) LABELING.—

23 “(1) Labeling accompanying an in vitro clinical
24 test, including labeling in the form of a package in-
25 sert, standalone laboratory reference document, or

1 other similar document except the labeling specified
2 in paragraph (2), shall include adequate directions
3 for use and shall meet the requirements set forth in
4 section 809.10(b) and (g) of title 21 of the Code of
5 Federal Regulations, or any successor regulation, ex-
6 cept as provided in subsection (d). Labeling in the
7 form of a package insert shall also include the infor-
8 mation in paragraph (2)(A) through (C). The Sec-
9 retary shall amend such regulation, as necessary, to
10 ensure its applicability to in vitro clinical tests. Until
11 such amendment takes effect, such regulation shall
12 be interpreted to apply to in vitro clinical tests.

13 “(2) Labeling accompanying an in vitro clinical
14 test that is in the form of a test report template or
15 ordering information shall include—

16 “(A) the test notification number that was
17 provided to the developer at the time of notifi-
18 cation;

19 “(B) instructions for how and where to re-
20 port an adverse event under section 587L;

21 “(C) instructions for how and where to ac-
22 cess the performance summary data displayed
23 in the notification database for the test;

24 “(D) the intended use of the in vitro clin-
25 ical test;

1 “(E) any warnings;

2 “(F) contraindications; and

3 “(G) limitations.

4 “(3) Labeling for an in vitro clinical test used
5 for immunohematology testing shall meet the fol-
6 lowing additional requirements set forth in part 660
7 of the Code of Federal Regulations (or any successor
8 regulation), as they appear on the date of enactment
9 of this subchapter if to the extent such test fell with-
10 in the scope of such regulations immediately prior to
11 such date of enactment:

12 “(A) Section 660.28 (a)(1)(i); (a)(1)(ii)(A)
13 and (F); (a)(2)(i) and (xiv); and (a)(4);

14 “(B) Section 660.35 (a)(1)(ii); (a)(2) - (4);
15 (a)(6) - (9); and

16 “(C) Section 660.55 (a)(1)(i); (a)(1)(ii)(A)
17 and (H).

18 The Secretary shall amend such regulations, as nec-
19 essary, to ensure their applicability to in vitro clin-
20 ical tests. Until such amendment takes effect, such
21 regulations shall be interpreted to apply to in vitro
22 clinical tests.

23 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-
24 MENTS.—

1 “(1) IN GENERAL.—For an in vitro clinical test
2 that is designed, manufactured, and used solely
3 within a single high complexity laboratory certified
4 by the Secretary under section 353 of the Public
5 Health Service Act, and owned and operated by the
6 developer of such in vitro clinical test, the require-
7 ment in section 809.10(b) of title 21 of the Code of
8 Federal Regulations that the labeling ‘state in one
9 place’ all of the required information may be satis-
10 fied by the laboratory posting such required infor-
11 mation on its website or in multiple documents, if
12 such documents are maintained and accessible in
13 one place.

14 “(2) LABELING.—The labeling for a test plat-
15 form, when such platform is not committed to spe-
16 cific diagnostic procedures or systems, is not re-
17 quired to bear the information indicated in para-
18 graphs (3), (4), (5), (7), (8), (9), (10), (11), (12),
19 and (13) of section 809.10(b) of title 21 of the Code
20 of Federal Regulations, as it appears on the date of
21 enactment of this subchapter and amended there-
22 after.

23 “(3) REAGENT LABELING.—For purposes of
24 compliance with subsection (c)(1), the labeling for a
25 reagent intended for use as a replacement in a diag-

1 nostic system may be limited to that information
2 necessary to identify the reagent adequately and to
3 describe its proper use in the system.

4 “(4) LAB RESEARCH OR INVESTIGATIONAL
5 USE.—A shipment or other delivery of an in vitro di-
6 agnostic test shall be exempt from the requirements
7 of subsection (b) and (c)(1) and from any standard
8 promulgated under part 861 of title 21 of the Code
9 of Federal Regulations, or any successor regulation,
10 provided that the conditions set forth in 809.10(c)
11 of such title, as it appears on the date of enactment
12 of this subchapter and amended thereafter are met.
13 The Secretary shall amend such regulations, as nec-
14 essary, to ensure their applicability to in vitro clin-
15 ical tests. Until such amendment takes effect, such
16 regulations shall be interpreted to apply to in vitro
17 clinical tests.

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

24 “(6) ANALYTE SPECIFIC REAGENTS.—The la-
25 beling of analyte specific reagents, such as

1 monoclonal antibodies, deoxyribonucleic acid probes,
2 viral antigens, ligands and other similar items, shall
3 bear the information set forth in part 809.10(e)(1)
4 through (2) of title 21 of the Code of Federal Regu-
5 lations as it appears on the date of enactment of
6 this subchapter and amended thereafter and shall
7 bear the following statement: ‘This product is in-
8 tended solely for further development of an in vitro
9 clinical test and is exempt from most FDA regula-
10 tion. This product must be evaluated by the in vitro
11 clinical test developer in accordance with supplier
12 controls if it is used with or in the development of
13 an in vitro clinical test.’. If the labeling of an
14 analyte specific reagent bears the information set
15 forth in this paragraph, it need not bear the infor-
16 mation required by subsection (c)(1).

17 “(7) OVER-THE-COUNTER TEST SAMPLE COL-
18 LECTION SYSTEMS LABELING.—The labeling for
19 over-the-counter (OTC) test sample collection sys-
20 tems for drugs of abuse testing shall bear the name
21 and place of business of the developer and the infor-
22 mation specified in part 809.10(f) of title 21 of the
23 Code of Federal Regulations as it appears on the
24 date of enactment of this subchapter and amended
25 thereafter, in language appropriate for the intended

1 users. If the labeling of such OTC test sample collec-
2 tion system bears the information set forth in this
3 paragraph (4)(G), it need not bear the information
4 required by subsection (c)(1).

5 “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-
6 PILE.—

7 “(1) The Secretary may grant an exception or
8 alternative to any provision listed in this section, un-
9 less explicitly required by a statutory provision out-
10 side this section, for specified lots, batches, or other
11 units of an in vitro clinical test, if the Secretary de-
12 termines that compliance with such labeling require-
13 ment could adversely affect the safety, effectiveness,
14 or availability of such products that are or will be
15 included in the Strategic National Stockpile.

16 “(2) The Secretary may issue regulations
17 amending section 809.11 of title 21 of the Code of
18 Federal Regulations or any successor regulation to
19 apply in full or in part to in vitro clinical tests and
20 in vitro clinical test developers.

21 “(f) GUIDANCE.—The Secretary may, in collabora-
22 tion with developers, issue guidance on standardized, gen-
23 eral content and format for in vitro clinical test labeling
24 to help ensure compliance with applicable requirements in
25 this subsection.

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

2 “(a) APPLICABILITY.—

3 “(1) Each in vitro clinical test developer shall
4 establish, maintain, and implement a system for re-
5 porting adverse events in accordance with subsection
6 (b), except as provided in section 587A.

7 “(2) The Secretary shall amend part 803 of
8 title 21 of the Code of Federal Regulations (or any
9 successor regulations) to apply to in vitro clinical
10 tests. Until such amendment takes effect, such part
11 shall be interpreted to apply to in vitro clinical tests.

12 “(3) The Secretary may by regulation require
13 reporting of such other adverse events as determined
14 by the Secretary to be necessary to be reported to
15 assure the analytical and clinical validity of in vitro
16 clinical tests, and in addition, the safety of articles
17 for taking or deriving specimens from the human
18 body.

19 “(b) ADVERSE EVENT REPORTING REQUIRE-
20 MENTS.—

21 “(1) Each in vitro clinical test developer shall
22 report to the Secretary whenever the developer re-
23 ceives or otherwise becomes aware of information
24 that reasonably suggests that one of its in vitro clin-
25 ical tests—

1 “(A) may have caused or contributed to a
2 death or serious injury;

3 “(B) has malfunctioned and the in vitro
4 clinical test, or a similar in vitro clinical test de-
5 veloped or marketed by the in vitro clinical test
6 developer, would be likely to cause or contribute
7 to a death or serious injury if the malfunction
8 were to recur; and

9 “(C) such adverse event cannot be directly
10 attributed to laboratory error.

11 “(2) For purposes of this section, the term ‘se-
12 rious injury’ shall mean—

13 “(A) a critical delay in diagnosis or caus-
14 ing the absence, delay, or discontinuation of ap-
15 propriate medical treatment; or

16 “(B) an injury that—

17 “(i) is life threatening;

18 “(ii) results in permanent impairment
19 of a body function or permanent damage
20 to a body structure; or

21 “(iii) necessitates medical or surgical
22 intervention to preclude permanent impair-
23 ment of a body function or permanent
24 damage to a body structure.

1 “(3) Reports required under this section shall
2 be submitted as follows:

3 “(A) An individual adverse event reports
4 shall be submitted for the following events not
5 later than—

6 “(i) 5 calendar days after an in vitro
7 clinical test developer receives or otherwise
8 becomes aware of information that reason-
9 ably suggests the adverse event involves a
10 patient death; or

11 “(ii) 5 calendar days after an in vitro
12 clinical test developer receives or otherwise
13 becomes aware of information that reason-
14 ably suggests the event presents an immi-
15 nent threat to public health.

16 “(B) Quarterly reports shall be submitted
17 for all other adverse events and no later than
18 the end of the quarter following the quarter in
19 which the adverse event information was re-
20 ceived by the in vitro clinical test developer.

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

22 “(a) APPLICABILITY.—

23 “(1) The Secretary shall amend part 806 of
24 title 21 of the Code of Federal Regulations (or any
25 successor regulations) to apply to in vitro clinical

1 tests. Until such amendment takes effect, such part
2 shall be interpreted to apply to in vitro clinical tests.

3 “(2) The Secretary may by regulation require
4 reporting of such corrections and removals as deter-
5 mined by the Secretary to be necessary to be re-
6 ported to assure the analytical and clinical validity
7 of in vitro clinical tests, and in addition, the safety
8 of articles for taking or deriving specimens from the
9 human body.

10 “(b) REPORTS OF REMOVALS AND CORRECTIONS.—
11 Each in vitro clinical test developer or importer shall re-
12 port to the Secretary any correction or removal of an in
13 vitro clinical test undertaken by such developer or im-
14 porter if the removal or correction was undertaken—

15 “(1) to reduce the risk to health posed by the
16 in vitro clinical test;

17 “(2) to remedy a violation of this Act caused by
18 the in vitro clinical test which may present a risk to
19 health;

20 “(3) the developer or importer shall submit any
21 report required under this subsection to the Sec-
22 retary within 10 business days of initiating such cor-
23 rection or removal; or

24 “(4) a developer or importer of an in vitro clin-
25 ical test who undertakes a correction or removal of

1 an in vitro clinical test which is not required to be
2 reported under this subsection shall keep a record of
3 such correction or removal.

4 “(c) DEFINITIONS.—For purposes of this section, the
5 terms ‘correction’ and ‘removal’ do not include routine
6 servicing.

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

8 “(a) APPLICABILITY.—

9 “(1) IN GENERAL.—The Secretary, in issuing
10 an approval [or precertification] of an in vitro clin-
11 ical test of a category described in paragraph (3)
12 may require that such test be restricted to sale, dis-
13 tribution, or use upon such conditions as the Sec-
14 retary may prescribe under paragraph (2).

15 “(2) CONDITIONS PRESCRIBED BY THE SEC-
16 RETARY.—The conditions prescribed by the Sec-
17 retary under this paragraph, with respect to an in
18 vitro clinical test described in paragraph (3), are
19 those conditions which the Secretary determines due
20 to the potentiality for harmful effect of such test (in-
21 cluding any resulting absence, delay, or discontinu-
22 ation of appropriate medical treatment), are nec-
23 essary to assure the analytical or clinical validity of
24 the test, or the safety of an article for taking or de-
25 riving specimens from the human body.

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

7 “(4) PROMULGATION OF REGULATIONS.—In
8 addition to imposing restrictions under paragraph
9 (1), the Secretary may promulgate regulations re-
10 stricting the sale, distribution, or use of any in vitro
11 clinical test described in paragraph (3), based on
12 such conditions as may be prescribed by the Sec-
13 retary under paragraph (2) with respect to such
14 test.

15 “(b) LABELING AND ADVERTISING OF A RESTRICTED
16 IN VITRO CLINICAL TEST.—***[To be supplied]***

17 “(c) REQUIREMENTS PRIOR TO ENACTMENT.—An in
18 vitro clinical test that was offered, sold, or distributed as
19 a restricted device prior to the enactment date of this sub-
20 chapter shall continue to comply with the applicable re-
21 strictions imposed under section 515 or section 520(e)
22 until the effective date of restrictions issued under sub-
23 section (a).

1 **“SEC. 587O. APPEALS.**

2 “(a) IN GENERAL.—The Secretary shall establish by
3 guidance an appeals process for the review of determina-
4 tions made by the Secretary under this subchapter, within
5 **[X]** months after the effective date of **[this subchapter]**.

6 “(b) TIMING FOR CERTAIN APPEALS.—With respect
7 to a premarket determination approving or disapproving
8 an application under sections 587B, 587D, 587R, or 587S
9 the applicant may, by petition filed on or before the day
10 that is 30 days after the date on which the Secretary
11 issues the order approving or disapproving such applica-
12 tion, obtain review of such determination under the ap-
13 peals process established pursuant to subsection (a).

14 “(c) FINAL ACTION FOR JUDICIAL REVIEW.—The
15 process established under subsection (a) shall provide for
16 a decision constituting final agency action not later than
17 180 calendar days after the date on which the appeal is
18 first submitted.

19 “(d) ADVISORY PANELS.—The process established
20 under subsection (a) shall permit the appellant to request
21 review by an advisory committee established under section
22 587G.

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

24 “(a) IN GENERAL.—

25 **【“(1) REVIEW OF APPLICATIONS.—】**

1 【“(A) The Secretary may accredit persons
2 for the purpose of reviewing applications for
3 【precertification】 and applications for pre-
4 market approval of an in vitro clinical test, and
5 making recommendations to the Secretary with
6 respect to such applications, subject to the re-
7 quirements of this section.】

8 【“(B) The Secretary shall issue guidance
9 on the factors that the Secretary will use in de-
10 termining whether a test group or a scope of
11 【precertification】 is eligible for review by an
12 accredited person.】

13 【“(C) In making a recommendation to the
14 Secretary under this paragraph, an accredited
15 person shall notify the Secretary in writing of
16 the reasons for the recommendation concerning
17 the application.】

18 【“(D) Not later than 【X】 days after the
19 date on which the Secretary is notified of a rec-
20 ommendation under subparagraph (C) by an
21 accredited person with respect to an applica-
22 tion, the Secretary shall make a determination
23 with respect to such application.】

24 “(2) INSPECTIONS.—

1 “(A) The Secretary may accredit persons
2 for the purpose of conducting inspections under
3 section 704 of in vitro clinical test developers
4 and other persons required to register pursuant
5 to section 587I, subject to the requirements of
6 this section.

7 “(B) The Secretary shall issue guidance on
8 the factors that the Secretary will use in deter-
9 mining whether an in vitro clinical test devel-
10 oper or other registered person is eligible for in-
11 spection by an accredited person.

12 “(C) Persons accredited to conduct inspec-
13 tions, when conducting such inspections, shall
14 record in writing their specific observations and
15 shall present their observations to the establish-
16 ment’s designated representative. Additionally,
17 such accredited person shall prepare and submit
18 to the Secretary an inspection report in a form
19 and manner designated by the Secretary for
20 conducting inspections, taking into consider-
21 ation the goals of international harmonization
22 of quality systems standards. Any official classi-
23 fication of the inspection shall be determined by
24 the Secretary.

1 “(D) Any statement or representation
2 made by an employee or agent of an establish-
3 ment to a person accredited to conduct inspec-
4 tions shall be subject to section 1001 of title
5 18, United States Code.

6 “(E) Nothing in this section affects the
7 authority of the Secretary to inspect any in
8 vitro clinical test developer or other person reg-
9 istered under section 587I.

10 “(b) ACCREDITATION.—

11 “(1) ACCREDITATION PROGRAM.—

12 “(A) The Secretary may provide for ac-
13 creditation of persons to perform the duties
14 specified under **【subsection (a)】** for some or all
15 eligible in vitro clinical tests through programs
16 administered by the Food and Drug Adminis-
17 tration, by other non-Federal government agen-
18 cies, or by qualified nongovernmental organiza-
19 tions.

20 “(B) The Secretary shall issue guidance on
21 the criteria that the Secretary will use to ac-
22 credit or deny accreditation to a person who re-
23 quests to perform any of the duties specified
24 under **【subsection (a)】**.

1 “(C) The Secretary shall not accredit or
2 maintain accreditation for a person unless such
3 person meets the minimum qualifications re-
4 quired under subsection (c).

5 “(D) The Secretary shall publish on the
6 website of the Food and Drug Administration a
7 list of persons who are accredited under this
8 section. Such list shall be updated on at least
9 a monthly basis. The list shall specify the par-
10 ticular activity or activities under this section
11 for which the person is accredited.

12 “(2) ACCREDITATION PROCESS.—

13 “(A) The Secretary shall issue guidance
14 specifying the process for submitting a request
15 for accreditation and reaccreditation under this
16 section, including the form and content of infor-
17 mation to be submitted in such a request.

18 “(B) The Secretary shall respond to a re-
19 quest for accreditation or reaccreditation within
20 90 days of the receipt of the request. The Sec-
21 retary’s response may be to accredit or re-
22 accredit the person, to deny accreditation, or to
23 request additional information in support of the
24 request.

1 “(C) The accreditation of a person shall
2 specify the particular activity or activities under
3 **【subsection (a)】** for which such person is ac-
4 credited, including if the activity is limited to
5 certain eligible in vitro clinical tests.

6 “(D) The Secretary may audit the per-
7 formance of persons accredited under this sec-
8 tion for purposes of assuring that they continue
9 to meet the published criteria for accreditation,
10 and may modify the scope or particular activi-
11 ties for which a person is accredited if the Sec-
12 retary determines that such person fails to meet
13 one or more criteria for accreditation.

14 “(E) The Secretary may suspend or with-
15 draw accreditation of any person accredited
16 under this section, after providing notice and an
17 opportunity for an informal hearing, when such
18 person is substantially not in compliance with
19 the requirements of this section or the pub-
20 lished criteria for accreditation, or poses a
21 threat to public health, or fails to act in a man-
22 ner that is consistent with the purposes of this
23 section.

24 “(F) Accredited persons must be reaccred-
25 ited at least every 2 years.

1 “(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

2 “(1) An accredited person shall, at a minimum,
3 meet the following requirements:

4 “(A) Such person may not be an employee
5 of the Federal Government.

6 “(B) Such person shall not engage in the
7 development of in vitro clinical tests and shall
8 not be a person required to register under sec-
9 tion 587I.

10 “(C) Such person shall not be owned or
11 controlled by, and shall have no organizational,
12 material or financial affiliation with, an in vitro
13 clinical test developer or other person required
14 to register under section 587I.

15 “(D) Such person shall be a legally con-
16 stituted entity permitted to conduct the activi-
17 ties for which it seeks accreditation.

18 “(E) The operations of such person shall
19 be in accordance with generally accepted profes-
20 sional and ethical business practices.

21 “(F) Such person shall include in its re-
22 quest for accreditation a commitment to, at the
23 time of accreditation and at any time it is per-
24 forming activities pursuant to this section—

1 “(i) certify that the information re-
2 ported to the Secretary accurately reflects
3 the data or operations reviewed;

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

6 “(iii) treat information received or
7 learned, records, reports, and recommenda-
8 tions as proprietary information of the per-
9 son submitting such information; and

10 “(iv) in conducting the activities for
11 which the person is accredited in respect to
12 a particular in vitro clinical test, protect
13 against the use of any employee or consult-
14 ant who has a financial conflict of interest
15 regarding that in vitro clinical test.

16 “(2) The Secretary may waive any requirements
17 in subparagraphs (1)(A), (1)(B), or (1)(C) upon
18 making a determination that such person has imple-
19 mented other appropriate controls sufficient to en-
20 sure a competent and impartial review.

21 “(d) COMPENSATION OF ACCREDITED PERSONS.—

22 [“(1) [Compensation of an accredited person
23 who reviews an application for [precertification] or
24 an application for premarket approval shall be deter-
25 mined by agreement between the accredited person

1 and the person who engages the services of the ac-
2 credited person, and shall be paid by the person who
3 engages such services.】】

4 “(2) Compensation of an accredited person who
5 is conducting an inspection under section 704 shall
6 be determined by agreement between the accredited
7 person and the person who engages the services of
8 the accredited person, and shall be paid by the per-
9 son who engages such services.

10 “(e) COOPERATIVE AGREEMENTS.—The Secretary is
11 authorized to enter into cooperative arrangements with of-
12 ficials of foreign countries to ensure that adequate and
13 effective means are available for purposes of determining,
14 from time to time, whether in vitro clinical tests intended
15 for use in the United States by a person whose facility
16 is located outside the United States shall be refused ad-
17 mission on any of the grounds set forth in section 801(a).

18 **“SEC. 587Q. STANDARDS.**

19 “(a) IN GENERAL.—The Secretary may by order es-
20 tablish performance standards for an in vitro clinical test
21 or test group to provide reasonable assurance of the ana-
22 lytical validity, clinical validity, or as applicable safety, of
23 that in vitro clinical test or test group.

24 “(b) CONSENSUS STANDARDS.—In establishing per-
25 formance standards under subsection (a), the Secretary

1 may recognize and adopt, in whole or in part, consensus
2 standards developed by national or international standards
3 development organizations. The Secretary shall issue guid-
4 ance establishing the criteria and process for such recogni-
5 tion and adoption.

6 “(c) ORDER PROCESS.—In establishing a standard
7 under this section, the Secretary shall issue a draft order
8 proposing to establish a performance standard and shall
9 provide for a comment period of not less than 60 days.
10 The Secretary in his discretion, at his own initiative or
11 in response to a petition by any interested person, may
12 choose to seek the recommendation of an advisory com-
13 mittee concerning a proposed standard either prior to or
14 after issuance of a proposed order. After considering the
15 comments, the Secretary shall issue a final order adopting
16 the proposed standard, adopting a modification of the pro-
17 posed standard, or terminating the proceeding.

18 “(d) AMENDMENT PROCESS.—The procedures estab-
19 lished in this section or in guidance issued under this sec-
20 tion shall apply to amendment of an existing performance
21 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 587V.

3 “(b) AMENDMENTS.—The Secretary shall amend
4 part 812 of title 21 of the Code of Federal Regulations,
5 or successor regulations, to apply as the Secretary deems
6 appropriate to in vitro clinical tests and to implement the
7 requirements in subsection (c). The Secretary shall amend
8 parts 50, 54, and 56 of title 21 of the Code of Federal
9 Regulations, or successor regulations, to apply as the Sec-
10 retary deems appropriate to in vitro clinical tests. Until
11 each such amendment takes effect, each such regulation
12 shall be interpreted to apply to in vitro clinical tests.

13 “(c) APPLICATION FOR AN EXEMPTION.—

14 “(1) IN GENERAL.—

15 “(A) In the case of an in vitro clinical test
16 the investigational use of which poses a signifi-
17 cant risk, a sponsor of an investigation of such
18 a test seeking an investigational use exemption
19 shall submit to the Secretary an investigational
20 use application with respect to the test in ac-
21 cordance with paragraphs (2) and (3). For pur-
22 poses of this subparagraph, the term ‘signifi-
23 cant risk’ means, with respect to an in vitro
24 clinical test that is the subject of an investiga-
25 tional use application, that the use of the test—

1 “(i) is a use of substantial importance
2 in performing an activity or activities de-
3 scribed in subsection (ss)(1)(A) for, a seri-
4 ous or life-threatening disease or condition
5 without confirmation of the diagnosis by a
6 medically established means;

7 “(ii) requires an invasive sampling
8 procedure; or

9 “(iii) otherwise presents a reasonably
10 foreseeable serious risk to the health of a
11 human subject.

12 “(B) In the case of an in vitro clinical test,
13 the investigational use of which does not pose
14 a significant risk—

15 “(i) the sponsor of such investigation
16 shall comply with—

17 “(I) the requirements specified in
18 paragraphs (3)(A), (3)(B), and
19 (5)(A)(iii); and

20 “(II) such other requirements as
21 the Secretary may determine to be
22 necessary for the protection of the
23 public health and safety, including the
24 monitoring of investigations conducted
25 with such test, the establishment and

1 maintenance of records, or the sub-
2 mission to the Secretary of reports of
3 data obtained as a result of the inves-
4 tigational use of the in vitro clinical
5 test during the period covered by the
6 exemption; and

7 “(ii) the sponsor may rely on any ex-
8 ception or exemption identified in para-
9 graph (5)(B) or as established by the Sec-
10 retary in regulations issued under sub-
11 section (b).

12 “(2) APPLICATION CONTENTS.—An investiga-
13 tional use application shall be submitted in such
14 time and manner and contain such information as
15 the Secretary may require in regulation, and shall
16 include assurances to the satisfaction of the Sec-
17 retary that the sponsor involved shall, with respect
18 to the in vitro clinical test that is the subject of the
19 application—

20 “(A) establish and maintain any records
21 relevant to such in vitro clinical test; and

22 “(B) submit to the Secretary reports of
23 data obtained as a result of the investigational
24 use of the in vitro clinical test during the period
25 covered by the exemption that the Secretary

1 reasonably determines will enable the Sec-
2 retary—

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.—An investiga-
11 tional use application with respect to an in vitro clin-
12 ical test shall only be approved if each of the fol-
13 lowing conditions is met:

14 “(A) The Secretary finds that the risks to
15 the subjects of the in vitro clinical test are out-
16 weighed by the anticipated benefits to the sub-
17 jects and the importance of the knowledge to be
18 gained, informed consent is adequate or waived,
19 the investigation is scientifically sound, and
20 there is no reason to believe that the in vitro
21 clinical test as used is ineffective.

22 “(B) The proposed labeling for the in vitro
23 clinical test involved clearly and conspicuously
24 states ‘For investigational use’.

1 “(C) The sponsor submitting such applica-
2 tion complies with the requirements of this sec-
3 tion and such other requirements as the Sec-
4 retary determines to be necessary for the pro-
5 tection of the public health and safety and re-
6 quires in regulation.

7 “(4) COORDINATION WITH INVESTIGATIONAL
8 NEW DRUG APPLICATIONS.—Any requirement for
9 the submission of a report to the Secretary pursuant
10 to an investigational new drug application involving
11 an in vitro clinical test shall supersede the reporting
12 requirement in paragraph (2)(B), but only to the ex-
13 tent the requirement with respect to the investiga-
14 tional new drug application is duplicative of the re-
15 porting requirement under such paragraph.

16 “(5) INVESTIGATION PLAN REQUIREMENTS.—

17 “(A) IN GENERAL.—With respect to a plan
18 submitted under paragraph (3)(B), the sponsor
19 submitting such plan shall—

20 “(i) in the case of such a plan sub-
21 mitted to an institutional review com-
22 mittee, promptly notify the Secretary of
23 the approval or the suspension or termi-
24 nation of the approval of such plan by an
25 institutional review committee;

1 “(ii) in the case of an in vitro clinical
2 test to be distributed or otherwise made
3 available to investigators for clinical test-
4 ing, obtain, and submit to the Secretary,
5 signed agreements from each of the indi-
6 viduals carrying out the investigation that
7 is the subject of such plan that—

8 “(I) any testing under such plan
9 involving human subjects will be
10 under the supervision of such indi-
11 vidual;

12 “(II) any testing under such plan
13 will be conducted in compliance with
14 the investigational plan and applicable
15 regulations;

16 “(III) the individual will ensure
17 that informed consent is obtained
18 from each such human subject, except
19 in cases specifically exempted pursu-
20 ant to this section; and

21 “(IV) the individual will comply
22 with additional investigator obliga-
23 tions as set forth in the final rule
24 issued pursuant to subsection (b); and

1 “(iii) submit an assurance to the Sec-
2 retary that informed consent will be ob-
3 tained from each human subject (or the
4 representative of such subject) of proposed
5 clinical testing involving such in vitro clin-
6 ical test, except in the following cases, for
7 which informed consent is not required,
8 subject to such other conditions as the Sec-
9 retary may prescribe—

10 “(I) the proposed clinical testing
11 poses no more than minimal risk to
12 the human subject and includes ap-
13 propriate safeguards to protect the
14 rights, safety, and welfare of the
15 human subject; or

16 “(II) the investigator conducting
17 or supervising the proposed clinical
18 testing determines (subject to sub-
19 paragraph (B)(ii), with the concu-
20 rence of a licensed physician who is
21 not involved in the testing of the
22 human subject) in writing that—

23 “(aa) there exists a life-
24 threatening situation involving
25 the human subject of such test-

1 ing which necessitates the use of
2 such in vitro clinical test;

3 “(bb) it is not feasible to ob-
4 tain informed consent from the
5 subject; and

6 “(cc) there is not sufficient
7 time to obtain such consent from
8 a representative of such subject.

9 “(B) EXCEPTIONS.—

10 “(i) SIGNED AGREEMENTS NOT RE-
11 QUIRED.—Subparagraph (A)(iii) shall not
12 apply to the distribution of or other ar-
13 rangements by a sponsor to make available
14 an in vitro clinical test to an investigator
15 that is employed by the sponsor.

16 “(ii) CONCURRENCE OF PHYSICIAN
17 NOT REQUIRED.—The requirement to ob-
18 tain the concurrence of a licensed physi-
19 cian or informed consent from the human
20 subject’s representative with respect to a
21 determination under subparagraph
22 (A)(iii)(II) shall not apply if—

23 “(I) immediate use of the in vitro
24 clinical test in the investigation in-

1 volved is required to save the life of
2 the human subject; and

3 “(II) there is not sufficient time
4 to obtain such concurrence.

5 “(iii) INFORMED CONSENT NOT RE-
6 QUIRED WITH RESPECT TO CERTAIN
7 SPECIMENS.—Notwithstanding subpara-
8 graph (A)(iii)(II), the informed consent of
9 human subjects shall not be required with
10 respect to clinical testing conducted as
11 part of an investigation, if—

12 “(I) the clinical testing uses rem-
13 nants of specimens collected for rou-
14 tine clinical care or analysis that
15 would have been discarded, leftover
16 specimens that were previously col-
17 lected for other research purposes, or
18 specimens obtained from specimen re-
19 positories;

20 “(II) the identity of the subject
21 of the specimen is not known to, and
22 may not readily be ascertained by, the
23 investigator or any other individual
24 associated with the investigation, in-
25 cluding the sponsor;

1 “(III) any clinical information
2 that accompanies the specimens does
3 not make the specimen source identifi-
4 able to the investigator or any other
5 individual associated with the inves-
6 tigation, including the sponsor;

7 “(IV) the individuals caring for
8 the human subjects as patients are
9 different from, and do not share infor-
10 mation about the patient with, the in-
11 dividuals conducting the investigation;
12 and

13 “(V) the specimens are provided
14 to the investigators without personally
15 identifiable information and the sup-
16 plier of the specimens has established
17 policies and procedures to prevent the
18 release of personally identifiable infor-
19 mation.

20 “(6) VARIATION.—The requirements imposed
21 under this subsection with respect to an investiga-
22 tional use application may vary based on—

23 “(A) the scope and duration of clinical
24 testing to be conducted under investigation that
25 is the subject of such application;

1 “(B) the number of human subjects that
2 are to be involved in such testing;

3 “(C) the need to permit changes to be
4 made in the in vitro clinical test involved during
5 testing conducted in accordance with a plan re-
6 quired under paragraph (3)(B); or

7 “(D) whether the clinical testing of such in
8 vitro clinical test is for the purpose of devel-
9 oping data to obtain approval to offer such test.

10 “(d) REVIEW OF APPLICATIONS.—

11 “(1) IN GENERAL.—The Secretary may issue
12 an order approving an investigation as proposed, ap-
13 proving it with conditions or modifications, or dis-
14 approving it.

15 “(2) FAILURE TO ACT.—Unless the Secretary,
16 not later than the date that is 30 calendar days
17 after the date of the submission of an investigational
18 use application that meets the requirements of sub-
19 section (c)(2), issues an order under subsection
20 (d)(1) and notifies the sponsor submitting the appli-
21 cation, the application shall be treated as approved
22 as of such date without further action by the Sec-
23 retary.

24 “(3) DISAPPROVAL.—The Secretary may dis-
25 approve an investigational use application submitted

1 under this subsection if the Secretary determines
2 that the investigation with respect to which the ap-
3 plication is submitted does not conform to the re-
4 quirements of subsection (c)(3). A notification of
5 such disapproval submitted to the sponsor with re-
6 spect to such an application shall contain the order
7 of disapproval and a complete statement of the rea-
8 sons for the Secretary's disapproval of the applica-
9 tion.

10 “(e) WITHDRAWAL OF APPROVAL.—

11 “(1) IN GENERAL.—The Secretary may, by ad-
12 ministrative order, withdraw the approval of an ex-
13 emption granted under this subsection with respect
14 to an in vitro clinical test, including an exemption
15 granted based on the Secretary's failure to act pur-
16 suant to subsection (d)(2), if the Secretary deter-
17 mines that the test does not meet the applicable con-
18 ditions under subsection (c)(3) for such approval.

19 “(2) OPPORTUNITY TO BE HEARD.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (B), an order withdrawing the approval
22 of an exemption granted under this subsection
23 may be issued only after the Secretary provides
24 the applicant or sponsor of the test with an op-
25 portunity for an informal hearing.

1 “(B) EXCEPTION.—An order referred to in
2 subparagraph (A) with respect to an exemption
3 granted under this subsection may be issued on
4 a preliminary basis before the provision of an
5 opportunity for an informal hearing if the Sec-
6 retary determines that the continuation of test-
7 ing under the exemption will result in an unrea-
8 sonable risk to the public health. The Secretary
9 will provide an opportunity for an informal
10 hearing promptly following any preliminary ac-
11 tion under this subparagraph.

12 “(f) CHANGES.—

13 “(1) IN GENERAL.—The amended regulations
14 under subsection (b) shall provide, with respect to
15 an in vitro clinical test for which an exemption
16 under this subsection is in effect, procedures and
17 conditions under which the changes to the test are
18 allowed without the additional approval of an appli-
19 cation for an exemption or the approval of a supple-
20 ment to such an application. Such regulations shall
21 provide that such a change may be made if—

22 “(A) the sponsor or applicant determines,
23 on the basis of credible information (as defined
24 by the Secretary) that the change meets the
25 conditions specified in paragraph (2); and

1 “(B) the sponsor or applicant submits to
2 the Secretary, not later than 5 calendar days
3 after making the change, a notice of the
4 change.

5 “(2) CONDITIONS.—The conditions specified in
6 this paragraph are that—

7 “(A) in the case of developmental changes
8 to an in vitro clinical test (including manufac-
9 turing changes), the changes—

10 “(i) do not constitute a significant
11 change in design or in basic principles of
12 operation;

13 “(ii) do not affect the rights, safety,
14 or welfare of the human subjects (if any)
15 involved in the investigation; and

16 “(iii) are made in response to infor-
17 mation gathered during the course of an
18 investigation; and

19 “(B) in the case of changes to clinical pro-
20 tocols applicable to the test, the changes do not
21 affect—

22 “(i) the validity of data or information
23 resulting from the completion of an ap-
24 proved clinical protocol;

1 “(ii) the scientific soundness of a plan
2 submitted under subsection (cc)(3)(B); or

3 “(iii) the rights, safety, or welfare of
4 the human subjects (if any) involved in the
5 investigation.

6 “(g) CLINICAL HOLD.—

7 “(1) IN GENERAL.—At any time, the Secretary
8 may impose a clinical hold with respect to an inves-
9 tigation of an in vitro clinical test if the Secretary
10 makes a determination described in paragraph (2).
11 The Secretary shall, in imposing such clinical hold,
12 specify the basis for the clinical hold, including the
13 specific information available to the Secretary which
14 served as the basis for such clinical hold, and con-
15 firm such determination in writing. The applicant or
16 sponsor may immediately appeal any such deter-
17 mination pursuant to section 587O.

18 “(2) DETERMINATION.—For purposes of para-
19 graph (1), a determination described in this sub-
20 paragraph with respect to a clinical hold is a deter-
21 mination that—

22 “(A) the in vitro clinical test involved rep-
23 resents an unreasonable risk to the safety of
24 the persons who are the subjects of the clinical
25 investigation, taking into account the qualifica-

1 tions of the clinical investigators, information
2 about the in vitro clinical test, the design of the
3 clinical investigation, the condition for which
4 the in vitro clinical test is to be investigated,
5 and the health status of the subjects involved;

6 “(B) the clinical hold should be issued for
7 such other reasons as the Secretary may by
8 regulation establish: or

9 “(C) any written request to the Secretary
10 from the sponsor of an investigation that a clin-
11 ical hold be removed shall receive a decision, in
12 writing and specifying the reasons therefor,
13 within 30 days after receipt of such request.
14 Any such request shall include sufficient infor-
15 mation to support the removal of such clinical
16 hold.

17 **“SEC. 587S. EMERGENCY USE AUTHORIZATION.**

18 “An in vitro clinical test may be authorized for use
19 in emergency, and used, held, and developed for such use,
20 pursuant to sections 564, 564A, 564B, and 564C.

21 **“SEC. 587T. COLLABORATIVE COMMUNITIES FOR IN VITRO**
22 **CLINICAL TESTS.**

23 “(a) IN GENERAL.—

24 “(1) The Secretary may initiate, establish and
25 participate in collaborative communities of public

1 and private participants that may provide rec-
2 ommendations and other advice to the Secretary on
3 the development and regulation of in vitro clinical
4 tests.

5 “(2) A collaborative community under this sec-
6 tion shall have broad representation of interested
7 private and public-sector stakeholder communities
8 and may include patients, care partners, academics,
9 healthcare professionals, healthcare systems, payers,
10 Federal and State agencies, international regulatory
11 bodies, industry, or other interested entities or com-
12 munities.

13 “(b) RECOMMENDATIONS.—A collaborative commu-
14 nity may make recommendations to the Secretary on mat-
15 ters including—

16 “(1) mitigating measures for in vitro clinical
17 tests;

18 “(2) standards development activities and per-
19 formance standards for in vitro clinical tests;

20 “(3) scientific and clinical evidence to support
21 new claims for in vitro clinical tests;

22 “(4) new technologies and methodologies for in
23 vitro clinical tests;

24 “(5) stakeholder engagement;

1 “(6) new approaches and solutions to multi-
2 faceted problems involving diverse stakeholders; and

3 “(7) development of effective policies and proc-
4 esses.

5 “(c) USE BY SECRETARY.—The Secretary may adopt
6 one or more recommendations made under subsection (b),
7 or otherwise incorporate the feedback from collaborative
8 communities, in its application of its authorities under this
9 subchapter to one or more in vitro clinical tests or a group
10 of in vitro clinical tests, as appropriate.

11 “(d) TRANSPARENCY.—The Secretary shall—

12 “(1) publish on the internet website of the Food
13 and Drug Administration matters for which it is
14 seeking comments or recommendations;

15 “(2) maintain a list of Collaborative Commu-
16 nities recognized by the Secretary and make this list
17 available on the internet website of the Food and
18 Drug Administration; and

19 “(3) post on the internet website of the Food
20 and Drug Administration at least once every year a
21 report on the recommendations it has adopted from
22 Collaborative Communities.

23 “(e) EXCEPTION.—The Federal Advisory Committee
24 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. 587U. COMPREHENSIVE TEST INFORMATION SYSTEM.**

4 **“[placeholder]**

5 **[“SEC. 587V. PREEMPTION.**

6 **““(a) IN GENERAL.—**No State, tribal, or local gov-
7 ernment (or political subdivision thereof) may establish or
8 continue in effect any requirement related to the develop-
9 ment, manufacture, labeling, distribution, sale, or use of
10 an in vitro clinical test that is different from, or in addi-
11 tion to, the requirements of this subchapter.]

12 **““(b) EXCEPTIONS.—**Subsection (a) shall not be con-
13 strued to affect the authority of a State, tribal, or local
14 government—]

15 **““(1) to license laboratory personnel, health**
16 **care practitioners, or health care facilities or to reg-**
17 **ulate any aspect of a health care practitioner-patient**
18 **relationship; or]**

19 **““(2) to enforce laws of general applicability,**
20 **such as zoning laws, environmental laws, labor laws,**
21 **and general business laws.]**

22 **““(c) CLARIFICATION.—**This section shall not be
23 construed to shift liability to health care practitioners or
24 other users.]

1 **“SEC. 587W. ADULTERATION.**

2 “An in vitro clinical test shall be deemed to be adul-
3 terated:

4 “(1) If it consists in whole or in part of any
5 filthy, putrid, or decomposed substance.

6 “(2) if it has been prepared, packed, or held
7 under insanitary conditions whereby it may have
8 been contaminated with filth, or whereby it may
9 have been rendered injurious to health.

10 “(3) if its package is composed, in whole or in
11 part, of any poisonous or deleterious substance
12 which may render the contents injurious to health.

13 “(4) if it bears or contains, for purposes of
14 coloring only, a color additive which is unsafe within
15 the meaning of section 721(a).

16 “(5) If its analytical or clinical validity, or if
17 applicable its safety, or its strength, purity, or qual-
18 ity, differs from or falls below that which it purports
19 or is represented to possess.

20 “(6) If it is required to be, declared to be, pur-
21 ports to be, or is represented as being, in conformity
22 with any standard established or recognized under
23 section 587Q unless such in vitro clinical test is in
24 all respects in conformity with such standard.

25 “(7) If it is required to be in conformity with
26 a mitigating measure established under section

1 587E unless such in vitro clinical test is in all re-
2 spects in conformity with such mitigating measure.

3 “(8) If it fails to have an approved premarket
4 application under section 587B unless such in vitro
5 clinical test can be lawfully offered—

6 “(A) for clinical use pursuant to an exemp-
7 tion under section 587A, [precertification]
8 under section 587D;

9 “(B) for emergency use pursuant to an au-
10 thorization under section 587S; or

11 “(C) for investigational use pursuant to
12 section 587R.

13 “(9) If it is not in conformity with any condi-
14 tion of approval established under section 587B,
15 587D, or 587S.

16 “(10) If it purports to be an in vitro clinical
17 test that is offered for clinical use or introduced into
18 interstate commerce subject to an exemption under
19 section 587A and it fails to meet or maintain any
20 requirement of such exemption.

21 “(11) If it has been granted an exemption
22 under section 587R for investigational use, and the
23 person granted such exemption or any investigator
24 who uses such in vitro clinical test under such ex-

1 emption fails to comply with a requirement pre-
2 scribed by or under such section.

3 “(12) If it fails to meet the quality system re-
4 quirements prescribed in or established under sec-
5 tion 587J, or the methods used in, or facilities or
6 controls used for, its manufacture, packing, storage,
7 or installation are not in conformity with applicable
8 requirements established under such section.

9 “(13) If it has been manufactured, processed,
10 packed or held in any establishment, factory, or
11 warehouse and the owner, operator or agent of such
12 establishment, factory, or warehouse delays, denies,
13 or limits an inspection, or refuses to permit entry or
14 inspection.

15 “(14) If it is not in compliance with any restric-
16 tion established under section 587N.

17 “(15) If it is a banned in vitro clinical test.

18 **“SEC. 587X. MISBRANDING.**

19 “ An in vitro clinical test shall be deemed to be mis-
20 branded:

21 “(1) If its labeling is false or misleading in any
22 particular.

23 “(2) If in a package form unless it bears a label
24 containing—

1 “(A) the name and place of business of the
2 test developer, manufacturer, packer, or dis-
3 tributor; and

4 “(B) an accurate statement of the quantity
5 of contents in terms of weight, measure, or nu-
6 merical count, subject to the authority of the
7 Secretary to issue guidance to establish exemp-
8 tions from the requirements of this subpara-
9 graph with respect to small packages.

10 “(3) If any word, statement, or other informa-
11 tion required by or under authority of this Act to
12 appear on the label or labeling, including a test re-
13 port, is not prominently placed thereon with such
14 conspicuousness (as compared with other words,
15 statements, designs, or devices, in the labeling) and
16 in such terms as to render it likely to be read and
17 understood by the ordinary individual under cus-
18 tomary conditions of purchase and use.

19 “(4) If it has an established name, unless its
20 label bears, to the exclusion of any other nonpropri-
21 etary name, its established name prominently print-
22 ed in type at least half as large as that used thereon
23 for any proprietary name or designation for such in
24 vitro clinical test; provided, that the Secretary may
25 issue guidance regarding exemptions to the extent

1 compliance with this requirement is impracticable or
2 unnecessary. The term ‘established name’ means the
3 applicable official name established by the Secretary
4 pursuant to regulation or the official name or title
5 recognized in an official compendium, or if neither
6 of these apply, then the common or usual name of
7 such in vitro clinical test.

8 “(5) Unless its labeling bears adequate direc-
9 tions for use and such adequate warnings as are
10 necessary for the protection of users of the in vitro
11 clinical test and recipients of the results of such in
12 vitro clinical test, including patients, consumers, do-
13 nors, and related health care professionals. Required
14 labeling for in vitro clinical tests intended for use in
15 health care facilities or by a health care professional
16 may be made available solely by electronic means,
17 provided that the labeling complies with all applica-
18 ble requirements of law, and that the test developer,
19 manufacturer, or distributor affords such users the
20 opportunity to request the labeling in paper form,
21 and after such request, promptly provides the re-
22 quested information without additional cost.

23 “(6) If it is dangerous to health, including
24 through absence, delay, or discontinuation in diag-
25 nosis or treatment, when used in the manner pre-

1 scribed, recommended, or suggested in the labeling
2 thereof.

3 “(7) If it was developed, manufactured, pre-
4 pared, propagated, compounded, or processed in an
5 establishment not duly registered under section 587I
6 or it was not included in a notification under section
7 587I.

8 “(8) In the case of any in vitro clinical test sub-
9 ject to restrictions established under section 587N,
10 (1) if its advertising is false or misleading in any
11 particular, (2) if it is offered for clinical use, sold,
12 distributed, or used in violation of such restrictions,
13 or (3) unless the test developer, manufacturer, or
14 distributor includes in all advertisements and other
15 descriptive printed matter that such person issues or
16 causes to be issued, a brief statement of the in-
17 tended uses of the in vitro clinical test and relevant
18 warnings, precautions, side effects, and contraindica-
19 tions. This subsection shall not be applicable to any
20 printed matter that the Secretary determines to be
21 labeling as defined in section 201(m) or section
22 587K.

23 “(9) If it was subject to a mitigating measure
24 established under section 587E, unless it bears such

1 labeling as may be prescribed in such mitigating
2 measure.

3 “(10) If it was subject to a standard estab-
4 lished under section 587Q, unless it bears such la-
5 beling as may be prescribed in such standard.

6 “(11) Unless it bears such labeling as may be
7 prescribed by or established under an applicable la-
8 beling requirement under this Act.

9 “(12) If there was a failure or refusal to comply
10 with any requirement prescribed under section 587I,
11 or to comply with a requirement under section 587Y,
12 or to provide any report, material, or information re-
13 quired under sections 587B, 587C, 587D, 587F,
14 587L, 587M, 587R, or 587S.

15 **“SEC. 587Y. POSTMARKET SURVEILLANCE.**

16 “(a) IN GENERAL.—

17 “(1) In addition to other applicable require-
18 ments under this Act, the Secretary may require a
19 developer to conduct postmarket surveillance of an
20 in vitro clinical test (A) as a condition of approval
21 under section 587B or by order at any time there-
22 after, or (B) as a mitigating measure established
23 under section 587E.

24 “(2) The Secretary may order postmarket sur-
25 veillance when he determines it necessary to assure

1 that an in vitro clinical test will meet the relevant
2 standard for its intended use or to mitigate a risk
3 of patient harm from use of the in vitro clinical test.

4 “(b) SURVEILLANCE APPROVAL.—

5 “(1) Each developer required to conduct a sur-
6 veillance of an in vitro clinical test shall submit,
7 within 30 days of receiving an order from the Sec-
8 retary, a plan for the required surveillance. The Sec-
9 retary, within 60 days of the receipt of such plan,
10 shall determine if the person designated to conduct
11 the surveillance has the appropriate qualifications
12 and experience to undertake such surveillance and if
13 the plan will result in useful data that can reveal un-
14 foreseen adverse events or other information nec-
15 essary to protect the health of patients or the public.

16 “(2) The developer shall commence surveillance
17 under this section not later than 15 months after
18 the day on which the Secretary orders such
19 postmarket surveillance.

20 “(3) The Secretary may order a prospective
21 surveillance period of up to 36 months, except that
22 the Secretary may require a longer period of pro-
23 spective surveillance when necessary to assure the
24 clinical validity or, as applicable, safety of an in vitro
25 clinical test or test group.

1 **“SEC. 587Z. ELECTRONIC FORMAT FOR SUBMISSIONS.**

2 “(a) IN GENERAL.—All presubmissions and submis-
3 sions to FDA for an in vitro clinical test shall include an
4 electronic copy of such presubmission or submission.

5 “(b) ELECTRONIC FORMAT.—Beginning on such date
6 as the Secretary specifies in final guidance issued under
7 subsection (c), presubmissions and submissions for in vitro
8 clinical tests (and any appeals of action taken by the Sec-
9 retary with respect to such presubmissions and submis-
10 sions) shall be submitted solely in such electronic format
11 as specified by the Secretary in such guidance.

12 “(c) GUIDANCE.—The Secretary shall issue guidance
13 implementing this section. In such guidance, the Secretary
14 may—

15 “(1) provide standards for the electronic copy
16 required under subsection (a) or the submission in
17 electronic format required under subsection (b);

18 “(2) set forth criteria for waivers of or exemp-
19 tions from the requirements of subsections (a) or
20 (b); and

21 “(3) provide any other information for the effi-
22 cient implementation and enforcement of this sec-
23 tion.

24 **“SEC. 587AA. POSTMARKET REMEDIES.**

25 “(a) SAFETY NOTICE.—

1 “(1) If the Secretary determines that an in
2 vitro clinical test presents an unreasonable risk of
3 substantial harm to the public health, and notifica-
4 tion under this subsection is necessary to eliminate
5 the unreasonable risk of such harm and no more
6 practicable means is available under the provisions
7 of this Act (other than this section) to eliminate the
8 risk, the Secretary may issue such order as may be
9 necessary to assure that adequate safety notice is
10 provided in an appropriate form, by the persons and
11 means best suited under the circumstances, to all
12 health professionals who prescribe, order, or use the
13 in vitro clinical test and to any other person (includ-
14 ing developers, manufacturers, importers, distribu-
15 tors, retailers, and users) who should properly re-
16 ceive such notice.

17 “(2) An order under this subsection shall re-
18 quire that the individuals subject to the risk with re-
19 spect to which the order is to be issued be included
20 in the persons to be notified of the risk unless the
21 Secretary determines that notice to such individuals
22 would present a greater danger to the health of such
23 individuals than no such notice. If the Secretary
24 makes such a determination with respect to such in-
25 dividuals, the order shall require that the health pro-

1 professionals who prescribed, ordered, or used the in
2 vitro clinical test provide notice to the individuals for
3 whom the health professionals prescribed, ordered,
4 or used such test, of the risk presented by such in
5 vitro clinical test and of any action which may be
6 taken by or on behalf of such individuals to elimi-
7 nate or reduce such risk.

8 “(b) REPAIR, REPLACEMENT, OR REFUND.—

9 “(1)(A) If, after affording opportunity for an
10 informal hearing, the Secretary determines that—

11 “(i) an in vitro clinical test presents an un-
12 reasonable risk of substantial harm to the pub-
13 lic health,

14 “(ii) there are reasonable grounds to be-
15 lieve that the in vitro clinical test was not prop-
16 erly designed or manufactured with reference to
17 the state of the art as it existed at the time of
18 its design or manufacture,

19 “(iii) there are reasonable grounds to be-
20 lieve that the unreasonable risk was not caused
21 by failure of a person other than a developer,
22 manufacturer, importer, distributor, or retailer
23 of the in vitro clinical test to exercise due care
24 in the installation, maintenance, repair, or use
25 of the in vitro clinical test, and

1 “(iv) the notice authorized by subsection
2 (a) would not by itself be sufficient to eliminate
3 the unreasonable risk and action described in
4 paragraph (2) of this subsection is necessary to
5 eliminate such risk,
6 the Secretary may order the developer, manu-
7 facturer, importer, or any distributor of such in
8 vitro clinical test, or any combination of such
9 persons, to submit to him within a reasonable
10 time a plan for taking one or more of the ac-
11 tions described in paragraph (2). An order
12 issued under the preceding sentence which is di-
13 rected to more than one person shall specify
14 which person may decide which action shall be
15 taken under such plan and the person specified
16 shall be the person who the Secretary deter-
17 mines bears the principal, ultimate financial re-
18 sponsibility for action taken under the plan un-
19 less the Secretary cannot determine who bears
20 such responsibility or the Secretary determines
21 that the protection of the public health requires
22 that such decision be made by a person (includ-
23 ing a health professional or user of the in vitro
24 clinical test) other than the person he deter-
25 mines bears such responsibility.

1 “(B) The Secretary shall approve a plan sub-
2 mitted pursuant to an order issued under subpara-
3 graph (A) unless he determines (after affording op-
4 portunity for an informal hearing) that the action or
5 actions to be taken under the plan or the manner in
6 which such action or actions are to be taken under
7 the plan will not assure that the unreasonable risk
8 with respect to which such order was issued will be
9 eliminated. If the Secretary disapproves a plan, he
10 shall order a revised plan to be submitted to him
11 within a reasonable time. If the Secretary deter-
12 mines (after affording opportunity for an informal
13 hearing) that the revised plan is unsatisfactory or if
14 no revised plan or no initial plan has been submitted
15 to the Secretary within the prescribed time, the Sec-
16 retary shall (i) prescribe a plan to be carried out by
17 the person or persons to whom the order issued
18 under subparagraph (A) was directed, or (ii) after
19 affording an opportunity for an informal hearing, by
20 order prescribe a plan to be carried out by a person
21 who is a manufacturer, importer, distributor, or re-
22 tailer of the in vitro clinical test with respect to
23 which the order was issued but to whom the order
24 under subparagraph (A) was not directed.

1 “(2) The actions which may be taken under a
2 plan submitted under an order issued under para-
3 graph (1) are as follows:

4 “(A) To repair the in vitro clinical test so
5 that it does not present the unreasonable risk
6 of substantial harm with respect to which the
7 order under paragraph (1) was issued.

8 “(B) To replace the in vitro clinical test
9 with a like or equivalent test which is in con-
10 formity with all applicable requirements of this
11 Act.

12 “(C) To refund the purchase price of the
13 in vitro clinical test (less a reasonable allowance
14 for use if such in vitro clinical test has been in
15 the possession of the user for one year or more
16 at the time of notice ordered under subsection
17 (a), or at the time the user receives actual no-
18 tice of the unreasonable risk with respect to
19 which the order was issued under paragraph
20 (1), whichever occurs first).

21 “(3) No charge shall be made to any person
22 (other than a developer, manufacturer, importer, dis-
23 tributor or retailer) for availing himself of any rem-
24 edy, described in paragraph (2) and provided under
25 an order issued under paragraph (1), and the person

1 subject to the order shall reimburse each person
2 (other than a developer, manufacturer, importer,
3 distributor, or retailer) who is entitled to such a
4 remedy for any reasonable and foreseeable expenses
5 actually incurred by such person in availing himself
6 of such remedy.

7 “(c) REIMBURSEMENT.—An order issued under sub-
8 section (b) of this section with respect to an in vitro clin-
9 ical test may require any person who is a developer, manu-
10 facturer, importer, distributor, or retailer of the in vitro
11 clinical test to reimburse any other person who is a devel-
12 oper, manufacturer, importer, distributor, or retailer of
13 such in vitro clinical test for such other person’s expenses
14 actually incurred in connection with carrying out the order
15 if the Secretary determines such reimbursement is re-
16 quired for the protection of the public health. Any such
17 requirement shall not affect any rights or obligations
18 under any contract to which the person receiving reim-
19 bursement or the person making such reimbursement is
20 a party.

21 “(d) RECALL AUTHORITY.—

22 “(1) If the Secretary finds that there is a rea-
23 sonable probability that an in vitro clinical test
24 would cause serious, adverse health consequences or
25 death, including by the absence, delay, or discontinu-

1 ation of diagnosis or treatment, the Secretary shall
2 issue an order requiring the appropriate person (in-
3 cluding the developers, manufacturers, importers,
4 distributors, or retailers of the in vitro clinical
5 test)—

6 “(A) to immediately cease distribution of
7 such in vitro clinical test, and

8 “(B) to immediately notify health profes-
9 sionals and user facilities of the order and to
10 instruct such professionals and facilities to
11 cease use of such in vitro clinical test.

12 “(2) The order issued under paragraph (1)
13 shall provide the person subject to the order with an
14 opportunity for an informal hearing, to be held not
15 later than 10 days after the date of the issuance of
16 the order, on the actions required by the order and
17 on whether the order should be amended to require
18 a recall of such in vitro clinical test. If, after pro-
19 viding an opportunity for such a hearing, the Sec-
20 retary determines that inadequate grounds exist to
21 support the actions required by the order, the Sec-
22 retary shall vacate the order.

23 “(3)(A) If, after providing an opportunity for
24 an informal hearing under paragraph (2), the Sec-
25 retary determines that the order should be amended

1 to include a recall of the in vitro clinical test with
2 respect to which the order was issued, the Secretary
3 shall, except as provided in subparagraphs (B) and
4 (C), amend the order to require a recall. The Sec-
5 retary shall specify a timetable in which the recall
6 will occur and shall require periodic reports to the
7 Secretary describing the progress of the recall.

8 “(B) An amended order under subparagraph
9 (A)—

10 “(i) shall—

11 “(I) not include recall of the in vitro
12 clinical test from individuals, and

13 “(II) not include recall of an in vitro
14 clinical test from device user facilities if
15 the Secretary determines that the risk of
16 recalling such in vitro clinical test from the
17 facilities presents a greater health risk
18 than the health risk of not recalling the in
19 vitro clinical test from use, and

20 “(ii) shall provide for notice to individuals
21 subject to the risks associated with the use of
22 such in vitro clinical test. In providing the no-
23 tice required by this clause, the Secretary may
24 use the assistance of health professionals who

1 prescribed, ordered, or used such an in vitro
2 clinical test for individuals.

3 “(4) The remedy provided by this subsection
4 shall be in addition to remedies provided by sub-
5 sections (a), (b), and (c).

6 “(e) BANNING AUTHORITY.—

7 “(1) Whenever the Secretary finds, based on all
8 available data and information, that an in vitro clin-
9 ical test presents substantial deception or an unrea-
10 sonable and substantial risk of illness or injury, the
11 Secretary may initiate a proceeding to issue an order
12 to make such an in vitro clinical test a banned in
13 vitro clinical test.

14 “(2) The order issued under paragraph (1)
15 shall provide the person subject to the order with an
16 opportunity for an informal hearing, to be held not
17 later than 10 days after the date of the issuance of
18 the order, on the actions required by the order. If,
19 after providing an opportunity for such a hearing,
20 the Secretary determines that inadequate grounds
21 exist to support the actions required by the order,
22 the Secretary shall vacate the order.

23 “(3) If the Secretary determines to issue a final
24 order banning the in vitro clinical test, the order
25 may be made immediately effective.

1 “(f) EFFECT ON OTHER LIABILITY.—Compliance
2 with an order issued under this section shall not relieve
3 any person from liability under federal or state law. In
4 awarding damages for economic loss in an action brought
5 for the enforcement of any such liability, the value to the
6 plaintiff in such action of any remedy provided him under
7 such order shall be taken into account.”.

8 **SEC. 4. PROHIBITED ACTS, ENFORCEMENT, AND OTHER**
9 **PROVISIONS.**

10 (a) PROHIBITED ACTS.—Section 301 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
12 ed—

13 (1) in paragraphs (a), (b), (c), (g), (k), (q), (r),
14 and (y), by inserting “in vitro clinical test,” after
15 “device,” each place it appears; and—

16 (A) by adding at the end, the following:

17 “(fff)(1) The introduction or delivery for introduction
18 into interstate commerce of an in vitro clinical test in vio-
19 lation of section 587B(a).

20 “(2) The false, fraudulent, or deceptive claiming for
21 an in vitro clinical test of an exemption from the pre-
22 market review required under section 587B.

23 “(3) When claiming an exemption under section
24 587A from the premarket review required under section
25 587B, the failure to maintain complete and accurate docu-

1 mentation for the exemption as required under section
2 587A or the failure to provide labeling required under sec-
3 tion 587A.

4 “(4) With respect to an in vitro clinical test, the sub-
5 mission of any report that is required by or under this
6 Act that is false or misleading in any material respect.

7 “(5) The making of a false, fraudulent, or materially
8 deceptive analytical or clinical claim for an in vitro clinical
9 test—

10 “(A) in any application, report, or notification
11 submitted to the Secretary under this Act; or

12 “(B) in the labeling or advertising of an in vitro
13 clinical test.

14 “(6) The failure to comply with a condition of ap-
15 proval, performance standard, mitigating measure, or re-
16 striction established in an order approving an application
17 or supplement under section 587B or 587C; the failure
18 to perform a risk analysis required by section 587B(f)(1);
19 the failure to submit an annual report required under sec-
20 tion 587B(j) or 587C(f); or the failure to complete
21 postmarket studies required under section 587Y.

22 “(7) The marketing of an in vitro clinical test in vio-
23 lation of—

24 “(A) an order issued by the Secretary under
25 section 587(a)(4); or

1 “(B) any requirement under section 587(a)(5).

2 “(8) **■**With respect to precertification under section
3 587D, the refusal to permit, or unreasonable delay in per-
4 mitting, an inspection authorized under section
5 587D(d)(3); the failure to comply with applicable require-
6 ments to submit an application or report under section
7 587D(e); or the failure to comply with applicable mainte-
8 nance requirements under section 587D(f).**■**

9 “(9) The failure to comply with an applicable miti-
10 gating measure established under section 587E or to
11 maintain the documentation required under section
12 587E(c); or the failure to comply with a performance
13 standard established under section 587Q.

14 “(10) The failure to register in accordance with sec-
15 tion 587I, the failure to provide information required
16 under section 587I(b), or the failure to maintain or submit
17 information required under section 587I(c).

18 “(11) The failure to submit a report required under
19 section 587L or 587M; the failure to comply with a re-
20 striction imposed under section 587N; or the failure to
21 comply with labeling and advertising requirements under
22 section 587N(b).

23 “(12) The failure to comply with the requirements
24 of section 587P (relating to accredited persons).

1 “(13) The failure to comply with any requirement
2 prescribed or established under section 587R; the failure
3 to furnish any notification, information, material, or re-
4 port required under section 587R; or the failure to comply
5 with an order issued under section 587R.”.

6 (b) PENALTIES.—Section 303(f)(1) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)) is
8 amended—

9 (1) in subparagraph (A), by inserting “or in
10 vitro clinical tests” after “devices”; and

11 (2) in subparagraph (B)(i)—

12 (A) by inserting “, or 587J or 587L,”
13 after “520(f)”; and

14 (B) by inserting “, or who violates section
15 587M(b) with respect to a correction report”
16 after “risk to public health”.

17 (c) SEIZURE.—Section 304 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

19 (1) in subsection (a)(2)—

20 (A) by striking “and” before “(E) Any”;
21 and

22 (B) by inserting “, and (F) Any adulter-
23 ated or misbranded in vitro clinical test” after
24 “tobacco product”;

1 (2) in subsection (d)(1), by inserting “in vitro
2 clinical test,” after “device,”; and

3 (3) in subsection (g)—

4 (A) in paragraph (1), by inserting “, in
5 vitro clinical test,” after “device” each place it
6 appears; and

7 (B) in paragraph (2)—

8 (i) in subparagraph (A), by inserting
9 “, in vitro clinical test,” after “device”;
10 and

11 (ii) in subparagraph (B), by inserting
12 “or in vitro clinical test” after “device”
13 each place it appears.

14 (d) DEBARMENT, TEMPORARY DENIAL OF AP-
15 PROVAL, AND SUSPENSION.—Section 306 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
17 amended by adding at the end the following:

18 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-
19 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND
20 REVIEWS.—

21 “(1) IN GENERAL.—If the Secretary finds that
22 a person has been convicted of a felony under sec-
23 tion 301(gg), 301(fff)(2), 301(fff)(5), or 301(fff)(8),
24 the Secretary shall debar such person from being ac-
25 credited under section 587P and from carrying out

1 activities under an agreement described in section
2 803(b).

3 “(2) DEBARMENT PERIOD.—The Secretary
4 shall debar a person under paragraph (1) for the fol-
5 lowing periods:

6 “(A) The period of debarment of a person
7 (other than an individual) shall not be less than
8 1 year or more than 10 years, but if an act
9 leading to a subsequent debarment under such
10 paragraph occurs within 10 years after such
11 person has been debarred under such para-
12 graph, the period of debarment shall be perma-
13 nent.

14 “(B) The debarment of an individual shall
15 be permanent.

16 “(3) TERMINATION OF DEBARMENT; JUDICIAL
17 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),
18 (e), (i), (j), and (l)(1) apply with respect to a person
19 (other than an individual) or an individual who is
20 debarred under paragraph (1) to the same extent
21 and in the same manner as such subsections apply
22 with respect to a person who is debarred under sub-
23 section (a)(1), or an individual who is debarred
24 under subsection (a)(2), respectively.”.

1 (e) JUDICIAL REVIEW.—Section 517(a) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a))
3 is amended—

4 (1) in paragraph (8), by striking “or” at the
5 end;

6 (2) in paragraph (9), by inserting “or” after
7 the comma at the end; and

8 (3) before the matter that follows paragraph
9 (9), by inserting the following:

10 “(10) an order issued pursuant to sections
11 587B, 587D, 587R, or 587S.”.

12 (f) AGENCY DOCUMENTATION AND REVIEW OF SIG-
13 NIFICANT DECISIONS REGARDING DEVICES.—Section
14 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 360g–1(a)(1)) is amended by striking “section
16 515C, or” and inserting “section 515C, an application
17 under section 587B, an application for exemption under
18 section 587R, or”.

19 (g) EXPANDED ACCESS TO UNAPPROVED THERAPIES
20 AND DIAGNOSTICS.—Section 561 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-
22 ed—

23 (1) in subsections (a) through (d)—

24 (A) by striking “or investigational devices”
25 each place it appears and inserting “, investiga-

1 tional devices, or investigational in vitro clinical
2 tests”; and

3 (B) by striking “or investigational device”
4 each place it appears (other than the second
5 such place in paragraph (3)(A)) and inserting
6 “, investigational device, or investigational in
7 vitro clinical test”;

8 (2) in subsection (c)—

9 (A) by amending the subsection heading to
10 read: “TREATMENT INVESTIGATIONAL NEW
11 DRUG APPLICATIONS, TREATMENT INVESTIGA-
12 TIONAL DEVICE EXEMPTIONS, AND TREAT-
13 MENT INVESTIGATIONAL IN VITRO CLINICAL
14 TEST EXEMPTIONS”;

15 (B) in paragraph (3)(A), by striking “or
16 investigational device exemption in effect under
17 section 520(g)” and inserting “, investigational
18 device exemption in effect under section 520(g),
19 or investigational in vitro clinical test exemp-
20 tion”; and

21 (C) by striking “or treatment investiga-
22 tional device exemption” each place it appears
23 and inserting “, treatment investigational device
24 exemption, or treatment investigational in vitro
25 clinical test exemption”; and

1 (3) by amending subsection (e) to read as fol-
2 lows:

3 “(e) DEFINITIONS.—In this section, the terms ‘inves-
4 tigational drug’, ‘investigational device’, ‘investigational in
5 vitro clinical test’, ‘treatment investigational new drug ap-
6 plication’, ‘treatment investigational device exemption’,
7 and ‘treatment investigational in vitro clinical test exemp-
8 tion’ shall have the meanings given the terms in regula-
9 tions prescribed by the Secretary.”.

10 (h) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section
11 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360bbb–8a(b)) is amended by inserting “an in
13 vitro clinical test, as defined in subsection (ss) of such sec-
14 tion,” before “or a biological product”.

15 (i) PATIENT PARTICIPATION IN MEDICAL PRODUCT
16 DISCUSSION.—The heading of subsection (a) of section
17 569C of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 360bbb–8c) is amended by striking “DRUGS AND
19 DEVICES” and inserting “DRUGS, DEVICES, AND IN
20 VITRO CLINICAL TESTS”.

21 (j) REGULATIONS AND HEARINGS.—Section
22 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting
24 “ and in vitro clinical tests” after “devices”.

1 (k) FACTORY INSPECTION.—Section 704 of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other
3 than subsection (g)) is amended—

4 (1) by striking “drugs or devices” each place it
5 appears and inserting “drugs, devices, or in vitro
6 clinical tests”;

7 (2) 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 (3) by inserting “in vitro clinical test,” after
13 “device,” each place it appears;

14 (4) 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 (5) in subsection (e), by inserting “, or section
18 587L, 587M, or 587R,” after “section 519 or
19 520(g)”; and

20 (6) 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 (l) 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 (m) PRESUMPTION.—Section 709 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379a) is
9 amended by inserting “in vitro clinical test,” after “de-
10 vice,”.

11 (n) IMPORTS AND EXPORTS.—Section 801 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
13 is amended—

14 (1) in subsection (a)—

15 (A) by inserting “in vitro clinical tests,”
16 after “devices,” each place it appears;

17 (B) by inserting “in the case of an in vitro
18 clinical test, the test does not conform to the
19 requirements of section 587J, or” after “re-
20 quirements of section 520(f), or” ;

21 (2) in subsection (d)(3)—

22 (A) in subparagraph (A)—

23 (i) in the matter preceding clause (i),
24 by inserting “and no component of an in
25 vitro clinical test or other article of in vitro

1 clinical test that requires further pro-
2 cessing,” after “health-related purposes”;

3 (ii) in clause (i), by striking “drug or
4 device” and inserting “drug, device, or in
5 vitro clinical test”; and

6 (iii) in clause (i)(I), by inserting “in
7 vitro clinical test,” after “device,”; and

8 (B) in subparagraph (B), by inserting “in
9 vitro clinical test,” after “device,”; and

10 (3) in subsection (e)(1), by inserting “in vitro
11 clinical test,” after “device,”.

12 (o) 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 system requirements established under section
21 587J; 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 (p) 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 (q) 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 (r) 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 inserting “in vitro clin-
23 ical test developers,” before “health professionals”.

1 **SEC. 5. TRANSITION.**

2 (a) **FUNDING.**—For the purposes of carrying out this
3 Act and the amendments made by this Act, there is au-
4 thorized to be appropriated **[\$X MILLION]** for **[fiscal**
5 **year X]**.

6 (b) **IMPLEMENTATION.**—The amendments made by
7 this Act apply beginning on **[DATE X]** (in this section
8 and in subchapter J of chapter V of the Federal Food,
9 Drug, and Cosmetic Act, as added by this Act, referred
10 to in this Act and the amendments made by this Act as
11 the effective date of this Act), except that the Secretary
12 of Health and Human Services (in this section referred
13 to as the “Secretary”) may take such actions, and expend
14 such funds, as the Secretary deems necessary to ensure
15 an orderly transition.

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

23 (1) Any such product or test that was offered,
24 sold, or distributed prior to the enactment date of
25 this Act, except for those addressed in subsection
26 (d), shall continue to comply with the applicable de-

1 vice provisions of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 301 et seq.) and the Public
3 Health Service Act (42 U.S.C. 201 et seq.) until the
4 effective date of this Act.

5 (2) Before any product or test that is an in
6 vitro clinical test as defined in section 201(ss) of the
7 Federal Food, Drug, and Cosmetic Act, as added by
8 this Act, is first offered, sold, or distributed after
9 the date of enactment of this Act, but prior to the
10 effective date of this Act, such product or test shall
11 comply with the applicable device provisions of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 301 et seq.) and the Public Health Service Act (42
14 U.S.C. 201 et seq.), except that a product or test
15 described in subsection (d) shall likewise be subject
16 to the provisions of that subsection.

17 (3) For any product or test that is an in vitro
18 clinical test as defined in section 201(ss) of the Fed-
19 eral Food, Drug, and Cosmetic Act, as added by this
20 Act, for which a submission for marketing authoriza-
21 tion under section 515, clearance under section
22 510(k), authorization under section 513(f)(2), ap-
23 proval under section 520(m), or emergency use au-
24 thorization under section 564 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 360e, 360(k),

1 360c(f)(2), 360j(m), 360bbb–3) or approval under
2 the Public Health Service Act (42 U.S.C. 201 et
3 seq.) is pending on the effective date of this Act, the
4 Secretary may review and take action on such sub-
5 mission after the effective date of this Act according
6 to the statutory provision under which such submis-
7 sion was submitted.

8 (d) APPLICATION OF AUTHORITIES TO TRANSI-
9 TIONAL AND GRANDFATHERED IN VITRO CLINICAL
10 TESTS.—

11 (1) TRANSITIONAL TESTS.—

12 (A) DEFINITION.—For purposes of this
13 paragraph, the term “transitional in vitro clin-
14 ical test” means an in vitro clinical test, as de-
15 fined in section 201(ss) of the Federal Food,
16 Drug, and Cosmetic Act, as added by this Act,
17 that—

18 (i) was developed by a laboratory cer-
19 tified by the Secretary under section 353
20 of the Public Health Service Act (42
21 U.S.C. 263a) that meets the requirements
22 for performing high-complexity testing for
23 use only within that certified laboratory;

24 (ii) does not have an approval under
25 section 515, a clearance under section

1 510(k), an authorization under 513(f)(2),
2 an approval under section 520(m), or an
3 emergency use authorization under section
4 564 of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 360e, 360(k),
6 360e(f)(2), 360j(m), 360bbb-3) or ap-
7 proval under the Public Health Service Act
8 (42 U.S.C. 201 et seq.); and

9 (iii) is first offered for clinical use
10 during the period beginning on the date
11 that is 90 days before the date of enact-
12 ment of this Act and ending on the date of
13 applicability described in subsection (b).

14 (B) CONTINUED OFFERING.—Notwith-
15 standing subsection (c), a transitional in vitro
16 clinical test may continue to be offered for clin-
17 ical use until the effective date of this Act, ex-
18 cept that the Secretary retains authority to en-
19 force the device provisions of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 301 et
21 seq.) and the Public Health Service Act (42
22 U.S.C. 201 et seq.) for any specific transitional
23 in vitro clinical test, or any type of transitional
24 in vitro clinical test, as the Secretary deter-

1 mines necessary to protect the public from a se-
2 rious risk to health.

3 (C) PREMARKET REVIEW OR
4 PRECERTIFICATION.—A transitional in vitro
5 clinical test that is the subject of an application
6 for premarket review under section 587B of the
7 Federal Food, Drug, and Cosmetic Act [or
8 precertification application under section 587C
9 of such Act], as added by this Act, that is sub-
10 mitted on or within [_____] days of the effec-
11 tive date of this Act may continue to be offered,
12 sold, or distributed until completion of the Sec-
13 retary’s review of the premarket application [or
14 precertification application].

15 (2) GRANDFATHERED TESTS.—An in vitro clin-
16 ical test that meets the criteria for a grandfathered
17 test as set forth in section 587A(c)(2) of the Federal
18 Food, Drug, and Cosmetic Act, as added by this
19 Act, may continue to be offered for clinical use until
20 the effective date of this Act, except that the Sec-
21 retary retains authority to enforce the device provi-
22 sions of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 301 et seq.) and the Public Health Serv-
24 ice Act (42 U.S.C. 201 et seq.) for any specific prod-
25 uct or test or any type of product or test as the Sec-

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

3 (e) CONVERSION.—

4 (1) DEEMED PREMARKET APPROVAL.—Any in
5 vitro clinical test (as defined in section 201(ss) of
6 the Federal Food, Drug, and Cosmetic Act, as
7 added by this Act) with a premarket approval under
8 section 515, a clearance under section 510(k), an
9 authorization under section 513(f), or a licensure
10 under section 351 of the Public Health Service Act
11 (42 U.S.C. 262) is deemed to have an approved ap-
12 plication under section 587B of the Federal Food,
13 Drug, and Cosmetic Act, as added by this Act, after
14 the effective date of this Act.

15 (2) DEEMED INVESTIGATIONAL USE AP-
16 PROVAL.—Any in vitro clinical test (as defined in
17 section 201(ss) of the Federal Food, Drug, and Cos-
18 metic Act, as added by this Act) that has an ap-
19 proved investigational device exemption under sec-
20 tion 520(g) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 360j(g)) is deemed to have an
22 approved investigational use under section 587Q of
23 such Act, as added by this Act, after the effective
24 date of this Act.

1 (f) PLATFORMS.—A test platform (as defined in sec-
2 tion 587 of the Federal Food, Drug, and Cosmetic Act,
3 as added by this Act) that was purchased prior to the date
4 of enactment of this Act and was not cleared, authorized,
5 or approved by the Food and Drug Administration at the
6 time of purchase may continue to be used by the purchaser
7 to develop and introduce into interstate commerce an in
8 vitro clinical test during the period beginning on the date
9 of enactment of this Act and ending **[5 years]** after such
10 date of enactment. Beginning at the end of such period,
11 any new in vitro clinical test that is developed and intro-
12 duced into interstate commerce shall be based on a test
13 platform that complies with the requirements of the Fed-
14 eral Food, Drug, and Cosmetic Act, as amended by this
15 Act.

16 (g) RELATION TO IN VITRO CLINICAL TEST PROVI-
17 SION.—This section applies notwithstanding section
18 587A(a)(1)(C) of the Federal Food, Drug, and Cosmetic
19 Act, as added by this Act.

20 **SEC. 6. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

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

23 (1) in subsection (a)(1)(C)—

1 (A) by inserting “and clear, approve, or ex-
2 empt under subchapter J,” before “anti-
3 microbial susceptibility”; and

4 (B) by striking “testing devices” and in-
5 serting “tests”;

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

9 (3) in subsection (e)—

10 (A) by striking “and 515,” and inserting
11 “515, and section 587B”;

12 (B) by striking “antimicrobial suscepti-
13 bility testing device” and inserting “anti-
14 microbial susceptibility in vitro clinical test”;

15 (C) in the heading of subsection (e), by
16 striking “TESTING DEVICES” and inserting “IN
17 VITRO CLINICAL TESTS”;

18 (D) in the heading of subsection (e)(2), by
19 striking “TESTING DEVICES” and inserting “IN
20 VITRO CLINICAL TESTS”;

21 (E) after making the amendments in sub-
22 paragraphs (B), (C), and (D), by striking “de-
23 vice” each place it appears and inserting “in
24 vitro clinical test”; and

1 (F) in paragraph (2), by amending sub-
2 paragraph (C) to read as follows:

3 “(C) The antimicrobial susceptibility in
4 vitro clinical test meets all other requirements
5 to be approved under section 587B **【**or exempt-
6 ed from premarket review under section
7 587D.**】**”;

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

10 “(1) The term ‘antimicrobial susceptibility in
11 vitro clinical test’ means an in vitro clinical test that
12 utilizes susceptibility test interpretive criteria to de-
13 termine and report the in vitro susceptibility of cer-
14 tain microorganisms to a drug (or drugs).”;

15 (5) in subsection (g)(2), by amending the mat-
16 ter preceding subparagraph (A) to read as follows:

17 “(2) with respect to approving in vitro clinical
18 tests under section 587B **【**or exempting in vitro
19 clinical tests from premarket review under section
20 587D**】**—”;

21 (6) in subsection (g)(2)(A)—

22 (A) by striking “device” and inserting “in
23 vitro clinical test”; and

1 (B) by striking “antimicrobial suscepti-
2 bility testing device” and inserting “anti-
3 microbial susceptibility in vitro clinical test”.

4 **SEC. 7. COMBINATION PRODUCTS.**

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

8 (1) in paragraph (1)(A)—

9 (A) by inserting “(except for a combination
10 product constituted of a device and an in vitro
11 clinical test)” after “agency center,”; and

12 (B) by inserting “in vitro clinical test,” be-
13 fore “or biological product”;

14 (2) in paragraph (1)(D), by striking “If the
15 Secretary determines” and inserting “Except for a
16 combination product constituted of a device and an
17 in vitro clinical test. For other combination prod-
18 ucts, if the Secretary determines”;

19 (3) in paragraph (1)(D)(ii)—

20 (A) by inserting “or in vitro clinical test”
21 after “device”; and

22 (B) by inserting “and in vitro clinical
23 tests” before “shall”;

24 (4) in paragraph (3), by striking “safety and
25 effectiveness or substantial equivalence” and insert-

1 ing “safety and effectiveness, substantial equiva-
2 lence, or analytical validity and clinical validity” be-
3 fore “for the approved constituent part”;

4 (5) in paragraph (4)(A), by striking “or
5 513(f)(2) (submitted in accordance with paragraph
6 (5))” and inserting “, 513(f)(2) (submitted in ac-
7 cordance with paragraph (5)), or 587B”; and

8 (6) in paragraph (4)(B), by inserting “or
9 587B” after “section 515”;

10 (7) in paragraph (5)(A), by striking “or
11 510(k)” and inserting “, 510(k), or 587(b)”;

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

15 (9) in paragraph (8), by inserting “This para-
16 graph shall not apply to a combination product con-
17 stituted of a device and an in vitro clinical test”;

18 (10) in paragraph (9)(C)(i), by striking “or”
19 before “520(g)” and inserting “or 587B” at the
20 end; and

21 (11) in paragraph (9)(D), by striking “or” be-
22 fore “520” and inserting “or 587B” before “of this
23 Act. . .”.

1 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 360bbb–2) is amended—

4 (1) in subsection (a), by inserting “in vitro clin-
5 ical test,” after “device,” and by inserting “, except
6 for a combination product constituted of a device
7 and an in vitro clinical test,” before “respecting the
8 component”;

9 (2) in subsection (b), by inserting “except for a
10 combination product constituted of a device and an
11 in vitro clinical test” before “the component of the”;
12 and

13 (3) in subsection (c), by inserting “except for a
14 combination product constituted of a device and an
15 in vitro clinical test” before “the component of the”.

16 **SEC. 8. USER FEES.**

17 (a) FINDINGS.— The Congress finds that—

18 (1) the establishment of a regulatory framework
19 for in vitro clinical tests is critical to the improve-
20 ment of the public health so that patients have con-
21 fidence in the ability of in vitro clinical tests to iden-
22 tify, screen, measure, detect, predict, prognose, ana-
23 lyze, or monitor a disease or a condition, and will
24 advance innovation that will benefit public health;

1 (2) the public health will be served by making
2 additional funds available for the purpose of aug-
3 menting the resources of the Food and Drug Admin-
4 istration that are devoted to the process for the re-
5 view of in vitro clinical tests and the assurance of
6 in vitro clinical test analytical validity and clinical
7 validity; and,

8 (3) the fees authorized by this section will be
9 dedicated to meeting the goals identified in the let-
10 ters from the Secretary of Health and Human Serv-
11 ices to the Committee on Energy and Commerce of
12 the House of Representatives and the Committee on
13 Health, Education, Labor, and Pensions of the Sen-
14 ate, as set forth in the Congressional Record.

15 (b) ESTABLISHMENT OF USER FEE PROGRAM.—

16 (1) DEVELOPMENT OF USER FEES FOR IN
17 VITRO CLINICAL TESTS.—

18 (A) IN GENERAL.—Beginning not later
19 than October 1, 2019, the Secretary of Health
20 and Human Services (in this section referred to
21 as the “Secretary”) shall develop recommenda-
22 tions to present to Congress with respect to the
23 goals, and plans for meeting the goals, for the
24 process for the review of in vitro clinical test
25 applications submitted under subchapter J of

1 chapter V of the Federal Food Drug, and Cos-
2 metic Act, as added by this Act, for the first
3 **【3】** fiscal years after **【fiscal year 2020】**. In de-
4 veloping such recommendations, the Secretary
5 shall consult with—

6 (i) the Committee on Energy and
7 Commerce of the House of Representa-
8 tives;

9 (ii) the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate;

11 (iii) scientific and academic experts;

12 (iv) health care professionals;

13 (v) representatives of patient and con-
14 sumer advocacy groups; and

15 (vi) the regulated industry.

16 (B) 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 Congressional committees specified in such
22 subparagraph;

23 (ii) publish such recommendations in
24 the Federal Register;

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

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

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

10 (C) TRANSMITTAL OF RECOMMENDA-
11 TIONS.—Not later than June 1, 2020, the Sec-
12 retary shall transmit to Congress the revised
13 recommendations under subparagraph (B), a
14 summary of the views and comments received
15 under such subparagraph, and any changes
16 made to the recommendations in response to
17 such views and comments.

18 (2) ESTABLISHMENT OF USER FEE PRO-
19 GRAM.—It is the sense of the Congress that, based
20 on the recommendations transmitted to Congress by
21 the Secretary pursuant to paragraph (1)(C), the
22 Congress should authorize a program, effective on
23 the [effective date of _____], for the collec-
24 tion of user fees relating to the submission of in
25 vitro clinical test applications submitted under sub-

1 chapter J of chapter V of the Federal Food Drug,
2 and Cosmetic Act, as added by this Act.

3 (3) TRANSITIONAL PROVISIONS FOR USER FEES
4 FOR CERTAIN IN VITRO CLINICAL TESTS.—A sub-
5 mission for approval or clearance made by a manu-
6 facturer pursuant to section 5 of this Act shall be
7 subject to a user fee pursuant to section 738 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379j).

10 (4) AUDIT.—

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

24 (B) ALTERATION OF USER FEE.—If the
25 audit performed under paragraph (1) indicates

1 that the user fees applicable to applications
2 submitted under such subchapter J exceed
3 【____】 percent of the costs of reviewing such
4 applications, then the Secretary shall alter the
5 user fees applicable to applications submitted
6 under such subchapter J such that the user
7 fees do not exceed such percentage.

8 (C) ACCOUNTING STANDARDS.—The Sec-
9 retary shall perform an audit under paragraph
10 (1) in conformance with the accounting prin-
11 ciples, standards, and requirements prescribed
12 by the Comptroller General of the United
13 States under section 3511 of title 31, United
14 State Code, to ensure the validity of any poten-
15 tial variability.