

115TH CONGRESS
1ST SESSION

H. R. _____

To establish a regulatory framework for in vitro clinical tests that advances innovation for patient benefit, protects patients, provides a predictable and timely path to market, ensures reasonable risk-based regulation, avoids duplicative regulation, advances precision medicine, and applies the same regulatory principles to the same activity regardless of entity type, 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 establish a regulatory framework for in vitro clinical tests that advances innovation for patient benefit, protects patients, provides a predictable and timely path to market, ensures reasonable risk-based regulation, avoids duplicative regulation, advances precision medicine, and applies the same regulatory principles to the same activity regardless of entity type, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Diagnostic Accuracy and Innovation Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. In vitro clinical tests defined.
- Sec. 3. Regulation of in vitro clinical tests.
- Sec. 4. FDA fees.
- Sec. 5. Certification of laboratories (CLIA).
- Sec. 6. Transitional provisions.

6 **SEC. 2. IN VITRO CLINICAL TESTS DEFINED.**

7 (a) **DEFINITIONS.**—Section 201 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
9 adding at the end the following:

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

11 “(A) means a laboratory test protocol or fin-
12 ished product intended by its developer to be used
13 in the collection, preparation, analysis, or in vitro
14 clinical examination of specimens taken or derived
15 from the human body for the purpose of identifying,
16 screening, measuring, detecting, predicting, moni-
17 toring, or assisting in selecting treatment for, a dis-
18 ease or other condition;

19 “(B) excludes any test that—

20 “(i) meets the definition of a ‘biological
21 product’ under section 351 of the Public Health
22 Service Act; and

1 “(ii) is intended to—

2 “(I) screen human blood, human cells,
3 tissues, cellular or tissue-based products
4 (HCT/Ps), or organs for infectious dis-
5 eases; or

6 “(II) determine the compatibility of a
7 donor or patient to ensure the safe trans-
8 fusion or transplantation of blood, human
9 cells, tissues, cellular or tissue-based prod-
10 ucts (HCT/Ps), or organs; and

11 “(C) excludes any test intended by its developer
12 solely for nonclinical use.

13 “(2) The term ‘laboratory test protocol’—

14 “(A) means the final design of a test not pro-
15 duced, provided, purchased, or sold as a finished
16 product; and

17 “(B) excludes laboratory operations (as defined
18 in section 353(a)(3) of the Public Health Service
19 Act).

20 “(3) The term ‘finished product’—

21 “(A) means any article of personal property
22 other than a laboratory test protocol that is suitable,
23 and capable of functioning, for its intended use as
24 described in paragraph (1)(A) without further pro-
25 duction activity; and

1 “(B) excludes any component, part, or raw ma-
2 terial.”.

3 (b) EXCLUSION FROM DEFINITIONS OF DRUGS, DE-
4 VICES, AND BIOLOGICAL PRODUCTS.—

5 (1) DRUG DEFINITION.—Section 201(g)(1) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 321(g)(1)) is amended by striking “means”
8 and inserting “excludes any in vitro clinical test and
9 any component, part, raw material, or accessory of
10 an in vitro clinical test and means”.

11 (2) DEVICE DEFINITION.—Section 201(h) of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 321(h)) is amended by striking “means” and
14 inserting “excludes any in vitro clinical test and any
15 component, part, raw material, or accessory of an in
16 vitro clinical test and means”.

17 (3) BIOLOGICAL PRODUCT.—Section 351(i)(1)
18 of the Public Health Service Act (42 U.S.C.
19 262(i)(1)) is amended by striking “means” and in-
20 serting “excludes any in vitro clinical test and any
21 component, part, raw material, or accessory of an in
22 vitro clinical test and means”.

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

2 (a) IN GENERAL.—Chapter V of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
4 ed by adding at the end the following new subchapter:

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

6 **“SEC. 590. REGULATION OF IN VITRO CLINICAL TEST DE-**
7 **VELOPMENT ACTIVITIES.**

8 “(a) IN GENERAL.—The Secretary of Health and
9 Human Services shall, in accordance with the provisions
10 of this subtitle, establish procedures and processes for the
11 regulation of in vitro clinical tests.

12 “(b) SCOPE OF AUTHORITY.—

13 “(1) IN GENERAL.—The design, development,
14 validation, production, manufacture, preparation,
15 propagation, assembly, and modification of an in
16 vitro clinical test—

17 “(A) shall be regulated by the Secretary
18 under this subchapter; and

19 “(B) shall not be regulated by the Sec-
20 retary under section 353 of the Public Health
21 Service Act.

22 “(2) LIMITATIONS.—

23 “(A) LABORATORY OPERATIONS.—The
24 provisions of this subchapter shall not apply to
25 laboratory operations, as defined in section 353
26 of the Public Health Service Act.

1 “(B) PUBLIC HEALTH SURVEILLANCE AC-
2 TIVITIES.—

3 “(i) IN GENERAL.—The provisions of
4 this subchapter shall not apply to a test in-
5 tended to be used solely for public health
6 surveillance.

7 “(ii) DEFINITION.—In this subpara-
8 graph, the term ‘public health surveillance’
9 means ongoing systematic activities, in-
10 cluding collection, analysis, and interpreta-
11 tion of health-related data, essential to
12 planning, implementing, and evaluating
13 public health practice.

14 “(C) OTHER LIMITATIONS.—Nothing in
15 this subchapter shall be construed to limit or
16 interfere with the authority of a health care
17 practitioner to prescribe, order, or use the re-
18 sults of an in vitro clinical test with respect to
19 a patient for any purpose within a health care
20 practitioner-patient relationship, as defined by
21 applicable State law.

22 “(c) AGENCY CENTER.—Not later than 90 calendar
23 days after the date of enactment of the Diagnostic Accu-
24 racy and Innovation Act, the Secretary shall establish
25 within the Food and Drug Administration the Center for

1 In Vitro Clinical Tests, which shall report to the Commis-
2 sioner of Food and Drugs in the same manner as the other
3 agency centers within the Food and Drug Administration.
4 The Center shall be responsible for the implementation of
5 this subchapter and closely related matters assigned by
6 the Commissioner. Senior management of the Center shall
7 include at least one person with management experience
8 in clinical laboratory operations and at least one person
9 with management experience in the development or com-
10 mercialization of finished products.

11 “(d) DEFINITIONS.—In this subchapter:

12 “(1) The terms ‘analytical validity’ and ‘analyt-
13 ically valid’ mean, with respect to an in vitro clinical
14 test, the ability of the in vitro clinical test—

15 “(A) to identify, measure, detect, calculate,
16 or analyze one or more analytes, biomarkers,
17 substances, or other targets intended to be
18 identified, measured, detected, calculated, or
19 analyzed by the test; or

20 “(B) as applicable, the ability of the in
21 vitro clinical test to assist in such identification,
22 measurement, detection, calculation, or anal-
23 ysis, as claimed by the developer.

24 “(2) The terms ‘clinical validity’ and ‘clinically
25 valid’—

1 “(A) mean, with respect to an in vitro clin-
2 ical test, the reliability and accuracy with which
3 the test, as claimed by the developer—

4 “(i) identifies, screens, measures, de-
5 tects, calculates, predicts, monitors, or as-
6 sists in selecting treatment for, a disease
7 or other condition in humans;

8 “(ii) identifies, screens, measures, de-
9 tects, predicts, or monitors characteristics
10 related to an individual’s clinical status; or

11 “(iii) as applicable, assists in such
12 identification, screening, measurement, de-
13 tection, calculation, or analysis; and

14 “(B) exclude clinical utility.

15 “(3) The term ‘developer’ means the person re-
16 sponsible for the design, development, validation,
17 production, manufacture, preparation, propagation,
18 assembly, or initial importation of an in vitro clinical
19 test.

20 “(4) The terms ‘laboratory’, ‘laboratory oper-
21 ations’, and ‘standard operating procedures’ have
22 the meanings given to such terms in section
23 353(a)(3) of the Public Health Service Act.

24 “(5) The term ‘mitigating measures’ means,
25 with respect to an in vitro clinical test, one or more

1 measures that the Secretary determines, based on
2 available evidence, are necessary to provide a reason-
3 able assurance of the analytical validity and clinical
4 validity, or probable clinical validity, as applicable, of
5 an in vitro clinical test for its intended use, in a par-
6 ticular risk classification.

7 “(6) The term ‘modification’, with respect to an
8 in vitro clinical test—

9 “(A) means—

10 “(i) any change to a finished product;

11 or

12 “(ii) a change to the design or in-
13 tended use of a laboratory test protocol;

14 “(B) excludes any change to, or activity
15 that constitutes, laboratory operations; and

16 “(C) excludes any activity that constitutes
17 the practice of medicine.

18 “(7) The term ‘offer’ means to make available
19 for purchase, order, prescription, or use.

20 “(8) The term ‘platform’ means an in vitro clin-
21 ical test that is hardware intended by the hardware’s
22 developer to be used with one or more in vitro clin-
23 ical tests to generate a clinical test result, including
24 software used to effectuate the hardware’s
25 functionality.

1 “(9) The term ‘probable clinical validity’ means,
2 based on currently available evidence with respect to
3 an in vitro clinical test, it is more likely than not
4 that the in vitro clinical test is clinically valid.

5 “(10) The term ‘rare disease in vitro clinical
6 test’—

7 “(A) means an in vitro clinical test in-
8 tended to identify, measure, detect, predict,
9 monitor, or assist in selecting treatment for a
10 disease or condition with an incidence of 8,000
11 or fewer per year or a prevalence of 50,000 or
12 fewer in the United States; and

13 “(B) excludes an in vitro clinical test in-
14 tended solely for the screening of asymptomatic
15 patients or predicting the occurrence of a future
16 disease or condition in asymptomatic patients.

17 “(11)(A) The term ‘reasonable assurance’
18 means the degree of valid scientific evidence for in
19 vitro clinical tests needed to demonstrate analytical
20 validity or clinical validity, for the intended use of
21 the in vitro clinical test, as applicable, which may
22 vary based upon the relevant—

23 “(i) population size;

24 “(ii) disease or condition;

25 “(iii) demographic representation;

1 “(iv) type of use claim (such as predictive,
2 prognostic, diagnostic, monitoring, treatment
3 selection, and screening uses);

4 “(v) risk classification;

5 “(vi) availability of warnings and restric-
6 tions or other mitigating measures;

7 “(vii) use environment;

8 “(viii) user;

9 “(ix) feasibility of data collection, including
10 for example as may be affected by disease or
11 condition prevalence;

12 “(x) impact of requiring additional data
13 collection on innovation;

14 “(xi) experience with similar in vitro clin-
15 ical tests;

16 “(xii) ease of use; or

17 “(xiii) other factors.

18 “(B) There is reasonable assurance of the ana-
19 lytical validity and clinical validity of an in vitro clin-
20 ical test when it can be determined, based upon valid
21 scientific evidence, that the use of the in vitro clin-
22 ical test for its intended use will provide results that
23 are analytically valid and clinically valid in a signifi-
24 cant portion of the intended-use population.

1 “(12)(A) The term ‘valid scientific evidence’
2 means, with respect to an in vitro clinical test, evi-
3 dence—

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 that there is a reasonable assurance of an-
12 alytical validity and clinical validity, or
13 probable clinical validity where applicable,
14 of the in vitro clinical test for its intended
15 use.

16 “(B) Subject to subparagraph (A), the term
17 ‘valid scientific evidence’ may, with respect to an in
18 vitro clinical test, include, alone or in combination—

19 “(i) peer-reviewed literature;

20 “(ii) clinical guidelines;

21 “(iii) reports of significant human experi-
22 ence with an in vitro clinical test;

23 “(iv) bench studies;

24 “(v) case studies or histories;

25 “(vi) clinical data;

1 “(vii) consensus standards;
2 “(viii) reference standards;
3 “(ix) data registries;
4 “(x) postmarket data;
5 “(xi) clinical trials; and
6 “(xii) data collected in countries other than
7 the United States.

8 **“SEC. 590A. CLASSIFICATION OF IN VITRO CLINICAL TESTS.**

9 “(a) RISK CLASSIFICATION.—

10 “(1) IN GENERAL.—The Secretary shall, based
11 on the intended use of an in vitro clinical test, estab-
12 lish the following risk classes and classify in vitro
13 clinical tests within such classes in accordance with
14 this section:

15 “(A) High-risk.

16 “(B) Moderate-risk.

17 “(C) Low-risk.

18 “(2) HIGH-RISK CLASS.—An in vitro clinical
19 test shall be regulated as high-risk if—

20 “(A) a clinically significant inaccurate re-
21 sult for the intended use would cause serious or
22 irreversible harm, prolonged disability, or death,
23 to the patient or public based on a failure to
24 treat, an incorrect treatment, or an invasive

1 procedure, if such inaccurate result were unde-
2 tected when used as intended;

3 “(B) none of the factors specified in para-
4 graph (5) has the capacity to prevent or detect
5 such inaccurate result or otherwise mitigate the
6 risk of such inaccurate result; and

7 “(C) the risk of adverse patient impact or
8 adverse public health impact caused by an inac-
9 curate result is not remote.

10 “(3) MODERATE-RISK CLASS.—An in vitro clin-
11 ical test shall be regulated as moderate-risk if—

12 “(A) the test meets the criteria specified in
13 paragraph (2)(A) for classification as high-risk,
14 but one or more factors described in paragraph
15 (5) has the capacity to prevent or detect the
16 clinically significant inaccurate result or other-
17 wise mitigate the risk; or

18 “(B)(i) a clinically significant inaccurate
19 result for the intended use would cause non-life-
20 threatening injury, injury that is medically re-
21 versible, or delay in necessary treatment if such
22 inaccurate result were undetected when used as
23 intended;

24 “(ii) none of the factors described in para-
25 graph (5) has the capacity to prevent or detect

1 such inaccurate result or otherwise mitigate the
2 risk of such inaccurate result; and

3 “(iii) the risk of adverse patient impact or
4 adverse public health impact caused by an inac-
5 curate result is not remote.

6 “(4) LOW-RISK CLASS.—An in vitro clinical test
7 shall be regulated as low-risk if—

8 “(A) the test meets the criteria for classi-
9 fication as moderate-risk specified in paragraph
10 (3)(B)(i), but one or more factors described in
11 paragraph (5) has the capacity to prevent or
12 detect the clinically significant inaccurate result
13 or otherwise mitigate the risk;

14 “(B) a clinically significant inaccurate re-
15 sult for the intended use would cause minimal
16 or no harm, immediately reversible harm, or no
17 disability if such inaccurate result were unde-
18 tected when used as intended; or

19 “(C) the risk of adverse patient impact or
20 adverse public health impact caused by an inac-
21 curate result is remote.

22 “(5) RISK REDUCING FACTORS.—A factor de-
23 scribed in this paragraph is one of the following:

24 “(A) The in vitro clinical test’s technology
25 and clinical use are well characterized.

1 “(B) Clinical circumstances in which the in
2 vitro clinical test is used, including clinical pres-
3 entation.

4 “(C) The availability of—

5 “(i) other tests, such as confirmatory
6 or adjunctive tests; or

7 “(ii) relevant materials standards.

8 “(D) Such other factors as the Secretary
9 considers necessary.

10 “(E) Mitigating measures.

11 “(b) PRECLASSIFICATION MEETING.—Before submit-
12 ting a request under subsection (c) or (d) for classification
13 or reclassification, as applicable, of an in vitro clinical
14 test—

15 “(1) the developer of the test or any other in-
16 terested person may submit to the Secretary a writ-
17 ten request for a meeting to discuss and provide in-
18 formation relating to classification or reclassification
19 of the test; and

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

22 “(A) within 30 calendar days after such
23 receipt, or by such later date as may be agreed
24 to by the developer or other interested person
25 submitting the request, meet with such devel-

1 oper or other interested person who submitted
2 the request; and

3 “(B) within 30 calendar days after such
4 meeting, provide a written record or response
5 describing the issues discussed and conclusions
6 reached in the meeting.

7 “(c) CLASSIFICATION PROCESS.—

8 “(1) CLASSIFICATION BY OPERATION OF
9 LAW.—Subject to any reclassification made pursuant
10 to subsection (d), if a type of in vitro clinical test
11 has been classified by the Secretary under this sec-
12 tion, and such classification remains in effect, any in
13 vitro clinical test within such type is deemed to be
14 in the same class.

15 “(2) CLASSIFICATION BY SECRETARY.—

16 “(A) SUBMISSION OF REQUEST.—In the
17 case of an in vitro clinical test that is not clas-
18 sified pursuant to paragraph (1) or subsection
19 (e), the developer of the in vitro clinical test or
20 any other interested person may submit a re-
21 quest to the Secretary for classification of the
22 in vitro clinical test.

23 “(B) FORM OF REQUEST.—A request
24 under subparagraph (A) shall be in such form,
25 submitted in such manner, and contain such in-

1 formation as the Secretary may require. At a
2 minimum, any such request shall contain each
3 of the following:

4 “(i) A detailed description of the in
5 vitro clinical test, including its intended
6 uses, a description of its composition, and
7 an explanation of the mechanism by which
8 it functions.

9 “(ii) A recommended classification, in-
10 cluding a rationale for the recommended
11 classification.

12 “(iii) Proposed mitigating measures, if
13 any, and an explanation of how the pro-
14 posed mitigating measures support the rec-
15 ommended classification.

16 “(C) DISPOSITION OF REQUEST.—The
17 Secretary shall—

18 “(i) not later than 60 calendar days
19 after receiving a request under subpara-
20 graph (B), issue a written order—

21 “(I) rejecting, modifying, or ac-
22 cepting the recommended classifica-
23 tion of the in vitro clinical test; and

24 “(II) explaining the reasons for
25 such decision and in the case of a

1 modification or rejection of the rec-
2 ommended classification, the reason
3 for the modification or rejection of the
4 recommended classification, including
5 the reasons why the information and
6 explanations submitted by the devel-
7 oper or other interested person (in-
8 cluding any valid scientific evidence
9 relating to the in vitro clinical test in-
10 volved) do not support the rec-
11 ommended classification; and

12 “(ii) not later than 60 calendar days
13 after issuing an order under clause (i) with
14 respect to a recommended classification for
15 an in vitro clinical test, publish a notice in
16 the Federal Register announcing the clas-
17 sification.

18 “(D) FAILURE TO ISSUE TIMELY
19 ORDER.—If the Secretary fails to issue an order
20 under subparagraph (C) within the time period
21 applicable under such subparagraph, the rec-
22 ommended classification submitted under sub-
23 paragraph (B)(ii) shall be the final classifica-
24 tion.

1 “(E) CLASSIFICATION APPEALS.—In the
2 case of a modification or rejection of a rec-
3 ommended classification of an in vitro clinical
4 test by order issued by the Secretary under sub-
5 paragraph (C)(i)—

6 “(i) such modification or rejection
7 shall be treated as final and immediately
8 subject to appeal by the developer or re-
9 questor under section 590F; and

10 “(ii) not later than 90 calendar days
11 after the date on which such modification
12 or rejection is issued, the developer of the
13 test may, as part of such an appeal, obtain
14 review of the recommended classification
15 by an advisory panel.

16 “(3) MULTIPLE INTENDED USES.—If a single
17 in vitro clinical test has multiple intended uses, any
18 such test shall be classified based on the intended
19 use with the highest risk class.

20 “(4) ACCESSORIES; PLATFORMS.—

21 “(A) ACCESSORIES.—

22 “(i) IN GENERAL.—An in vitro clinical
23 test, that is intended by its developer to be
24 used as an accessory to another in vitro
25 clinical test, shall be classified according to

1 its intended use and independently of any
2 classification of any in vitro clinical test
3 with which it is intended to be used.

4 “(ii) DEFINITION.—In this subpara-
5 graph, the term ‘accessory’ means a stand-
6 alone item intended by its developer to be
7 used in conjunction with one or more par-
8 ticular in vitro clinical tests to enable or
9 assist that in vitro clinical test in per-
10 forming its intended use.

11 “(B) PLATFORMS.—A platform shall be
12 classified and regulated under this title sepa-
13 rately from the in vitro clinical test or tests
14 with which it is used and shall be classified as
15 low-risk. An in vitro clinical test intended to be
16 performed on the platform shall be classified
17 according to its intended use and independently
18 of the platform.

19 “(d) RECLASSIFICATION PROCESS.—

20 “(1) IN GENERAL.—Based on new information
21 respecting an in vitro clinical test when used in ac-
22 cordance with its intended use, the Secretary may,
23 upon the Secretary’s own initiative or upon petition
24 of an interested person, by administrative order pub-
25 lished in the Federal Register—

1 “(A) change such in vitro clinical test’s
2 classification; and

3 “(B) revoke or revise, as appropriate, any
4 regulation or requirement issued in connection
5 with the in vitro clinical test’s previous classi-
6 fication, notwithstanding subchapter II of chap-
7 ter 5 of title 5, United States Code.

8 “(2) RECOMMENDATIONS OF ADVISORY
9 PANEL.—In publishing an order under paragraph
10 (1)—

11 “(A) the Secretary may secure, or the in-
12 terested person may require that the Secretary
13 secure, from an advisory panel, a recommenda-
14 tion respecting the proposed change in the in
15 vitro clinical test’s classification; and

16 “(B) the Secretary shall publish in the
17 Federal Register any recommendation sub-
18 mitted to the Secretary by the panel respecting
19 such change.

20 “(3) MEMBERSHIP OF ADVISORY PANELS.—Any
21 advisory panel convened to review the classification
22 change shall include persons with knowledge of in
23 vitro clinical tests, laboratory operations, and the
24 use of in vitro clinical tests.

25 “(4) DOWN-CLASSIFICATION.—

1 “(A) IN GENERAL.—If the Secretary, upon
2 the Secretary’s own initiative or upon petition,
3 intends to make a down-classification of an in
4 vitro clinical test, the Secretary shall publish a
5 notice in the Federal Register of such intent.
6 Such notice shall—

7 “(i) if the Secretary intends to modify
8 or add mitigating measures applicable to
9 the test involved—

10 “(I) describe and provide jus-
11 tification for such mitigating meas-
12 ures; and

13 “(II) provide for a 90-calendar-
14 day public comment period; and

15 “(ii) if the Secretary does not intend
16 to modify or add any such mitigating
17 measures, provide for a 60-calendar-day
18 public comment period.

19 “(B) PREVENTION OF UP-CLASSIFICA-
20 TION.—In the case of an in vitro clinical test
21 that the Secretary determines would be up-clas-
22 sified but for the withdrawal, modification, or
23 addition of mitigating measures applicable to an
24 in vitro clinical test, the Secretary shall publish
25 in the Federal Register a notice of the Sec-

1 retary’s intent to withdraw, modify, or add such
2 mitigating measures. Such notice shall—

3 “(i) describe and provide justification
4 for such mitigating measures; and

5 “(ii) provide for a 90-calendar-day
6 public comment period.

7 “(C) FINAL DETERMINATION.—Not later
8 than 60 calendar days after the close of the ap-
9 plicable public comment period under subpara-
10 graph (A) or (B), the Secretary shall—

11 “(i) decide whether to make the down-
12 classification of the in vitro clinical test in-
13 volved;

14 “(ii) publish a notice of such decision
15 in the Federal Register;

16 “(iii) if the Secretary decides to make
17 the down-classification, publish an admin-
18 istrative order—

19 “(I) in accordance with para-
20 graph (1); and

21 “(II) describing and providing
22 justifications for any mitigating meas-
23 ures applicable to such down-classi-
24 fication; and

1 “(iv) revoke or revise, as appropriate,
2 any regulation or requirement issued in
3 connection with the in vitro clinical test’s
4 previous classification.

5 “(5) UP-CLASSIFICATION.—In the case of a
6 proposed up-classification of an in vitro clinical test,
7 the Secretary—

8 “(A) shall make the up-classification by
9 written order in accordance with paragraph (1);

10 “(B) shall revoke or revise, as appropriate,
11 any regulation or requirement issued in connec-
12 tion with the in vitro clinical test’s previous
13 classification; and

14 “(C) shall not delegate authority to make
15 the up-classification to any employee or official
16 other than the chief scientific officer of the
17 Center for In Vitro Clinical Tests or another
18 member of the senior management of such Cen-
19 ter.

20 “(6) TRANSITION PERIOD.—When the Sec-
21 retary establishes, adds, or modifies a mitigating
22 measure, or makes a down-classification or up-classi-
23 fication, the Secretary shall provide an appropriate
24 transition period with respect to—

1 “(A) in vitro clinical tests under premarket
2 review; and

3 “(B) in vitro clinical tests not under pre-
4 market review, but for which the classification
5 or mitigating measures are inconsistent with
6 documented advice provided to the developer by
7 the Food and Drug Administration.

8 “(7) RECLASSIFICATION APPEALS.—In the case
9 of a modification or rejection of a recommended
10 classification change of an in vitro clinical test under
11 paragraph (1) or failure to make a determination
12 with respect to a down-classification within the time-
13 frame specified in paragraph (4)(C)—

14 “(A) such modification, rejection, or failure
15 shall be treated as final and immediately sub-
16 ject to appeal under section 590F; and

17 “(B) upon request of the developer made
18 not later than 180 calendar days after the date
19 of such modification, rejection, or failure, the
20 Secretary shall obtain the recommendation of
21 an advisory panel with respect to the reclassi-
22 fication.

23 “(e) INITIAL CLASSIFICATION OF PREVIOUSLY CLAS-
24 SIFIED IN VITRO CLINICAL TESTS.—

1 “(1) IN GENERAL.—An in vitro clinical test
2 classified under section 513(a) as of the date of en-
3 actment of the Diagnostic Accuracy and Innovation
4 Act shall be classified as follows:

5 “(A) An in vitro clinical test classified in
6 class I under section 513(a)(1)(A), as of such
7 date, is deemed to be classified as a low-risk in
8 vitro clinical test.

9 “(B) An in vitro clinical test classified as
10 class II under section 513(a)(1)(B), as of such
11 date, is deemed to be classified as a moderate-
12 risk in vitro clinical test.

13 “(C) An in vitro clinical test classified as
14 class III under section 513(a)(1)(C), as of such
15 date, is deemed to be classified as a high-risk
16 in vitro clinical test.

17 “(2) CONTINUED APPLICATION OF MITIGATING
18 MEASURES.—An in vitro clinical test described in
19 paragraph (1) that is subject to one or more miti-
20 gating measures as of the date specified in such
21 paragraph shall continue to be subject to such miti-
22 gating measures after such date, unless—

23 “(A) the classification of the test is
24 changed under this subsection; or

1 “(B) the mitigating measures applicable to
2 such classification are changed pursuant to this
3 subsection.

4 “(3) PUBLIC COMMENT.—Not later than 60
5 calendar days after the date of enactment of the Di-
6 agnostic Accuracy and Innovation Act, the Secretary
7 shall—

8 “(A) publish a notice in the Federal Reg-
9 ister that—

10 “(i) identifies, with supporting sci-
11 entific rationale, all in vitro clinical tests
12 for which the Secretary believes the classi-
13 fication pursuant to paragraph (1) is in-
14 correct;

15 “(ii) requests that interested per-
16 sons—

17 “(I) notify the Secretary of any
18 in vitro clinical test for which the in-
19 terested person believes the classifica-
20 tion pursuant to paragraph (1) is in-
21 correct; and

22 “(II) provide supporting scientific
23 rationale for such belief; and

24 “(iii) requests that interested per-
25 sons—

1 “(I) notify the Secretary of any
2 in vitro clinical test that was—

3 “(aa) offered as of the date
4 that is 90 calendar days prior to
5 the date of the enactment of the
6 Diagnostic Accuracy and Innova-
7 tion Act; and

8 “(bb) not classified under
9 section 513(a) as of such date;
10 and

11 “(II) provide a suggested classi-
12 fication with supporting scientific ra-
13 tionale; and

14 “(B) provide a 120-calendar-day public
15 comment period with respect to such notice.

16 “(4) REVIEW AND RECOMMENDATIONS BY AD-
17 VISORY PANELS.—

18 “(A) IN GENERAL.—Not later than 90 cal-
19 endar days after the date of enactment of the
20 Diagnostic Accuracy and Innovation Act, the
21 Secretary shall identify or establish one or more
22 advisory panels (in this subsection referred to
23 as an ‘advisory panel’)—

24 “(i) to review and consider the classi-
25 fication of each in vitro clinical test identi-

1 fied by the Secretary or an interested per-
2 son pursuant to paragraph (3); and

3 “(ii) to recommend the appropriate
4 classification of each such test in accord-
5 ance with this section.

6 “(B) MEMBERSHIP.—The members of an
7 advisory panel shall include a balanced rep-
8 resentation of persons representing physicians,
9 other health care professionals, consumers, and
10 the in vitro clinical test manufacturing and lab-
11 oratory industries.

12 “(C) INAPPLICABLE REQUIREMENTS.—
13 Section 14 of the Federal Advisory Committee
14 Act shall not apply for the duration of a panel
15 established under this paragraph.

16 “(5) TIMING OF RECOMMENDATIONS.—

17 “(A) ASSIGNMENT TO ADVISORY PANEL.—
18 Not later than 180 calendar days after the close
19 of the public comment period under paragraph
20 (3)(B) with respect to an in vitro clinical test,
21 the Secretary shall direct the respective advi-
22 sory panel to conduct the review required by
23 paragraph (4).

24 “(B) ISSUANCE OF RECOMMENDATION.—
25 Not later than 1 year after the Secretary di-

1 rects an advisory panel to review the classifica-
2 tion of an in vitro clinical test under subpara-
3 graph (A), the advisory panel shall, after taking
4 into consideration all public comments and, at
5 the advisory panel’s discretion, holding public
6 meetings, provide to the Secretary the advisory
7 panel’s recommended classification of the in
8 vitro clinical test.

9 “(6) CLASSIFICATION DETERMINATION.—

10 “(A) CLASSIFICATION.—Not later than
11 180 calendar days after the date on which the
12 Secretary receives the recommendation of an
13 advisory panel with respect to the classification
14 of an in vitro clinical test under paragraph (5),
15 the Secretary shall by administrative order pub-
16 lished in the Federal Register—

17 “(i) classify the in vitro clinical test in
18 accordance with the classes specified in
19 this section and publish such classification
20 in the Federal Register;

21 “(ii) if such classification differs from
22 the classification recommended by the ad-
23 visory panel, specifically rebut the
24 advisory’s panel’s classification with sci-
25 entific evidence;

1 “(iii) in the case of an up-classifica-
2 tion, include a public health justification
3 demonstrating the need for up-classifica-
4 tion; and

5 “(iv) subject to a final classification
6 determination under subparagraph (C)(iii),
7 revoke or revise, as appropriate, any regu-
8 lation or requirement issued in connection
9 with the in vitro clinical test’s previous
10 classification, notwithstanding subchapter
11 II of chapter 5 of title 5, United States
12 Code.

13 “(B) FINALITY OF CLASSIFICATION.—Sub-
14 ject to subparagraph (C), a classification under
15 subparagraph (A)(i) is deemed to be final upon
16 publication.

17 “(C) EXCEPTION FOR UP-CLASSIFICA-
18 TION.—With respect to any up-classification
19 published under subparagraph (A), the Sec-
20 retary—

21 “(i) shall provide a 60-calendar-day
22 period for public comment;

23 “(ii) shall not delegate authority to
24 make the up-classification to any employee
25 or official other than the chief scientific of-

1 ficier of the Center for In Vitro Clinical
2 Tests or another member of the senior
3 management of such Center; and

4 “(iii) not later than 90 calendar days
5 after the close of the public comment pe-
6 riod under clause (i), shall publish in the
7 Federal Register the final classification for
8 such in vitro clinical test by written order
9 published in the Federal Register classify
10 the in vitro clinical test and revoke or re-
11 vise, as appropriate, any regulation or re-
12 quirement issued in connection with the in
13 vitro clinical test’s previous classification,
14 notwithstanding subchapter II of chapter 5
15 of title 5, United States Code.

16 “(7) INACTION BY THE SECRETARY.—If the
17 Secretary fails to issue a final classification deter-
18 mination for an in vitro clinical test or type of in
19 vitro clinical test within the timeframes described in
20 paragraph (6), the recommendation of the respective
21 advisory panel under paragraph (5) shall be the final
22 classification for the in vitro clinical test or type of
23 in vitro clinical test.

24 “(8) DEEMED CLASSIFICATION TO BECOME
25 FINAL.—The deemed classification under paragraph

1 (1) shall be the final classification of any in vitro
2 clinical test or type of in vitro clinical test not sub-
3 mitted to an advisory panel pursuant to paragraph
4 (5).

5 “(9) APPEAL OF CLASSIFICATION.—Not later
6 than 60 calendar days after the date of the final
7 classification of an in vitro clinical test under para-
8 graph (6) or (7), the developer of the test may ap-
9 peal such classification under section 590F.

10 “(f) OTHER ADDITIONS OR CHANGES TO MITI-
11 GATING MEASURES.—If the Secretary intends to modify
12 or add mitigating measures other than as described in
13 subsection (d), the Secretary shall—

14 “(1) describe and provide justification for such
15 modification or addition; and

16 “(2) provide a 90-calendar-day public comment
17 period on such modification or addition.

18 “(g) DEFINITIONS.—In this section:

19 “(1) DOWN-CLASSIFICATION.—The term ‘down-
20 classification’ means—

21 “(A) reclassification from high-risk to
22 moderate- or low-risk; or

23 “(B) reclassification from moderate-risk to
24 low-risk.

1 “(2) UP-CLASSIFICATION.—The term ‘up-classi-
2 fication’ means—

3 “(A) reclassification from low-risk to
4 moderate- or high-risk; or

5 “(B) reclassification from moderate-risk to
6 high-risk.

7 “(3) WELL-CHARACTERIZED.—The term ‘well-
8 characterized’ means well-established and well-recog-
9 nized by the scientific or clinical community, as evi-
10 denced by one or more of the following:

11 “(A) Literature.

12 “(B) Practice guidelines.

13 “(C) Consensus standards.

14 “(D) Recognized standards of care.

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

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

18 “(G) Wide recognition or adoption by the
19 scientific or clinical community.

20 “(H) Availability of proficiency testing.

21 **“SEC. 590B. PREMARKET REVIEW.**

22 “(a) IN GENERAL.—The Secretary shall establish a
23 process for the premarket review of in vitro clinical tests
24 in accordance with this section.

1 “(b) PRESUBMISSION MEETING.—Before submitting
2 an application under subsection (c) or (d) for offering an
3 in vitro clinical test—

4 “(1) the developer of the test may submit to the
5 Secretary a written request for a meeting or con-
6 ference to discuss and provide information relating
7 to the submission process and the type and amount
8 of evidence expected to demonstrate a reasonable as-
9 surance of analytical validity and clinical validity, or
10 probable clinical validity, as applicable; and

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

13 “(A) within 30 calendar days after such
14 receipt, or within such time period as may be
15 agreed to by the developer, meet or confer with
16 the developer submitting the request; and

17 “(B) within 30 calendar days after such
18 meeting or conference, provide to the developer
19 a written record or response describing the
20 issues discussed and conclusions reached in the
21 meeting.

22 “(c) PREMARKET APPROVAL OF HIGH-RISK
23 TESTS.—

24 “(1) IN GENERAL.—Subject to disapproval
25 under subsection (g), the Secretary shall approve a

1 high-risk in vitro clinical test (other than an in vitro
2 clinical test submitted for approval under subsection
3 (f)) if, upon the submission to the Secretary of an
4 application by the developer of the test, the Sec-
5 retary determines that the application demonstrates
6 a reasonable assurance that the in vitro clinical test
7 is analytically valid and clinically valid for its in-
8 tended use. The Secretary shall, by regulation, de-
9 velop a process for such review and approval.

10 “(2) APPLICATION CONTENTS.—An application
11 submitted with respect to an in vitro clinical test
12 under paragraph (1) shall include—

13 “(A) the name, address, and establishment
14 registration number of the developer of the test;

15 “(B) in the case of an application sub-
16 mitted by a person other than the developer,
17 the name, address, and establishment registra-
18 tion number, if applicable, of the applicant;

19 “(C) the name of the in vitro clinical test;

20 “(D) the intended use of the in vitro clin-
21 ical test;

22 “(E) a summary description of the in vitro
23 clinical test, including as applicable—

24 “(i) the analyte, biomarker, substance,
25 or other target sought to be identified,

1 measured, detected, calculated, or analyzed
2 by the test;
3 “(ii) the specifications of the test;
4 “(iii) specimen types to be analyzed
5 by the test;
6 “(iv) the indications for use of the
7 test;
8 “(v) the intended users of, and user
9 environments for, the test;
10 “(vi) brief descriptions of components
11 of the test;
12 “(vii) principles of properties of the
13 test or the principles of operation of the
14 test;
15 “(viii) the software necessary for ap-
16 plication of the test, including risk mitiga-
17 tion for cybersecurity;
18 “(ix) any quality control material rec-
19 ommendations, as applicable, for the use of
20 the test; and
21 “(x) the method of specimen collection
22 and transport to be used with the test, as
23 applicable;
24 “(F) applicable performance standards,
25 voluntary standards, or mitigating measures re-

1 lied upon by the developer in determining the
2 analytical validity and clinical validity of the
3 test;

4 “(G) a summary of design controls for the
5 test and a declaration of the developer’s con-
6 formity to such design controls;

7 “(H) in the case of an in vitro clinical test
8 that is a finished product, a summary of rel-
9 evant process controls used in manufacturing
10 the test, a validation master plan for such proc-
11 ess, any acceptance activities or statistical tech-
12 niques used to ensure the validity of results
13 generated by the test, and any purchasing con-
14 trols applicable to the test;

15 “(I) proposed labeling for the test, which
16 shall—

17 “(i) account for the differences be-
18 tween an in vitro clinical test that is a lab-
19 oratory test protocol and an in vitro clin-
20 ical test that is a finished product, as ap-
21 propriate; and

22 “(ii) except to the extent that such in-
23 structions are standard operating proce-
24 dures as defined in section 353 of the Pub-
25 lic Health Service Act, provide instructions

1 that relate to protection of the individual
2 performing the test, including, as appro-
3 priate, disinfection, sterility, electrical safe-
4 ty, and sample handling;

5 “(J) a risk assessment for the test;

6 “(K) a statement attesting to the truthful-
7 ness and accuracy of the submission; and

8 “(L)(i) a summary of the valid scientific
9 evidence that is relevant to determining whether
10 or not there is a reasonable assurance of ana-
11 lytical validity and clinical validity for the in-
12 tended use of the in vitro clinical test; and

13 “(ii) the protocol and summary of results
14 and conclusions from any studies performed
15 with respect to such test, including, as required
16 by paragraph (3), the raw data from such stud-
17 ies.

18 “(3) SUBMISSION OF RAW DATA FROM STUD-
19 IES.—The Secretary shall by regulation—

20 “(A) set forth instances in which raw data
21 is not required to be submitted;

22 “(B) subject to subparagraph (C), only re-
23 quire the submission of raw data to the extent
24 necessary to address one or more questions—

1 “(i) directly raised in the relevant ap-
2 plication; and

3 “(ii) directly related to the reasonable
4 assurance of analytical validity and clinical
5 validity of the in vitro clinical test for the
6 intended use;

7 “(C) provide for submission of raw data to
8 address a question directly related to the rea-
9 sonable assurance of analytical validity and
10 clinical validity of the intended use but not di-
11 rectly raised in the relevant application only if
12 the Secretary demonstrates in writing signed by
13 the chief scientific officer of the Center for In
14 Vitro Clinical Tests or another member of the
15 senior management of such Center that the raw
16 data is necessary to address a public health risk
17 first arising after the date the application was
18 submitted;

19 “(D) provide for the submission of raw
20 data in the least onerous and most efficient
21 manner sufficient to demonstrate a reasonable;

22 “(E) limit the data required to be sub-
23 mitted to data in the possession of the devel-
24 oper or its agent unless the Secretary dem-
25 onstrates in writing signed by the chief sci-

1 entific officer of the Center for In Vitro Clinical
2 Tests or another member of the senior manage-
3 ment of such Center that data necessary to es-
4 tablish a reasonable assurance of analytical va-
5 lidity, a reasonable assurance of clinical valid-
6 ity, or, as applicable, probable clinical validity,
7 cannot otherwise be obtained for the intended
8 use; and

9 “(F) limit the Secretary’s use of submitted
10 raw data to analysis of reasonable assurance of
11 analytical validity and clinical validity for the
12 intended use and require that such use be in
13 conformance with predefined acceptance cri-
14 teria, if any.

15 “(4) APPROVAL PROCESS.—Not later than 120
16 calendar days after the date on which an application
17 is submitted under paragraph (1), the Secretary
18 shall—

19 “(A) issue an order approving or dis-
20 approving the application; and

21 “(B) in the case of an order disapproving
22 the application, specify in such order the sci-
23 entific rationale for such disapproval and the
24 measures required to place such application in
25 approvable form.

1 “(d) PREMARKET APPROVAL OF MODERATE-RISK
2 TESTS.—

3 “(1) IN GENERAL.—Subject to disapproval
4 under subsection (g), the Secretary shall approve a
5 moderate-risk in vitro clinical test (other than an in
6 vitro clinical test submitted for approval under sub-
7 section (f)) if, upon the submission to the Secretary
8 of an application by the developer of the test, the
9 Secretary determines that the application dem-
10 onstrates a reasonable assurance that the in vitro
11 clinical test is analytically valid and clinically valid
12 for its intended use. The Secretary shall, by regula-
13 tion, develop a process for such review and approval.

14 “(2) APPLICATION CONTENTS.—An application
15 submitted under paragraph (1) with respect to a
16 moderate-risk in vitro clinical test shall include—

17 “(A) the name, address, and establishment
18 registration number of the developer of the test;

19 “(B) in the case of an application sub-
20 mitted by a person other than the developer,
21 the name, address, and establishment registra-
22 tion number, if applicable, of the applicant;

23 “(C) the name of the in vitro clinical test;

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

- 1 “(E) a summary description of the in vitro
2 clinical test, including as applicable—
- 3 “(i) the analyte, biomarker, substance,
4 or other target sought to be identified,
5 measured, detected, calculated, or analyzed
6 by the test;
- 7 “(ii) the specifications of the test;
- 8 “(iii) specimen types to be analyzed
9 by the test;
- 10 “(iv) the indications for use of the
11 test;
- 12 “(v) the intended users of, and user
13 environments for, the test;
- 14 “(vi) brief descriptions of components
15 of the test;
- 16 “(vii) principles of properties of the
17 test or the principles of operation of the
18 test;
- 19 “(viii) the software necessary for ap-
20 plication of the test, including risk mitiga-
21 tion for cybersecurity;
- 22 “(ix) any quality control material rec-
23 ommendations, as applicable, for the use of
24 the test; and

1 “(x) the method of specimen collection
2 and transport to be used with the test, as
3 applicable;

4 “(F) applicable performance standards,
5 voluntary standards, or mitigating measures re-
6 lied upon by the developer in determining the
7 analytical validity and clinical validity of the
8 test;

9 “(G) a declaration of the developer’s con-
10 formity to design controls;

11 “(H) proposed labeling for the test, which
12 shall—

13 “(i) account for the differences be-
14 tween an in vitro clinical test that is a lab-
15 oratory test protocol and an in vitro clin-
16 ical test that is a finished product, as ap-
17 propriate; and

18 “(ii) except to the extent that such in-
19 structions are standard operating proce-
20 dures as defined in section 353 of the Pub-
21 lic Health Service Act, provide instructions
22 that relate to protection of the individual
23 performing the test, including, as appro-
24 priate, disinfection, sterility, electrical safe-
25 ty, and sample handling;

1 “(I) a summary of the risk assessment for
2 the test;

3 “(J) a statement attesting to the truthfulness and accuracy of the submission; and

4 “(K)(i) a summary of the valid scientific
5 evidence that is relevant to determining whether
6 or not there is a reasonable assurance of analytical validity and clinical validity for the intended use of the in vitro clinical test; and

7 “(ii) a summary of the protocol and summary of results and conclusions from any studies performed with respect to such test, including, as required by paragraph (3), the raw data from such studies.

8 “(3) SUBMISSION OF RAW DATA FROM STUDIES.—The Secretary shall not require that raw data from studies described in paragraph (2)(K)(ii) be routinely submitted. Subject to the preceding sentence, the Secretary shall by regulation—

9 “(A) set forth instances in which raw data is required to be submitted;

10 “(B) require the submission of raw data only if the chief scientific officer of the Center for In Vitro Clinical Tests or another member

1 of the senior management of such Center dem-
2 onstrates in writing that—

3 “(i) such data is necessary to address
4 one or more questions directly related to
5 clinical validity of an in vitro clinical of an
6 in vitro clinical test with a new intended
7 use or utilizing a new technology; and

8 “(ii) the requested data or equivalent
9 information is not reasonably available by
10 other means, including peer reviewed jour-
11 nals;

12 “(C) provide for the submission of raw
13 data in the least onerous, most efficient manner
14 sufficient to demonstrate a reasonable assur-
15 ance of clinical validity, or, as applicable, prob-
16 able clinical validity;

17 “(D) limit the data required to be sub-
18 mitted to data in the possession of the devel-
19 oper or its agent unless the Secretary dem-
20 onstrates in writing signed by the chief sci-
21 entific officer of the Center for In Vitro Clinical
22 Tests or another member of the senior manage-
23 ment of such Center that data necessary to es-
24 tablish a reasonable assurance of clinical valid-

1 ity, or, as applicable, probable clinical validity,
2 cannot otherwise be obtained; and

3 “(E) limit the Secretary’s use of submitted
4 raw data to analysis of clinical validity and re-
5 quire that such use be in conformance with any
6 predefined acceptance criteria.

7 “(4) APPROVAL PROCESS.—Not later than 75
8 calendar days after the date on which an application
9 is submitted under paragraph (1), the Secretary
10 shall—

11 “(A) issue an order approving or dis-
12 approving the application; and

13 “(B) in the case of an order disapproving
14 the application, specify in such order the sci-
15 entific rationale for such disapproval and the
16 measures required to place such application in
17 approvable form.

18 “(5) FAILURE TO ACT.—If the Secretary fails
19 to issue an order under paragraph (4)(A) within the
20 75-calendar-day period specified in such paragraph
21 with respect to an in vitro clinical test, the in vitro
22 clinical test may be legally marketed by the devel-
23 oper without further action by the Secretary and for
24 purposes of this Act shall be treated as having an
25 approved application in effect under this subsection.

1 “(6) THIRD-PARTY REVIEW PROCESS.—For
2 purposes of reviewing applications submitted under
3 paragraph (1), the Secretary shall establish by regu-
4 lation a process under which—

5 “(A) third parties may conduct such review
6 at the request of the developer;

7 “(B) the Secretary agrees or disagrees
8 with a third-party reviewer’s conclusion that the
9 developer has demonstrated a reasonable assur-
10 ance of analytical validity and clinical validity
11 or, as applicable, probable clinical validity for
12 the intended use of the in vitro clinical test; and

13 “(C) if the Secretary disagrees with the
14 third-party reviewer’s conclusion, the Secretary
15 must provide the developer with a written jus-
16 tification for such decision.

17 “(e) LISTING OF LOW-RISK AND RARE DISEASE
18 TESTS.—A low-risk in vitro clinical test or rare disease
19 in vitro clinical test may be legally marketed by the devel-
20 oper without further action by the Secretary and shall be
21 treated as having an approved application in effect under
22 this section so long as the developer of the test lists the
23 test with the Secretary in accordance with subsection (o).

24 “(f) SPECIAL PATHWAY FOR CERTAIN TESTS.—

1 “(1) STANDARD.—In lieu of approving under
2 subsection (c) or (d) a high- or moderate-risk in
3 vitro clinical test described in paragraph (2), the
4 Secretary, subject to subsection (g), shall as applica-
5 ble—

6 “(A) approve such an in vitro clinical test
7 under this subsection without confirmatory
8 postmarket obligations if the developer of the
9 test submits an application demonstrating a
10 reasonable assurance of—

11 “(i) analytical validity for its intended
12 use; and

13 “(ii) clinical validity for its intended
14 use;

15 “(B) approve such an in vitro clinical test
16 under this subsection subject to confirmatory
17 postmarket obligations under paragraph (6) if
18 the developer of the test submits an application
19 demonstrating—

20 “(i) a reasonable assurance of analyt-
21 ical validity for its intended use; and

22 “(ii) probable clinical validity for its
23 intended use; and

24 “(C) continue an approval under subpara-
25 graph (B) in effect without confirmatory

1 postmarket obligations under such subpara-
2 graph if the developer of the test submits a sup-
3 plemental application under paragraph (8) with
4 respect to the test and the Secretary —

5 “(i) finds that such application dem-
6 onstrates a reasonable assurance of clinical
7 validity for the intended use of the test; or

8 “(ii) does not disapprove the supple-
9 mental application under paragraph (9) by
10 the deadline applicable under such para-
11 graph.

12 “(2) ELIGIBILITY.—

13 “(A) IN GENERAL.—An in vitro clinical
14 test is eligible for approval or continuation of
15 approval, as applicable, under this subsection if
16 it is one of the following:

17 “(i) An unmet need in vitro clinical
18 test.

19 “(ii) A moderate-risk in vitro clinical
20 tests that offers a clinically significant ad-
21 vantage over in vitro clinical tests pre-
22 viously approved or cleared by the Sec-
23 retary or otherwise legally marketed.

24 “(B) EXCEPTIONS.—An in vitro clinical
25 test described in subparagraph (A) shall not be

1 eligible for approval or continuation of approval
2 under this subsection if—

3 “(i) a supplemental application sub-
4 mitted by the developer or its affiliate for
5 the in vitro clinical test was disapproved
6 under paragraph (9); or

7 “(ii) an approval with confirmatory
8 postmarket obligations under this sub-
9 section was—

10 “(I) granted to the developer or
11 its affiliate for the in vitro clinical
12 test; and

13 “(II) was withdrawn under para-
14 graph (12).

15 “(3) ELECTION OF PATHWAYS.—If an in vitro
16 clinical test is—

17 “(A) an unmet need in vitro clinical test,

18 “(B) a moderate-risk in vitro clinical test
19 that offers a clinically significant advantage
20 over in vitro clinical tests previously approved
21 or cleared by the Secretary or otherwise legally
22 marketed, or

23 “(C) an emergency use in vitro clinical test
24 under section 564,

1 the developer of the test may elect to seek review of
2 the test under the pathway for any such applicable
3 category or combination of applicable categories.

4 “(4) APPLICATION CONTENTS.—The developer
5 of an in vitro clinical test seeking approval of the
6 test under this subsection shall submit an applica-
7 tion to the Secretary in accordance with the fol-
8 lowing:

9 “(A) If the in vitro clinical test is classified
10 as high-risk, and the developer seeks approval
11 under paragraph (1)(A), the application shall
12 include information described in subsection
13 (c)(2).

14 “(B) If the in vitro clinical test is classified
15 as moderate-risk, and the developer seeks ap-
16 proval under paragraph (1)(A), the application
17 shall include the information described in sub-
18 section (d)(2).

19 “(C) If the in vitro clinical test is classified
20 as high-risk or moderate-risk, and the developer
21 seeks approval under paragraph (1)(B), the ap-
22 plication shall include—

23 “(i) the information described in sub-
24 section (d)(2) that is needed to establish a

1 reasonable assurance of analytical validity
2 for its intended use; and

3 “(ii) a proposed plan for collection of
4 confirmatory postmarket evidence.

5 “(D) If the in vitro clinical test is classi-
6 fied as high-risk or moderate-risk, and the de-
7 veloper seeks approval under paragraph (1)(C),
8 the application shall include the information
9 specifically required in the approved plan for
10 the collection of confirmatory postmarket evi-
11 dence demonstrating a reasonable assurance of
12 clinical validity.

13 “(5) APPROVAL PROCESS.—

14 “(A) IN GENERAL.—The Secretary shall—

15 “(i) issue an order approving or dis-
16 approving an application submitted under
17 paragraph (4)—

18 “(I) in the case of an unmet need
19 in vitro clinical test, not later than 30
20 calendar days after the date on which
21 such application is submitted; and

22 “(II) in the case of an in vitro
23 clinical test described in paragraph
24 (2)(A)(ii), not later than 75 calendar

1 days after the date on which such ap-
2 plication is submitted;

3 “(ii) approve an application submitted
4 under paragraph (4) unless the Secretary
5 determines that a ground for disapproval
6 of the application specified in subsection
7 (g) applies; and

8 “(iii) in any order disapproving an ap-
9 plication submitted under paragraph (4),
10 specify the scientific rationale for the dis-
11 approval and the measures required to
12 place such application in approvable form.

13 “(B) FAILURE TO APPROVE OR DIS-
14 APPROVE.—If the Secretary fails to issue an
15 order approving or disapproving an application
16 submitted under paragraph (4) within a time
17 period applicable under subparagraph (A), the
18 in vitro clinical test may be legally marketed by
19 the developer, subject to the confirmatory
20 postmarket obligations proposed by the devel-
21 oper in its application, without further action
22 by the Secretary, and shall be treated as having
23 an approved application in effect under this sec-
24 tion.

1 “(6) CONFIRMATORY POSTMARKET OBLIGA-
2 TIONS.—

3 “(A) AGREED UPON OBLIGATIONS.—If,
4 pursuant to paragraph (1)(B), the Secretary
5 approves an application that demonstrates a
6 reasonable assurance that the in vitro clinical
7 test is analytically valid for its intended use and
8 demonstrates probable clinical validity for its
9 intended use without demonstrating a reason-
10 able assurance of clinical validity for its in-
11 tended use—

12 “(i) the Secretary shall specify in the
13 order granting such approval the confirm-
14 atory postmarket obligations agreed to by
15 the Secretary and the developer of the test,
16 including information and dates regarding
17 the commencement and performance of
18 such obligations;

19 “(ii) such confirmatory postmarket
20 obligations—

21 “(I) shall facilitate the devel-
22 oper’s collection of additional valid
23 scientific evidence as necessary to
24 demonstrate a reasonable assurance

1 that the test is clinically valid for its
2 intended use;

3 “(II) may include reporting re-
4 quirements related to such obliga-
5 tions; and

6 “(iii) the developer shall complete the
7 confirmatory postmarket obligations.

8 “(B) MODIFICATIONS TO OBLIGATIONS.—
9 The confirmatory postmarket obligations agreed
10 to under subparagraph (A) may be modified at
11 any time by the mutual agreement of the Sec-
12 retary and the developer.

13 “(C) LABEL REQUIREMENT.—An order ap-
14 proving an in vitro clinical test under para-
15 graph (1)(B) shall require the labeling of the
16 test to state the following: ‘Approved with con-
17 firmatory postmarket obligations’.

18 “(7) LAPSE OF APPROVAL.—

19 “(A) IN GENERAL.—An approval with con-
20 firmatory postmarket obligations under this
21 subsection shall automatically lapse—

22 “(i) on the date that is three years
23 after the date of such approval if an exten-
24 sion has not been granted by the Secretary
25 and if the developer of the in vitro clinical

1 test has not submitted a supplemental ap-
2 plication pursuant to paragraph (8) at
3 least three months prior to such date;

4 “(ii) on the date specified in an exten-
5 sion order issued by the Secretary, if an
6 extension is mutually agreed upon by the
7 Secretary and the developer of the in vitro
8 clinical test and if the developer has not
9 submitted a supplemental application pur-
10 suant to paragraph (8) at least three
11 months prior to the agreed upon extension
12 date;

13 “(iii) on the date that is thirty cal-
14 endar days after the date on which the
15 Secretary issues an order disapproving a
16 supplemental application submitted pursu-
17 ant to paragraph (9) with respect to the in
18 vitro clinical test, if the applicant does not
19 appeal the order; or

20 “(iv) if the applicant submitting a
21 supplemental application pursuant to para-
22 graph (8) appeals an order disapproving
23 the application, on the date on which the
24 Director of the Center for In Vitro Clinical

1 Tests issues a decision upholding the dis-
2 approval.

3 “(B) DURATION OF EXTENSION.—The
4 term of any extension described in subpara-
5 graph (A)(ii) shall not extend beyond the date
6 that is four years after the date of approval
7 with confirmatory postmarket obligations for
8 the in vitro clinical test.

9 “(8) SUPPLEMENTAL APPLICATION.—The de-
10 veloper of an in vitro clinical test approved under
11 this subsection subject to confirmatory postmarket
12 obligations may submit a supplemental application
13 containing the contents specified in paragraph
14 (4)(D), as applicable, at any time prior to the dead-
15 line for submission under paragraph (7).

16 “(9) DISAPPROVAL OF SUPPLEMENTAL APPLI-
17 CATION.—

18 “(A) IN GENERAL.—If the Secretary deter-
19 mines that a supplemental application sub-
20 mitted under paragraph (8) does not dem-
21 onstrate a reasonable assurance of clinical va-
22 lidity for the intended use of the in vitro clinical
23 test—

24 “(i) the Secretary shall, within 60 cal-
25 endar days after submission of such appli-

1 cation, issue an order disapproving the
2 supplemental application;

3 “(ii) such order shall specify the sci-
4 entific rationale for such decision; and

5 “(iii) such decision shall set forth a
6 reasonable timeframe, not to exceed 30 cal-
7 endar days, after which the developer of
8 the in vitro clinical test shall cease to offer
9 such test.

10 “(B) STAY OF DEADLINES.—A deadline
11 set forth pursuant to subparagraph (A)(iii)
12 shall be stayed during the pendency of an ap-
13 peal under paragraph (10).

14 “(10) APPEAL OF DISAPPROVAL.—

15 “(A) IN GENERAL.—Not later than 30 cal-
16 endar days after the date on which an initial
17 decision is issued under paragraph (9) dis-
18 approving a supplemental application with re-
19 spect to an in vitro clinical test, the developer
20 of the test may appeal the disapproval directly
21 to the Director of the Center for In Vitro Clin-
22 ical Tests.

23 “(B) DETERMINATION OF DIRECTOR.—
24 The Director of the Center for In Vitro Clinical

1 Tests shall determine whether to uphold the
2 disapproval that is the subject of the appeal—

3 “(i) not later than 45 calendar days
4 after submission of the appeal; or

5 “(ii) if the developer requests in the
6 appeal an in-person meeting or teleconfer-
7 ence with the Director, not later than 30
8 calendar days after the date of such meet-
9 ing or teleconference.

10 “(C) EFFECT OF DETERMINATION UP-
11 HOLDING DISAPPROVAL.—If the Director of the
12 Center for In Vitro Clinical Tests upholds a dis-
13 approval of a supplemental application under
14 paragraph (9), such disapproval shall constitute
15 final action by the Secretary and may not be
16 appealed within the Food and Drug Adminis-
17 tration.

18 “(11) TERMINATION OF POSTMARKET OBLIGA-
19 TIONS.—The approval of an in vitro clinical test
20 under paragraph (1)(B) shall continue in effect as
21 described in paragraph (1)(C), and any confirmatory
22 postmarket obligations imposed under this sub-
23 section with respect to an in vitro clinical test, in-
24 cluding the labeling requirement in paragraph
25 (6)(C), shall terminate, if the Secretary approves a

1 supplemental application submitted under paragraph
2 (8) with respect to the test.

3 “(12) WITHDRAWAL OF APPROVAL WITH CON-
4 FIRMATORY POSTMARKET OBLIGATIONS.—The Sec-
5 retary may, after providing notice to the developer
6 of the test and an opportunity for an informal hear-
7 ing, withdraw an approval of an in vitro clinical test
8 made subject to confirmatory postmarket obligations
9 under this subsection at any time before such ap-
10 proval would otherwise lapse under this subsection if
11 the Secretary determines, based on new valid sci-
12 entific evidence, that—

13 “(A) the developer of the test can no
14 longer demonstrate a reasonable assurance of
15 the analytical validity, and probable clinical va-
16 lidity, of the test for its intended use; or

17 “(B) the test presents an unreasonable
18 risk to human health.

19 “(13) PUBLIC DATABASE.—The Secretary may
20 establish a public database that—

21 “(A) lists each in vitro clinical test ap-
22 proved subject to confirmatory postmarket obli-
23 gations under this subsection;

1 “(B) may include, with respect to each
2 such test, the end date and status of such con-
3 firmatory postmarket obligations; and

4 “(C) is updated to reflect any change in
5 the status of such a test within 10 calendar
6 days of that change in status.

7 “(14) INCENTIVES.—For in vitro clinical tests
8 reviewed under this subsection, the Secretary shall—

9 “(A) provide review priority; and

10 “(B) provide additional personnel for re-
11 view of applications.

12 “(15) DEFINITIONS.—In this subsection:

13 “(A) CLINICALLY SIGNIFICANT ADVAN-
14 TAGE.—The term ‘clinically significant advan-
15 tage’ means a reasonable potential to improve
16 the ability to identify, measure, detect, predict,
17 monitor, or assist in selecting treatment for a
18 disease or other condition, including by pro-
19 viding for—

20 “(i) increased patient access;

21 “(ii) reduced sample size;

22 “(iii) expanded sample types;

23 “(iv) faster diagnosis;

24 “(v) improved analytical or clinical
25 performance;

1 “(vi) less intrusive methods; or

2 “(vi) other improvements or benefit to
3 patients or public health.

4 “(B) UNMET NEED IN VITRO CLINICAL
5 TEST.—The term ‘unmet need in vitro clinical
6 test’ means an in vitro clinical test intended to
7 be used to identify, measure, detect, predict,
8 monitor, or assist in selecting treatment for, a
9 serious or life-threatening disease or condition
10 for which there is no approved or legally mar-
11 keted in vitro clinical test with the same in-
12 tended use.

13 “(16) CUSTOM IVCTS.—A high-risk or mod-
14 erate-risk in vitro clinical test shall not be subject to
15 the requirements of subsection (c) or (d), or of para-
16 graphs (1) through (15) of this subsection, if the
17 test—

18 “(A) is developed or modified in order to
19 comply with the order of an individual physi-
20 cian, dentist, or other health care professional
21 (or any other specially qualified person des-
22 ignated under regulations promulgated by the
23 Secretary after an opportunity for an oral hear-
24 ing);

1 “(B)(i) is intended to meet the special
2 needs of such physician, dentist, or other health
3 care professional (or other specially qualified
4 person so designated) in the course of the pro-
5 fessional practice of such physician, dentist, or
6 other health care professional; or

7 “(ii) is intended for use by an individual
8 patient named in such order of such physician,
9 dentist, or health care professional (or other
10 specially qualified person so designated);

11 “(C) in order to comply with an order de-
12 scribed in subparagraph (A), necessarily devi-
13 ates from an otherwise applicable requirement
14 under this section;

15 “(D) is not generally available in the
16 United States in finished form for its intended
17 use, as demonstrated through labeling or adver-
18 tising by the developer, importer, or distributor
19 of the test;

20 “(E) is designed to treat a unique pathol-
21 ogy or physiological condition for which no
22 other in vitro clinical test is available in the
23 United States;

24 “(F) is developed, assembled from compo-
25 nents, or manufactured and finished on a case-

1 by-case basis, to accommodate the unique needs
2 of a patient of a health care professional de-
3 scribed in subparagraph (A); and

4 “(G) may have standardized design charac-
5 teristics, chemical and material compositions,
6 and manufacturing processes in common with
7 commercially distributed in vitro clinical tests.

8 “(g) APPROVAL OF APPLICATIONS AND WITH-
9 DRAWAL OR SUSPENSION OF APPROVAL.—

10 “(1) APPROVAL.—

11 “(A) GROUNDS FOR DISAPPROVAL.—The
12 Secretary shall disapprove an application for an
13 in vitro clinical test under subsection (c), (d), or
14 (f) only if, upon the basis of the information
15 submitted to the Secretary as part of the appli-
16 cation and any other valid scientific evidence
17 before the Secretary with respect to such in
18 vitro clinical test, the Secretary finds that—

19 “(i) there is a lack of a showing of
20 reasonable assurance that such in vitro
21 clinical test is analytically valid and clini-
22 cally valid, or, as applicable under sub-
23 section (f), there is a lack of a showing of
24 a reasonable assurance of analytical valid-
25 ity and probable clinical validity for such

1 in vitro clinical test, for the intended uses
2 specified in the proposed labeling thereof;

3 “(ii) subject to subsection (h) (con-
4 cerning premarket inspections not being
5 required), the methods used in, or the fa-
6 cilities or controls used for, the manufac-
7 ture, packing, or installation of the in vitro
8 clinical test under review do not conform
9 to the requirements of section 590D and
10 such failures to conform with such require-
11 ments directly impact the analytical valid-
12 ity or clinical validity of the in vitro clinical
13 test under review for the intended uses set
14 forth in the proposed labeling thereof;

15 “(iii) based on a fair evaluation of all
16 material facts, the proposed labeling is
17 false or misleading in any particular or
18 otherwise does not provide adequate in-
19 structions for the use of the in vitro clin-
20 ical test for the intended uses specified in
21 the proposed labeling thereof;

22 “(iv) the application for such in vitro
23 clinical test under subsection (c), (d), or
24 (f) contains one or more material false
25 statements, and after being given an op-

1 opportunity to correct such statements within
2 a reasonable time, the applicant fails to do
3 so;

4 “(v) the application for such in vitro
5 clinical test demonstrates that the in vitro
6 clinical test fails to satisfy an established
7 mitigating measure required for such test
8 pursuant to section 590A; or

9 “(vi) the application for such in vitro
10 clinical test under subsection (c), (d), or
11 (f) fails to include material information
12 that is required to be part of the applica-
13 tion, and, after being given an opportunity
14 to correct such failure within a reasonable
15 time, the applicant fails to do so.

16 “(B) RELIANCE ON PROPOSED LABEL-
17 ING.—In determining whether a ground for dis-
18 approval of an application specified in subpara-
19 graph (A) applies, the Secretary shall—

20 “(i) rely on the intended uses speci-
21 fied in the proposed labeling of the in vitro
22 clinical test as the basis for determining
23 whether there is a reasonable assurance of
24 analytical validity and clinical validity, so

1 long as the proposed labeling is neither
2 false nor misleading; and

3 “(ii) in determining whether such la-
4 beling is false or misleading, fairly evaluate
5 all material facts pertinent to the proposed
6 labeling.

7 “(C) RESTRICTIONS.—An order approving
8 an application for an in vitro clinical test issued
9 under subsection (c), (d), or (f) may require, as
10 a condition on such approval, that a restriction
11 to be imposed with respect to the sale and dis-
12 tribution of the in vitro clinical test, including
13 a restriction that the test be used or performed
14 only pursuant to a prescription, physician
15 order, or order of another health care profes-
16 sional (as authorized by State law).

17 “(D) ACCEPTANCE OF VALID SCIENTIFIC
18 EVIDENCE.—With respect to a determination on
19 whether there is a reasonable assurance of ana-
20 lytical validity and clinical validity of an in vitro
21 clinical test under subsection (c) or (d), or, as
22 applicable under subsection (f), a reasonable as-
23 surance of analytical validity and probable clin-
24 ical validity of an in vitro clinical test, the Sec-

1 retary shall accept and review valid scientific
2 evidence—

3 “(i) derived from investigations of an
4 earlier version of the in vitro clinical test,
5 notwithstanding the in vitro clinical test
6 having been modified during or after the
7 investigations (but prior to submission of
8 an application under subsection (c), (d), or
9 (f)) if that modification does not constitute
10 a significant change in the design or in the
11 basic principles of operation of the in vitro
12 clinical test that would invalidate the evi-
13 dence; or

14 “(ii) relating to another in vitro clin-
15 ical test approved under this section that is
16 relevant to the design and intended use of
17 the in vitro clinical test with respect to
18 which the determination is being made.

19 “(E) POSTSUBMISSION MEETINGS.—

20 “(i) IN GENERAL.—The Secretary
21 shall, upon the written request of an appli-
22 cant submitting an application with respect
23 to an in vitro clinical test under subsection
24 (c), (d), or (f), meet with such applicant.

1 “(ii) SCHEDULE.—Unless the Sec-
2 retary and an applicant described in clause
3 (i) mutually agree to an alternate schedule,
4 a meeting requested under clause (i) shall
5 be held—

6 “(I) in the case of a request with
7 respect to a high-risk in vitro clinical
8 test, meet with the applicant not later
9 than 75 days after the receipt of the
10 application under subsection (c) relat-
11 ing to such test;

12 “(II) in the case of a request
13 with respect to a moderate-risk in
14 vitro clinical test, meet with the appli-
15 cant not later than 45 days after the
16 receipt of the application under sub-
17 section (d) relating to such test;

18 “(III) in the case of an unmet
19 need in vitro clinical test described in
20 subsection (f)(2)(A)(i) for which an
21 application is submitted under sub-
22 section (f), meet with the applicant
23 not later than 15 days after the re-
24 ceipt of such application; and

1 “(IV) in the case of a moderate-
2 risk in vitro clinical test described in
3 subsection (f)(2)(A)(ii) for which an
4 application is submitted under sub-
5 section (f), meet with the applicant
6 not later than 30 after the receipt of
7 such application.

8 “(iii) INFORMATION ON DEFICI-
9 CIENCIES.—Before the date on which any
10 meeting is held pursuant to this subpara-
11 graph, the Secretary shall—

12 “(I) transmit in writing to the
13 applicant requesting such meeting—

14 “(aa) a description of any
15 deficiencies in the application in-
16 volved that, as of such date, have
17 been identified by the Secretary
18 based on an interim review of the
19 entire application;

20 “(bb) the statutory and reg-
21 ulatory requirements that the ap-
22 plication is failing to meet; and

23 “(cc) the information that is
24 required to correct the defi-
25 ciencies so identified; and

1 “(II) notify the applicant
2 promptly of—

3 “(aa) any deficiency identi-
4 fied by the Secretary that is not
5 identified in the description
6 transmitted to the applicant
7 under subclause (I); or

8 “(bb) any additional infor-
9 mation required to achieve com-
10 pletion of the review and final ac-
11 tion on the application that was
12 not included in the information
13 transmitted under such sub-
14 clause.

15 “(2) WITHDRAWAL AND TEMPORARY SUSPEN-
16 SION OF APPROVAL OF APPLICATION.—

17 “(A) WITHDRAWAL.—The Secretary shall,
18 upon obtaining, where appropriate, advice on
19 scientific matters from a panel or panels, and
20 after providing due notice and opportunity for
21 an informal hearing to the holder of an ap-
22 proved application for an in vitro clinical test
23 under this section, issue an order withdrawing
24 approval of the application if the Secretary
25 finds—

1 “(i) on the basis of new information
2 before the Secretary with respect to such
3 in vitro clinical test, evaluated together
4 with the evidence available to the Secretary
5 when the application was approved, that
6 there is a lack of a showing of reasonable
7 assurance of analytical validity and clinical
8 validity, or probable clinical validity, as ap-
9 plicable, of the in vitro clinical test for its
10 intended use;

11 “(ii) that the application contained or
12 was accompanied by a material false state-
13 ment;

14 “(iii) that the applicant—

15 “(I) failed to establish a system
16 for maintaining records, or has re-
17 peatedly or deliberately failed to main-
18 tain records or to make reports, re-
19 quired under section 590E;

20 “(II) has refused to permit ac-
21 cess to, or copying or verification of,
22 such records as are required under
23 section 704; or

24 “(III) has not complied with the
25 requirements of section 590B;

1 “(iv) on the basis of new information
2 before the Secretary with respect to a fin-
3 ished product, evaluated together with the
4 evidence before the Secretary when the ap-
5 plication was approved, that the methods
6 used in, or the facilities and controls used
7 for, the manufacture, processing, packing,
8 or installation of such finished product do
9 not conform with the applicable require-
10 ments under section 590D and were not
11 brought into conformity with such require-
12 ments within a reasonable time after re-
13 ceipt of written notice from the Secretary
14 of nonconformity;

15 “(v) on the basis of new information
16 before the Secretary, evaluated together
17 with the evidence before the Secretary
18 when the application was approved, that
19 the labeling of such in vitro clinical test,
20 based on a fair evaluation of all material
21 facts, is false or misleading in any par-
22 ticular and was not corrected within a rea-
23 sonable time after receipt of written notice
24 from the Secretary of such fact;

1 “(vi) on the basis of new information
2 before the Secretary, evaluated together
3 with the evidence before the Secretary
4 when the application was approved, that
5 such in vitro clinical test is not shown to
6 conform in all material respects to an ap-
7 plicable performance standard or miti-
8 gating measure, which was part of the ap-
9 proval of the application and for which
10 there is a lack of adequate information to
11 justify the deviation from such standard;
12 or

13 “(vii) in the case of a finished prod-
14 uct, based upon a fair evaluation of all ma-
15 terial facts, including the use environment
16 and clinical role of the in vitro clinical test
17 used in accordance with directions for use
18 and warnings, the finished product pre-
19 sents an unreasonable risk of physical
20 harm to the individual when conducting
21 the test.

22 “(B) REVIEW OF ORDER BY HEARING.—
23 The holder of an application subject to an order
24 issued under this paragraph withdrawing ap-
25 proval of the application may, by petition filed

1 on or before the 30th day after the date upon
2 which the holder receives notice of such with-
3 drawal, obtain review of such order by hearing
4 in accordance with section 554 of title 5,
5 United States Code.

6 “(C) TEMPORARY SUSPENSION.—If, after
7 providing an opportunity for an informal hear-
8 ing, the Secretary determines there is reason-
9 able probability that the continued offering of
10 an in vitro clinical test pursuant to an applica-
11 tion approved under this section would cause
12 serious, adverse health consequences or death,
13 the Secretary shall by order temporarily sus-
14 pend the approval of the application. If the Sec-
15 retary issues such an order, the Secretary shall
16 proceed expeditiously under this paragraph to
17 withdraw such application.

18 “(h) PREMARKET INSPECTIONS NOT REQUIRED.—
19 The Secretary may not condition the approval of an appli-
20 cation under this section on the occurrence of a premarket
21 inspection or manufacturing review related to the applica-
22 tion. Nothing in the preceding sentence shall be construed
23 as limiting the authority of the Secretary to conduct qual-
24 ity system inspections under section 704 or other applica-
25 ble provisions of this Act.

1 “(i) LABORATORY TEST PROTOCOL TRANSFER OR
2 SALE.—

3 “(1) LISTING REQUIRED.—An in vitro clinical
4 test that is a laboratory test protocol and approved
5 under subsection (c), (d), or (f)(1) may be trans-
6 ferred, licensed, or sold to a third party for use pur-
7 suant to such approval, so long as, prior to the
8 transfer, licensure, or sale, the party transferring, li-
9 censing, or selling the laboratory test protocol sub-
10 mits a supplement to its listing of such laboratory
11 test protocol under subsection (o).

12 “(2) SHARING AMONG CORPORATE ENTITIES.—
13 The supplemental listing requirement under para-
14 graph (1) does not apply in the case of a transfer,
15 licensure, or sale from an entity to another entity
16 if—

17 “(A) the first entity controls or has the
18 power to control the other entity;

19 “(B) the other entity controls or has the
20 power to control the first entity; or

21 “(C) the two entities are under common
22 ownership or control of a third entity.

23 “(3) EFFECT OF LABORATORY TEST PROTOCOL
24 TRANSFER.—The transfer, license, or sale of less
25 than the full right, title, and interest in a laboratory

1 test protocol, without transfer or sale of the ap-
2 proval, does not transfer the regulatory obligations
3 of the developer under this subchapter to the trans-
4 feree, licensee, or purchaser.

5 “(j) TRANSFER OR SALE OF APPROVAL.—

6 “(1) NOTICE REQUIRED.—If a developer of an
7 in vitro clinical test transfers or sells the approval
8 of the test issued under subsection (c), (d), or (f)(1),
9 the transferor or seller shall submit a notice of the
10 transfer or sale to the Secretary.

11 “(2) EFFECT OF APPROVAL TRANSFER.—Upon
12 completion of a transfer or sale described in para-
13 graph (1), the transferee or purchaser shall have the
14 regulatory obligations of the developer of the in vitro
15 clinical test under this subchapter.

16 “(k) JUSTIFICATION FOR REQUIREMENT TO PRO-
17 VIDE EVIDENCE FROM CLINICAL TRIALS.—

18 “(1) WRITTEN JUSTIFICATION FOR MANDATORY
19 CLINICAL TRIAL.—The Secretary shall not require
20 the developer of an in vitro clinical test to conduct
21 a clinical trial as part of any application under this
22 subchapter, unless such application is for approval
23 of a high-risk in vitro clinical test and the Secretary
24 submits to the developer written notice that—

1 “(A) provides a justification for such re-
2 quirement, including an explanation of why the
3 Secretary determines that, based on scientific
4 or clinical criteria, other evidence is insufficient;
5 and

6 “(B) is signed by the chief scientific officer
7 of the Center for In Vitro Clinical Tests or an-
8 other member of the senior management of
9 such Center.

10 “(2) WRITTEN JUSTIFICATION FOR OTHER
11 CLINICAL STUDIES.—The Secretary shall not require
12 the developer of an in vitro clinical test to conduct
13 a clinical study other than a clinical trial as part of
14 any application under this subchapter unless the
15 Secretary submits to the developer written notice
16 that—

17 “(A) provides a justification for such re-
18 quirement, including an explanation of why the
19 Secretary determines that, based on scientific
20 or clinical criteria, other evidence is insufficient;
21 and

22 “(B) is signed by the chief scientific officer
23 of the Center for In Vitro Clinical Tests or an-
24 other member of the senior management of
25 such Center.

1 “(3) WRITTEN JUSTIFICATION FOR OTHER
2 CLINICAL STUDIES.—The Secretary shall limit the
3 size, scope, and nature of any clinical trial or other
4 clinical study required pursuant to paragraph (1) or
5 (2) to the size, scope, and nature necessary to estab-
6 lish the sufficient evidence not otherwise available,
7 taking into consideration the feasibility of such clin-
8 ical trial or other clinical study.

9 “(4) DEFINITION.—For purposes of this sub-
10 section, the term ‘clinical trial’ means a well-con-
11 trolled clinical study of prospectively collected
12 human specimens that is performed to demonstrate
13 or support clinical validity of the in vitro clinical
14 test.

15 “(1) GRANDFATHERED TESTS.—

16 “(1) IN GENERAL.—An in vitro clinical test
17 first offered on a date that occurs before the date
18 that is 90 calendar days prior to the date of enact-
19 ment of the Diagnostic Accuracy and Innovation
20 Act, and with respect to which the Secretary did not
21 require an approval under section 515, a clearance
22 under section 510(k), or a notification under section
23 510(j), or otherwise assert enforcement discretion
24 under such sections, is legally marketed and is not

1 subject to premarket review under this section, ex-
2 cept as provided in paragraph (4), if the developer—

3 “(A) lists such in vitro clinical test in ac-
4 cordance with subsection (o)(3); and

5 “(B) with respect to a non-reviewed, high-
6 risk test, submits to the Secretary, not later
7 than 5 years after the date of enactment of the
8 Diagnostic Accuracy and Innovation Act, a
9 summary of available analytical validity and
10 clinical validity evidence.

11 “(2) CONTENTS OF SUMMARY.—A summary re-
12 quired by paragraph (1)(B)—

13 “(A) need not contain any evidence other
14 than existing evidence readily available to the
15 developer and shall be provided in summary
16 form; and

17 “(B) shall not be subject to a user fee
18 under section 4 of the Diagnostic Accuracy and
19 Innovation Act.

20 “(3) NO ADDITIONAL APPLICATION RE-
21 QUIRED.—The developer of an in vitro clinical test
22 that is described in paragraph (1) and listed in ac-
23 cordance with subsection (o) need not submit any
24 application for premarket approval of such test

1 under subsection (c), (d), or (f), except as provided
2 in paragraph (4).

3 “(4) SUBMISSION OF CERTAIN TESTS.—

4 “(A) IN GENERAL.—The Secretary shall
5 provide written notification to the developer of
6 an in vitro clinical test described in paragraph
7 (1) if, after creating a related administrative
8 file, the Secretary determines, based on all
9 available evidence, including a literature review,
10 that such in vitro clinical test—

11 “(i) presents an unreasonable and
12 substantial risk of death or serious adverse
13 health consequences when used as intended
14 by its developer; or

15 “(ii) is being offered by its developer
16 with materially deceptive or fraudulent an-
17 alytical or clinical claims.

18 “(B) INCLUSION OF BASIS FOR DETER-
19 MINATION.—A notification under subparagraph
20 (A) shall set forth in detail the basis for the
21 Secretary’s determination.

22 “(C) MISBRANDING.—Upon receipt of a
23 written notification under subparagraph (A)—

24 “(i) the developer of such an in vitro
25 clinical test may avoid a finding of mis-

1 branding pursuant to clause (ii) by, not
2 later than 120 calendar days after the date
3 on which the developer receives such notifi-
4 cation or by such later date as may be
5 agreed to by the developer and the Sec-
6 retary —

7 “(I) submitting a proposed plan
8 and timeframe for addressing the con-
9 cerns identified in the notification;

10 “(II) submitting a premarket
11 submission for such test under sub-
12 section (c), (d), or (f), as applicable;

13 “(III) ceasing to offer such test;

14 “(IV) otherwise addressing the
15 agency’s concerns; and

16 “(ii) if the developer fails (by the
17 deadline applicable under clause (i)) to
18 submit a plan, to submit an application,
19 cease offering such test, or otherwise ad-
20 dress the agency’s concerns as described in
21 such clause, or if the Secretary disapproves
22 any application so submitted, the in vitro
23 clinical test is subject to a final agency ac-
24 tion finding such in vitro test to be mis-
25 branded under section 502.

1 “(D) APPLICATION CONSIDERATIONS.—In
2 reviewing a premarket submission submitted
3 under subparagraph (C)(i)(II), the Secretary
4 shall consider—

5 “(i) previously unpublished evidence
6 provided by the developer submitting such
7 application; and

8 “(ii) the developer’s description of the
9 past experience with the in vitro clinical
10 test.

11 “(E) TEMPORARY SALES PERIOD.—During
12 the period of the review of a premarket submis-
13 sion submitted under subparagraph (C)(i)(II),
14 the developer submitting such premarket sub-
15 mission with respect to an in vitro clinical test
16 may continue to offer the test, without limita-
17 tion, during the pendency of such submission
18 and if such submission is disapproved, until the
19 date specified by the Secretary.

20 “(5) DEFINITION.—In this subsection, the term
21 ‘non-reviewed, high-risk test’ means an in vitro clin-
22 ical test—

23 “(A) first offered on a date that occurs be-
24 fore the date that is 90 calendar days prior to
25 the date of enactment of the Diagnostic Accu-

1 racy and Innovation Act, and with respect to
2 which the Secretary did not require an approval
3 under section 515, a clearance under section
4 510(k), or a notification under section 510(j),
5 or otherwise assert enforcement discretion
6 under such sections;

7 “(B) for which the developer does not hold
8 an approval under section 515 or a clearance
9 under section 510(k);

10 “(C) which has not been approved by a
11 State pursuant to section 353 of the Public
12 Health Service Act, including the New York
13 State approval process established pursuant to
14 part 58 of title 10 (relating to health) of the
15 Official Compilation of Codes, Rules, and Regu-
16 lations of the State of New York and any modi-
17 fications to such process after the date of the
18 enactment of the Diagnostic Accuracy and In-
19 novation Act; and

20 “(D) which is classified as high-risk pursu-
21 ant to section 590A(e).

22 “(m) IN VITRO CLINICAL TESTS WITH MARKETING
23 AUTHORIZATION UNDER THE DEVICE AUTHORITIES.—If
24 an in vitro clinical test received marketing authorization
25 from the Food and Drug Administration as a device prior

1 to the date of enactment of the Diagnostic Accuracy and
2 Innovation Act:

3 “(1) If the test was approved under section
4 515—

5 “(A) such test is deemed to have an ap-
6 proved application in effect under subsection
7 (c); and

8 “(B) any conditions of approval or other
9 requirements under section 515 specifically ap-
10 plicable to such test pursuant to such approval
11 under section 515 shall continue to apply until
12 the effective date of the regulations imple-
13 menting this subchapter.

14 “(2) If the test was cleared under section
15 510(k)—

16 “(A) such test shall be deemed to have an
17 approved application in effect under subsection
18 (d); and

19 “(B) any requirements under section
20 510(k) specifically applicable to such test pur-
21 suant to such clearance shall continue to apply
22 until the effective date of the regulations imple-
23 menting this subchapter.

24 “(3) If the test was granted marketing author-
25 ization under section 513(f)(2)—

1 “(A) such test is deemed to have an ap-
2 proved application in effect under subsection
3 (d); and

4 “(B) any conditions of approval or other
5 requirements under section 513(f)(2) specifi-
6 cally applicable to such test pursuant to such
7 authorization under section 513(f)(2) shall con-
8 tinue to apply until the effective date of the
9 regulations implementing this subchapter.

10 “(n) PREMARKET REQUIREMENTS FOR MODIFICA-
11 TIONS.—

12 “(1) IN GENERAL.—For purposes of this sub-
13 chapter, a modification to an in vitro clinical test is
14 subject to approval or listing as required by sub-
15 section (c), (d), (e), or (f) in accordance with the fol-
16 lowing:

17 “(A) In the case of a modification made
18 with respect to a low-risk in vitro clinical test,
19 the modification is subject to such process only
20 if the modification—

21 “(i) changes the intended use or adds
22 a new intended use such that the low-risk
23 in vitro clinical test would be classified as
24 moderate-risk or high-risk; or

1 “(ii) results in a meaningful clinical
2 impact such that the test would be classi-
3 fied as a moderate-risk or high-risk test.

4 “(B) In the case of a modification made
5 with respect to a moderate-risk in vitro clinical
6 test, the modification is subject to such process
7 only if the modification—

8 “(i) changes the intended use or adds
9 a new intended use that is high-risk or
10 moderate-risk; or

11 “(ii) results in a meaningful clinical
12 impact.

13 “(C) In the case of a modification made
14 with respect to a high-risk in vitro clinical test,
15 the modification is subject to such process only
16 if the modification—

17 “(i) changes the intended use or adds
18 a new intended use of the test that is high-
19 risk or moderate-risk; or

20 “(ii) results in a meaningful clinical
21 impact.

22 “(2) TREATMENT OF MODIFIED CLASSIFICA-
23 TION.—In the case of a modification described in
24 paragraph (1), the applicable process for approval or
25 listing of the in vitro clinical test with respect to

1 which the modification is made shall be determined
2 in accordance with the risk classification of the test
3 as so modified, unless validation and verification
4 demonstrate that there is not a meaningful increase
5 in risk to the patient or user for the intended uses
6 compared to the risk assessment for the in vitro clin-
7 ical test as previously approved.

8 “(3) NOTIFICATION.—If the risk assessment for
9 the modification, prior to consideration of
10 verification and validation and considering relevant
11 existing mitigating measures, demonstrates that
12 there is a meaningful and not remote increase in
13 risk to the patient or user for the intended uses
14 compared to the risk assessment for the in vitro clin-
15 ical test as previously approved, but validation and
16 verification demonstrate that there is not a meaning-
17 ful increase in risk to the patient or user for the in-
18 tended uses compared to the risk assessment for the
19 in vitro clinical test as previously approved, the de-
20 veloper of the test shall, not later than the date on
21 which such test is first offered as so modified, sub-
22 mit to the Secretary a notification of such modifica-
23 tion. Such notification shall include—

24 “(A) the name of the in vitro clinical test;

1 “(B) a brief description of the modifica-
2 tion;

3 “(C) a brief summary of the meaningful
4 and not remote risks identified by the risk as-
5 sessment described in such paragraph; and

6 “(D) a brief summary of the validation
7 and verification methodologies or the mitigating
8 measures used with respect to the test, includ-
9 ing a brief summary of the results of validation
10 and verifications studies performed with respect
11 to the test.

12 “(4) EXCEPTION FOR MODIFICATIONS SATIS-
13 FYING RECOGNIZED STANDARDS.—

14 “(A) IN GENERAL.—Notwithstanding para-
15 graph (1), a premarket application shall not be
16 required to be submitted under subsection (c),
17 (d), or (f) with respect to a modification to a
18 moderate-risk or high-risk in vitro clinical test
19 if the developer of such test—

20 “(i) maintains records documenting
21 that the modification—

22 “(I) satisfies a standard applica-
23 ble to the modification that is recog-
24 nized by, or contained in a regulation

1 or guidance issued by, the Secretary;

2 or

3 “(II) is made pursuant to meth-
4 ods or criteria approved or included in
5 a premarket submission approved or
6 cleared by the Secretary for the in
7 vitro clinical test being modified;

8 “(ii) maintains any documentation re-
9 quired by the standard specified in clause
10 (i)(I) or methodology or criteria specified
11 in clause (i)(II); and

12 “(iii) submits to the Secretary on an
13 annual basis a report summarizing each
14 such modification to a high-risk in vitro
15 clinical test.

16 “(B) SPECIMEN-RELATED MODIFICA-
17 TIONS.—Notwithstanding paragraph (1), a pre-
18 market application or listing shall not be re-
19 quired to be submitted pursuant to subsection
20 (c), (d), (e), or (f) with respect to a modifica-
21 tion to an in vitro clinical test if the modifica-
22 tion is a specimen-related modification—

23 “(i) made pursuant to methods or cri-
24 teria approved or included in a premarket
25 submission to the Secretary for the in vitro

1 clinical test being modified or methods,
2 standards, or criteria otherwise approved
3 or recognized by the Secretary;

4 “(ii) made solely for the purpose of
5 extending specimen stability; or

6 “(iii) otherwise subject to an excep-
7 tion from, or not described in, paragraph
8 (1).

9 “(5) NEW PLATFORMS AND IN VITRO CLINICAL
10 TEST REPLACEMENTS.—

11 “(A) IN GENERAL.—When an in vitro clin-
12 ical test has been approved, or is otherwise le-
13 gally marketed pursuant to this section for use
14 on a specific platform that has been approved,
15 legally marketed, or deemed approved under
16 this section within a platform family, a submis-
17 sion under subsection (c), (d), or (f) shall not
18 be required for application of that in vitro clin-
19 ical test to a new platform within that platform
20 family.

21 “(B) PLATFORM FAMILIES.—A platform is
22 in a platform family if the developer dem-
23 onstrates and documents internally that the
24 platform and platform family—

1 “(i) have the same basic design and
2 performance characteristics;

3 “(ii) have the same intended use and
4 function;

5 “(iii) share the same measurement
6 principle; and

7 “(iv) produce a similar analytical re-
8 sult from samples of the same specimen
9 type.

10 “(6) OFFERING ALLOWED.—

11 “(A) IN GENERAL.—In the case of a modi-
12 fication subject to the notification requirement
13 under paragraph (3), notwithstanding para-
14 graph (1), the developer of the in vitro clinical
15 test involved may offer the test during the 30-
16 day period beginning on the date on which the
17 developer is notified of the Secretary’s receipt
18 of the notice of such modification, which shall
19 be no later than 5 days after actual receipt by
20 the Secretary, unless the Secretary, within such
21 30-day period—

22 “(i) informs the developer in writing
23 that the notice is not adequate to satisfy
24 the standard in paragraph (3); and

1 “(ii) informs the developer of such
2 further information or action that is re-
3 quired for acceptance of such modification
4 under paragraph (3).

5 “(B) ACCEPTANCE.—If the Secretary does
6 not take an action described in clause (i) or (ii)
7 of subparagraph (A) with respect to a modifica-
8 tion by the end of the 30-day period described
9 in such subparagraph—

10 “(i) the Secretary shall be considered
11 to have accepted the modification; and

12 “(ii) the developer may offer or con-
13 tinue to offer the in vitro clinical test.

14 “(C) REVIEW OF SUPPLEMENTAL APPLICA-
15 TION.—The Secretary shall review any submis-
16 sion required to be submitted pursuant to
17 clause (i) or (ii) of subparagraph (A) not later
18 than 120 days after the receipt of the supple-
19 mental submission for a high-risk in vitro clin-
20 ical test, or 75 days after the receipt of the sup-
21 plemental submission for a moderate-risk in
22 vitro clinical test. The number of days during
23 which the Secretary reviews a notice of such
24 modification shall be deducted from such 120-
25 day or 75-day review period.

1 “(7) DETERMINATION ON WHETHER TO MAKE
2 SUBMISSION.—The entity that modifies an in vitro
3 clinical test is the entity responsible for submitting
4 such modification for any approval or listing re-
5 quired by paragraph (1) and for any related quality
6 system requirements under section 590D.

7 “(8) SCOPE OF REVIEW.—In reviewing a modi-
8 fication to an in vitro clinical test pursuant to this
9 subsection, the Secretary shall limit the scope of the
10 review to the modification and the effect of such
11 modification and shall not conduct a de novo review
12 of the overall test.

13 “(9) DEFINITION OF MEANINGFUL CLINICAL
14 IMPACT.—In this subsection, the term ‘meaningful
15 clinical impact’ means, with respect to a modifica-
16 tion of an in vitro clinical test—

17 “(A) a modification that changes the diag-
18 nosis or therapy delivered to the patient;

19 “(B) a modification of, or an addition to,
20 the indications for use of the test that—

21 “(i) introduce new risks not typically
22 associated with the previous indications for
23 use;

1 “(ii) impact public health to a signifi-
2 cantly greater degree than the previous in-
3 dications for use;

4 “(iii) are not supported by a body of
5 evidence that reflects an understanding
6 within the scientific or clinical community
7 that the changed or additional indications
8 for use are a subset of previous indications
9 for use; or

10 “(iv) are such that performance char-
11 acteristics or clinical endpoints established
12 to evaluate the previous indications for use
13 cannot be applied to the changed or addi-
14 tional indications for use;

15 “(C) a modification that causes a low-risk
16 in vitro clinical test to no longer meet required
17 mitigating measures established for such test,
18 such that the modified test is classified as a
19 moderate-risk or high-risk test;

20 “(D) a modification to a moderate-risk or
21 high-risk in vitro clinical test if the risk assess-
22 ment for the modification, prior to consider-
23 ation of verification and validation and consid-
24 ering relevant existing mitigating measures,
25 demonstrates that there is a meaningful and

1 not remote increase in risk to the patient or
2 user for the intended uses, unless validation
3 and verification demonstrate that there is not a
4 meaningful increase in risk to the patient or
5 user for the intended uses compared to the risk
6 assessment for the test as previously approved;
7 or

8 “(E) in the case of a modification to a
9 moderate-risk or high-risk in vitro clinical test,
10 a modification that, if, following verification
11 and validation of the test, the in vitro clinical
12 test no longer meets the analytical or clinical
13 performance standards for the intended uses for
14 which the test is approved.

15 “(o) LISTING REQUIREMENT.—

16 “(1) IN GENERAL.—The Secretary shall estab-
17 lish and maintain a list of all in vitro clinical tests
18 approved or otherwise required to be listed under
19 this subchapter.

20 “(2) PROCESS AND CONTENT OF LISTING.—

21 The list under paragraph (1) shall, with respect to
22 each in vitro clinical test, include—

23 “(A) the name of the in vitro clinical test;

24 “(B) the name and contact information of
25 the developer;

1 “(C) with respect to a laboratory test pro-
2 tocol transferred, licensed, or purchased under
3 subsection (i), the name and contact informa-
4 tion of any transferee, licensee, or purchaser
5 and the completion date of such transfer, li-
6 cense, or purchase;

7 “(D) a statement of whether the in vitro
8 clinical test is a laboratory test protocol or a
9 finished product;

10 “(E) the intended use of the in vitro clin-
11 ical test; and

12 “(F) the classification, if available, or a
13 similar summary description of the in vitro clin-
14 ical test.

15 “(3) PROCESS AND TIMING OF LISTING.—The
16 developer of an in vitro clinical test that is approved
17 or otherwise required to be listed under this sub-
18 chapter shall list with the Secretary the information
19 described in paragraph (2)—

20 “(A) in the case of an in vitro clinical test
21 first offered on or after the date that is 180
22 calendar days after enactment of the Diagnostic
23 Accuracy and Innovation Act, not later than 10
24 calendar days after the date on which such in
25 vitro clinical test is first offered;

1 “(B) in the case of an in vitro clinical test
2 that has been first offered before the date that
3 is 180 calendar days after enactment of the Di-
4 agnostic Accuracy and Innovation Act, and
5 which continues to be so offered, not later than
6 180 calendar days after the date of the enact-
7 ment of such Act; and

8 “(C) in the case of a laboratory test pro-
9 tocol that is transferred, licensed, or sold under
10 subsection (i), the later of—

11 “(i) 180 calendar days after enact-
12 ment of the Diagnostic Accuracy and Inno-
13 vation Act; or

14 “(ii) 10 calendar days after the date
15 of completion of such transfer, license, or
16 sale.

17 “(4) UPDATED LISTING.—The developer of an
18 in vitro clinical test shall submit an updated listing
19 under paragraph (3) on an annual basis.

20 “(p) REGISTRATION.—

21 “(1) INITIAL REGISTRATION.—Before the ear-
22 lier of offering an in vitro clinical test or submitting
23 an application for approval of such a test under this
24 section, the developer of the test shall register with
25 the Secretary and include in such registration—

1 “(A) the developer’s name;

2 “(B) the developer’s place of business; and

3 “(C) a list of the establishments at which
4 the developer is engaged in the design, develop-
5 ment, validation, production, manufacture,
6 preparation, propagation, or assembly of an in
7 vitro clinical test.

8 “(2) ESTABLISHMENTS WITH GRANDFATHERED
9 IN VITRO CLINICAL TESTS.—Notwithstanding para-
10 graph (1), the developer of an in vitro clinical test
11 described in subsection (l)(1) shall register with Sec-
12 retary and include in such registration the informa-
13 tion listed in paragraph (1) not later than 180 cal-
14 endar days after the date of enactment of the Diag-
15 nostic Accuracy and Innovation Act.

16 “(3) ADDITIONAL ESTABLISHMENTS.—Every
17 developer of an in vitro clinical test required to be
18 registered under paragraph (1) or (2) shall register
19 with the Secretary any additional establishment at
20 which the developer begins the design, development,
21 validation, production, manufacture, preparation,
22 propagation, or assembly of an in vitro clinical test
23 not later than 30 calendar days after first engaging
24 in such activity.

1 “(4) ANNUAL UPDATES.—On or before Decem-
2 ber 31 of each year, every developer of an in vitro
3 clinical test shall submit an updated registration
4 under paragraph (1) or (2), as applicable.

5 “(5) INFORMATION CHANGES.—The developer
6 of an in vitro clinical test shall notify the Secretary
7 of any change to the registration information pro-
8 vided under this subsection not later than 30 cal-
9 endar days after such change.

10 “(6) AFFILIATE REGISTRATION.—Registration
11 information required to be submitted by a developer
12 of an in vitro clinical test under this subsection may
13 be submitted by a parent, subsidiary, or affiliate
14 company with respect to any establishment under
15 the joint ownership or control of the submitter and
16 the developer.

17 “(7) REGULATIONS.—The Secretary shall, to
18 the extent possible, harmonize regulations for car-
19 rying out this subsection with the corresponding reg-
20 ulations for registration with respect to devices.

21 “(q) LABELING.—Notwithstanding any provision of
22 this Act—

23 “(1) an in vitro clinical test may be labeled by
24 electronic means (including by directing health care
25 practitioners and other users to information posted

1 on the Internet) instead of physically affixing the in-
2 formation to the in vitro clinical test;

3 “(2) an in vitro clinical test need not be labeled
4 for purposes of transferring the test between entities
5 if—

6 “(A) the first entity controls or has the
7 power to control the other entity;

8 “(B) the other entity controls or has the
9 power to control the first entity; or

10 “(C) the two entities are under common
11 ownership or control of a third entity;

12 “(3) patient-specific test results from the use of
13 an in vitro clinical test or an interpretation of such
14 patient tests results shall not constitute labeling;

15 “(4) patient-specific scientific or clinical ex-
16 changes or discussion regarding one or more in vitro
17 clinical tests shall not constitute labeling;

18 “(5) the Secretary may require the developer of
19 a platform to receive approval from the Secretary
20 before making any claim regarding the clinical valid-
21 ity of the platform alone; and

22 “(6) in vitro clinical test labeling, advertising,
23 and promotion shall not be treated as misbranded or
24 adulterated by reason of—

1 “(A) the use of the terms in vitro diag-
2 nostic device or IVD in lieu of the terms in
3 vitro clinical test or IVCT; and

4 “(B) the use of internationally harmonized
5 symbols without accompanying text.

6 **“SEC. 590C. INVESTIGATIONAL AND RESEARCH USE IN**
7 **VITRO CLINICAL TESTS.**

8 “(a) IN GENERAL.—Except as provided in subsection
9 (b), an in vitro clinical test for investigational use shall
10 be exempt from the requirements of this subchapter other
11 than sections 590F, 590G, and 590H. Sections 502 and
12 721, made applicable to in vitro clinical tests by section
13 590H, shall not apply to such tests.

14 “(b) APPLICATION FOR AN EXEMPTION.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish a process under which—

17 “(A) the Secretary shall require that in the
18 case of an in vitro clinical test the investiga-
19 tional use of which the Secretary determines
20 poses a significant risk to the public health
21 (other than with respect to an investigation for
22 the collection of clinical data through processes
23 other than a prospective clinical trial), a spon-
24 sor of an investigation of such a test seeking an
25 exemption under subsection (a) submits to the

1 Secretary an investigational use application
2 with respect to the test in accordance with
3 paragraphs (2) and (3); and

4 “(B) in the case of an in vitro clinical test,
5 the investigational use of which the Secretary
6 does not determine poses such a risk—

7 “(i) the Secretary shall require that
8 the sponsor of such investigation complies
9 with—

10 “(I) the requirements specified in
11 paragraphs (3)(A), (3)(B), and
12 (5)(A)(iii); and

13 “(II) such other requirements as
14 the Secretary may reasonably deter-
15 mine to be necessary for the protec-
16 tion of the public health and safety,
17 including the monitoring of investiga-
18 tions conducted with such test, the es-
19 tablishment and maintenance of
20 records, and the submission to the
21 Secretary of reports of data obtained
22 as a result of the investigational use
23 of the in vitro clinical test during the
24 period covered by the exemption; and

1 “(ii) the exemptions specified in para-
2 graph (5)(B) and subsection (g) are avail-
3 able with respect to such test.

4 “(2) APPLICATION CONTENTS.—An investiga-
5 tional use application shall be submitted in such
6 time and manner and contain such information as
7 the Secretary may require, including assurances to
8 the satisfaction of the Secretary that the sponsor in-
9 volved shall, with respect to the in vitro clinical test
10 that is the subject of the application—

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

13 “(B) submit to the Secretary reports of
14 data obtained as a result of the investigational
15 use of the in vitro clinical test during the period
16 covered by the exemption that the Secretary
17 reasonably determines will enable the Sec-
18 retary—

19 “(i) to ensure compliance with the
20 conditions for approval specified in para-
21 graph (3);

22 “(ii) to review the progress of the in-
23 vestigation involved; and

24 “(iii) to evaluate the analytical valid-
25 ity and clinical validity of such test.

1 “(3) CONDITIONS OF APPROVAL.—An investiga-
2 tional use application shall only be approved if—

3 “(A) the proposed labeling for the in vitro
4 clinical test involved clearly and conspicuously
5 states ‘For investigational use’;

6 “(B) in the case of an application sub-
7 mitted with respect to an in vitro clinical test
8 the clinical testing of which involves human
9 subjects, the sponsor of the investigation—

10 “(i) if the Secretary has established
11 an institutional review committee to super-
12 vise clinical testing of such in vitro clinical
13 tests, submits—

14 “(I) to such committee a plan
15 that meets the requirements specified
16 in paragraph (5) for any proposed
17 clinical testing of the in vitro clinical
18 test and a report of prior investiga-
19 tions of the test adequate to justify
20 the proposed clinical testing; and

21 “(II) to the Secretary a summary
22 of such plan and a report of prior in-
23 vestigations; or

24 “(ii) if no such committee has been so
25 established or the Secretary finds that the

1 process of review by such a committee is
2 inadequate (whether or not the plan for
3 such testing has been approved by such
4 committee), for purposes of beginning clin-
5 ical testing of the test, submits to the Sec-
6 retary a plan that meets the requirements
7 specified in paragraph (5) for any pro-
8 posed clinical testing of the in vitro clinical
9 test and a report of prior investigations of
10 the test adequate to justify the proposed
11 clinical testing; and

12 “(C) the sponsor submitting such applica-
13 tion provides assurances to the Secretary that
14 the sponsor will comply with such other require-
15 ments as the Secretary may reasonably deter-
16 mine to be necessary for the protection of the
17 public health and safety.

18 “(4) COORDINATION WITH INVESTIGATIONAL
19 NEW DRUG APPLICATIONS.—Any requirement for
20 the submission of a report to the Secretary pursuant
21 to an investigational new drug application involving
22 an in vitro clinical test shall supersede the reporting
23 requirement in paragraph (2)(B), but only to the ex-
24 tent the requirement with respect to the investiga-

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

3 “(5) INVESTIGATION PLAN REQUIREMENTS.—

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

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

15 “(ii) in the case of an in vitro clinical
16 test to be distributed or otherwise made
17 available to investigators for clinical test-
18 ing, obtain, and submit to the Secretary,
19 signed agreements from each of the indi-
20 viduals carrying out the investigation that
21 is the subject of such plan that—

22 “(I) any testing under such plan
23 involving human subjects will be
24 under the supervision of such indi-
25 vidual; and

1 “(II) the individual will ensure
2 that informed consent is obtained
3 from each such human subject; and

4 “(iii) submit an assurance to the Sec-
5 retary that informed consent will be ob-
6 tained from each human subject (or the
7 representative of such subject) of proposed
8 clinical testing involving such in vitro clin-
9 ical test, except in cases in which, subject
10 to such other conditions as the Secretary
11 may prescribe—

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

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

1 “(aa) there exists a life-
2 threatening situation involving
3 the human subject of such test-
4 ing which necessitates the use of
5 such in vitro clinical test;

6 “(bb) it is not feasible to ob-
7 tain informed consent from the
8 subject; and

9 “(cc) there is not sufficient
10 time to obtain such consent from
11 his representative.

12 “(B) EXCEPTIONS.—

13 “(i) SIGNED AGREEMENTS NOT RE-
14 QUIRED FOR AFFILIATES.—Subparagraph
15 (A)(iii) shall not apply to the distribution
16 of or other arrangements by a sponsor to
17 make available an in vitro clinical test to
18 an investigator that is employed by or af-
19 filiated with the sponsor.

20 “(ii) CONCURRENCE OF PHYSICIAN
21 NOT REQUIRED.—The requirement to ob-
22 tain the concurrence of a licensed physi-
23 cian with respect to a determination under
24 subparagraph (A)(iii)(II) shall not apply
25 if—

1 “(I) immediate use of the in vitro
2 clinical test in the investigation in-
3 volved is required to save the life of
4 the human subject; and

5 “(II) there is not sufficient time
6 to obtain such concurrence.

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

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

22 “(II) the identity of the subject
23 of the specimen is not known to, and
24 may not readily be ascertained by, the
25 investigator or any other individual

1 associated with the investigation, in-
2 cluding the sponsor;

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

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

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

22 “(6) CLASSIFICATION.—If a developer seeks
23 classification of an in vitro clinical test during its in-
24 vestigational use, the Secretary shall use processes

1 and classifications that are consistent with the proc-
2 esses and classifications under section 590A.

3 “(7) VARIATION OF REQUIREMENTS AL-
4 LOWED.—The requirements of this subsection with
5 respect to an investigational use application may
6 vary based on—

7 “(A) the scope and duration of clinical
8 testing to be conducted under investigation that
9 is the subject of such application;

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

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

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

19 “(c) REVIEW OF APPLICATIONS.—

20 “(1) FAILURE TO ACT.—Unless the Secretary,
21 not later than the date that is 30 calendar days
22 after the date of the submission of an investigational
23 use application that meets the requirements of sub-
24 section (b)(2), issues an order disapproving the ap-
25 plication and notifies the sponsor submitting the ap-

1 plication of such disapproval, the application shall be
2 treated as approved as of such date without further
3 action by the Secretary.

4 “(2) DISAPPROVAL.—The Secretary may dis-
5 approve an investigational use application submitted
6 under this subsection only if the Secretary deter-
7 mines that the investigation with respect to which
8 the application is submitted does not conform to the
9 requirements of subsection (b)(3). A notification of
10 such disapproval submitted to the sponsor with re-
11 spect to such an application shall—

12 “(A) contain the order of disapproval and
13 a complete statement of the reasons for the
14 Secretary’s disapproval of the application; and

15 “(B) provide the sponsor with an oppor-
16 tunity for an informal hearing on the dis-
17 approval.

18 “(d) WITHDRAWAL OF APPROVAL.—

19 “(1) IN GENERAL.—The Secretary may, by ad-
20 ministrative order, withdraw the approval of an ex-
21 emption granted under this subsection with respect
22 to an in vitro clinical test if the Secretary deter-
23 mines that the test does not meet the applicable con-
24 ditions under subsection (b)(3) for such approval.

25 “(2) OPPORTUNITY TO BE HEARD.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), an order withdrawing the approval
3 of an exemption granted under this subsection
4 may be issued after the Secretary provides the
5 applicant or sponsor of the test with an oppor-
6 tunity for an informal hearing.

7 “(B) EXCEPTION.—An order referred to in
8 subparagraph (A) with respect to an exemption
9 granted under this subsection may be issued be-
10 fore the provision of an opportunity for an in-
11 formal hearing if the Secretary determines that
12 the continuation of testing under the exemption
13 will result in an unreasonable risk to the public
14 health.

15 “(e) CHANGES.—

16 “(1) IN GENERAL.—The Secretary shall by reg-
17 ulation establish, with respect to an in vitro clinical
18 test for which an exemption under this subsection is
19 in effect, procedures and conditions under which the
20 changes to the test are allowed without the addi-
21 tional approval of an application for an exemption or
22 the approval of a supplement to such an application.
23 Such regulations shall provide that such a change
24 may be made if—

1 “(A) the sponsor or applicant determines,
2 on the basis of credible information (as defined
3 by the Secretary) that the change meets the
4 conditions specified in paragraph (2); and

5 “(B) the sponsor or applicant submits to
6 the Secretary, not later than 5 calendar days
7 after making the change, a notice of the
8 change.

9 “(2) CONDITIONS.—The conditions specified in
10 this paragraph are that—

11 “(A) in the case of developmental changes
12 to an in vitro clinical test (including manufac-
13 turing changes), the changes—

14 “(i)(I) do not constitute a significant
15 change in design or in basic principles of
16 operation; or

17 “(II) do not constitute a significant
18 increase in risk to patients; and

19 “(ii) are made in response to informa-
20 tion gathered during the course of an in-
21 vestigation; and

22 “(B) in the case of changes to clinical pro-
23 tocols applicable to the test, the changes do not
24 affect—

1 “(i) the validity of data or information
2 resulting from the completion of an ap-
3 proved clinical protocol;

4 “(ii) the scientific soundness of a plan
5 submitted under subsection (b)(3)(B); or

6 “(iii) the rights, safety, or welfare of
7 the human subjects (if any) involved in the
8 investigation.

9 “(f) PRESUBMISSION MEETING.—

10 “(1) IN GENERAL.—In the case of an applicant
11 intending to investigate the analytical validity or
12 clinical validity of a high- or moderate-risk in vitro
13 clinical test, the Secretary shall ensure that the ap-
14 plicant has an opportunity, prior to submitting an
15 application to the Secretary under subsection (b)(1),
16 to submit to the Secretary for review an investiga-
17 tional plan (including a clinical protocol).

18 “(2) REQUEST FOR MEETING.—If the applicant
19 described in paragraph (1) submits a written request
20 for a meeting with the Secretary regarding the re-
21 view of an investigational plan described in such
22 paragraph, the Secretary shall, not later than 30
23 calendar days after receiving the request, meet with
24 the applicant for the purpose of reaching agreement

1 regarding the investigational plan. The written re-
2 quest shall include—

3 “(A) a detailed description of the in vitro
4 clinical test involved;

5 “(B) a detailed description of the proposed
6 conditions of use of such test; and

7 “(C) a proposed plan (including a clinical
8 protocol) for determining whether there is a
9 reasonable assurance of clinical validity or prob-
10 able clinical validity (as applicable) of, and, if
11 available, information regarding the expected
12 performance from, such test.

13 “(3) AGREEMENT.—

14 “(A) REDUCED TO WRITING.—Any agree-
15 ment under this subsection between the Sec-
16 retary and an applicant described in paragraph
17 (1) shall be in writing and part of the adminis-
18 trative record.

19 “(B) NO AMENDMENTS.—An agreement
20 described in paragraph (1) shall not be changed
21 except—

22 “(i) with the written agreement of the
23 applicant described in such paragraph; or

24 “(ii) pursuant to a decision, made in
25 accordance with subparagraph (C) by the

1 director of the center involved in the re-
2 view, that a substantial scientific issue es-
3 sential to determining the clinical validity
4 of the in vitro clinical test involved has
5 been identified.

6 “(C) DECISION BY DIRECTOR.—A decision
7 referred to in subparagraph (B)(ii) shall be in
8 writing, and may be made only after the Sec-
9 retary has provided to the applicant described
10 in paragraph (1) an opportunity for a meeting
11 at which the director and such applicant are
12 present and at which the director documents
13 the scientific issue involved, the decision, and
14 the rationale for the decision.

15 “(g) EXEMPTION FROM HUMAN SUBJECT REGULA-
16 TIONS.—An investigation conducted under an exemption
17 under this section with respect to an in vitro clinical test
18 that involves the collection or study of existing data, docu-
19 ments, records, pathological specimens, or diagnostic
20 specimens, is exempt from the rules in part 50 of title
21 21, Code of Federal Regulations (or any successor regula-
22 tions), if the information obtained during such investiga-
23 tion is recorded by the investigator in such a manner that
24 the subjects cannot be identified, directly or through per-
25 sonally identifiable information linked to the subjects.

1 “(h) CLINICAL HOLD.—

2 “(1) IN GENERAL.—At any time, the Secretary
3 may impose a clinical hold with respect to an inves-
4 tigation of an in vitro clinical test if the Secretary
5 makes a determination described in paragraph (2).
6 The Secretary shall, in imposing such clinical hold,
7 specify the basis for the clinical hold, including the
8 specific information available to the Secretary which
9 served as the basis for such clinical hold, and con-
10 firm such determination in writing. The applicant or
11 sponsor may immediately appeal any such deter-
12 mination pursuant to section 590F.

13 “(2) DETERMINATION.—For purposes of para-
14 graph (1), a determination described in this sub-
15 paragraph with respect to a clinical hold is a deter-
16 mination that—

17 “(A) based on credible evidence, the in
18 vitro clinical test involved presents an unreason-
19 able risk to the safety of the persons who are
20 the subjects of the investigation, taking into ac-
21 count the qualifications of the investigators, in-
22 formation about the in vitro clinical test, the
23 design of the investigation, the condition for
24 which the in vitro clinical test is to be inves-

1 tigated, and the health status of the subjects in-
2 volved; or

3 “(B) based on credible evidence, investi-
4 gator misconduct or applicant or sponsor non-
5 compliance with the requirements of this section
6 present an unreasonable risk to the safety of
7 the persons who are the subjects of the clinical
8 investigation.

9 “(3) APPEAL.—An applicant or sponsor of an
10 investigation may submit to the Secretary a written
11 request that a clinical hold imposed under this sub-
12 section be removed. Any such request shall include
13 sufficient information to support the removal of such
14 clinical hold. Not later than 30 calendar days after
15 receipt of such request, the Secretary shall respond
16 to such a request, in writing and, if denying such re-
17 quest, specify the reasons for such denial.

18 “(i) DEFINITIONS.—In this section:

19 “(1) The term ‘affiliated’ means, with respect
20 to an applicant or sponsor, owning the applicant or
21 sponsor, owned by the applicant or sponsor, under
22 common ownership with the applicant or sponsor, or
23 in a joint venture with the applicant or sponsor.

24 “(2) The term ‘clinical hold’ means an action
25 taken by the Secretary prohibiting the applicant or

1 sponsor of an investigation of an in vitro clinical test
2 from conducting the investigation.

3 “(3) The term ‘invasive sampling procedure’,
4 does not include venipuncture or other minimally
5 invasive sampling procedures, or the use of surplus
6 samples of body fluids or tissues that remain from
7 samples previously taken.

8 “(4) The term ‘investigational use application’
9 means, with respect to an in vitro clinical test, an
10 application submitted under subsection (b)(1)(A) for
11 the use of the test by experts qualified by scientific
12 training and experience to investigate the analytical
13 validity and clinical validity of the test.

14 “(5) The term ‘serious or life-threatening dis-
15 ease or condition’ means a disease or condition—

16 “(A) for which the likelihood of death
17 within one year is high unless the course of the
18 disease or condition is interrupted;

19 “(B) that results in permanent impairment
20 of a bodily function or permanent damage to a
21 bodily structure within one year unless the
22 course of the disease or condition is inter-
23 rupted; or

24 “(C) that necessitates medical or surgical
25 intervention within one year to preclude perma-

1 nent impairment of a bodily function or perma-
2 nent damage to a bodily structure.

3 “(6) The term ‘significant risk’ means, with re-
4 spect to an in vitro clinical test that is the subject
5 of an investigational use application, that the inves-
6 tigational use of the test—

7 “(A) is a use of substantial importance in
8 identifying, measuring, detecting, predicting,
9 monitoring, or assisting in selecting treatment
10 for, a serious or life-threatening disease or con-
11 dition without confirmation of the diagnosis by
12 a medically established means;

13 “(B) requires an invasive sampling proce-
14 dure; or

15 “(C) otherwise presents a reasonably fore-
16 seeable serious risk to the health of a human
17 subject.

18 “(j) EXCEPTION FOR TESTS USED ONLY IN RE-
19 SEARCH.—

20 “(1) RESEARCH-USE-ONLY TESTS.—

21 “(A) IN GENERAL.—Except as provided in
22 subparagraph (B), research-use-only in vitro
23 clinical tests shall not be subject to the require-
24 ments of this Act.

1 “(B) LABELING.—The Secretary shall re-
2 quire that any research-use-only in vitro clinical
3 test be labeled for research use only.

4 “(2) BASIC RESEARCH TESTS.—Basic research
5 tests shall not be subject to regulation under this
6 Act.

7 “(3) DEFINITIONS.—In this subsection:

8 “(A) RESEARCH-USE-ONLY IN VITRO CLIN-
9 ICAL TEST.—The term ‘research-use-only in
10 vitro clinical test’ means an in vitro clinical test
11 that is intended by the developer for use solely
12 in the laboratory phase of development and the
13 results of which are not intended for use in pa-
14 tient care. Such term does not include an in
15 vitro clinical test intended for investigational
16 use subject to subsection (a) or (b).

17 “(B) BASIC RESEARCH TEST.—The term
18 ‘basic research test’ means a test that—

19 “(i) is intended by the developer solely
20 for use in the conduct of nonclinical lab-
21 oratory research, and not for the develop-
22 ment of an in vitro clinical test; and

23 “(ii) is not an in vitro clinical test.

1 **“SEC. 590D. QUALITY REQUIREMENTS; UNIQUE IDENTIFI-**
2 **FIERS.**

3 “(a) IN GENERAL.—The Secretary shall establish, by
4 regulation, quality requirements for the development and
5 production of in vitro clinical tests offered under this sub-
6 chapter. In establishing such requirements, the Secretary
7 shall consider whether to include requirements for each
8 of the following:

9 “(1) Management responsibility.

10 “(2) Quality audit.

11 “(3) Personnel.

12 “(4) Design controls.

13 “(5) Document controls.

14 “(6) Purchasing controls.

15 “(7) Identification.

16 “(8) Production and process controls.

17 “(9) Acceptance activities.

18 “(10) Nonconforming products.

19 “(11) Corrective and preventive action.

20 “(12) Labeling and package controls.

21 “(13) Handling, storage, distribution, and in-
22 stallation.

23 “(14) Records.

24 “(15) Servicing.

25 “(16) Statistical techniques.

1 “(b) SCOPE.—The quality requirements under this
2 section shall—

3 “(1) apply only with respect to the design, de-
4 velopment, validation, production, manufacture,
5 preparation, propagation, or assembly of an in vitro
6 clinical test, offered under this subchapter;

7 “(2) account for differences between in vitro
8 clinical tests that are finished products and in vitro
9 clinical tests that are laboratory test protocols;

10 “(3) not apply with respect to laboratory oper-
11 ations; and

12 “(4) not apply to components or parts of an in
13 vitro clinical test or raw materials used in an in
14 vitro clinical test.

15 “(c) UNIQUE IDENTIFIERS.—

16 “(1) IN GENERAL.—The Secretary shall pro-
17 mulgate regulations establishing a unique identifica-
18 tion system for finished products requiring the label
19 of finished products to bear a unique identifier, un-
20 less the Secretary requires an alternative placement
21 or provides an exception for a particular finished
22 product.

23 “(2) REQUIREMENTS.—The unique identifier
24 shall adequately identify the finished product
25 through distribution and use, and may include infor-

1 mation on the lot or serial number of the product.
2 The Secretary shall, to the extent possible, har-
3 monize the unique identification system for finished
4 products with, and use tools and systems developed
5 by the Secretary for, the unique device identification
6 system established by the Secretary pursuant to sec-
7 tion 519(f). A unique identifier shall not be required
8 for a laboratory test protocol.

9 **“SEC. 590E. POSTMARKET REQUIREMENTS.**

10 “(a) ADVERSE EVENT REPORTING.—

11 “(1) IN GENERAL.—The developer of any in
12 vitro clinical test approved or listed under section
13 590B shall—

14 “(A) maintain records of any adverse event
15 that is associated with the test and is known by
16 the developer;

17 “(B) include in such records any informa-
18 tion, or references to such information, that is
19 in the developer’s possession and relates to the
20 adverse event, including documentation of the
21 developer’s deliberations used to determine
22 whether an in vitro clinical test error is re-
23 quired to be reported under subparagraph (C)
24 or (E);

1 “(C) submit to the Secretary a report on
2 an adverse event—

3 “(i) not later than 5 calendar days
4 after the adverse event becomes known to
5 the developer, if the adverse event involves
6 a patient death; or

7 “(ii) not later than 15 calendar days
8 after the adverse event becomes known to
9 the developer, if the adverse event presents
10 an imminent threat to public health;

11 “(D) include in any report under clause (i)
12 or (ii) of subparagraph (C), as applicable and
13 available, information regarding—

14 “(i) the patient;

15 “(ii) the in vitro clinical test;

16 “(iii) the adverse event;

17 “(iv) the person who reported the ad-
18 verse event to the developer;

19 “(v) the developer; and

20 “(vi) the laboratory;

21 “(E) not later than 30 calendar days after
22 the end of a calendar quarter, submit to the
23 Secretary a report on any adverse events that
24 are associated with the test and become known

1 to the developer during the preceding quarter of
2 the year, if any; and

3 “(F) include in any report under subpara-
4 graph (E)—

5 “(i) the number and type of such ad-
6 verse events which became known to the
7 developer during the quarter covered by
8 the report, identifying any new types of ad-
9 verse events;

10 “(ii) trend information for a statis-
11 tically meaningful sample period regarding
12 adverse events that are associated with the
13 test; and

14 “(iii) aggregated summary informa-
15 tion regarding the medical impact of such
16 adverse events on patients, if known.

17 “(2) LIMITATION ON SECRETARY’S AUTHORITY
18 TO REQUIRE ADDITIONAL INFORMATION.—With re-
19 spect to a report submitted under paragraph (1)(E),
20 the Secretary may not require that such report in-
21 clude any information other than the information
22 specified in clauses (i), (ii), and (iii) of paragraph
23 (1)(F).

24 “(3) STATEMENT REQUIRED IN LIEU OF INFOR-
25 MATION IN CERTAIN QUARTERS.—A report under

1 paragraph (1)(E) for any quarter in which no ad-
2 verse events occur shall be limited to a statement, to
3 the knowledge of the developer, that no reportable
4 adverse events occurred in such quarter.

5 “(4) LABORATORY ERRORS.—The developer of
6 an in vitro clinical test shall not be required to
7 maintain records or report under this section regard-
8 ing laboratory errors that are subject to section
9 353(f)(5) of the Public Health Service Act and cor-
10 rective and preventive actions to address such errors.

11 “(5) REPORT NOT AN ADMISSION.—A report or
12 other information submitted by a developer or other
13 responsible party under this subsection (and any re-
14 lease by the Secretary of that report or other infor-
15 mation) does not constitute an admission by the de-
16 veloper or other responsible party that, and shall not
17 be discoverable or admissible in a court of law as
18 evidence that, the in vitro clinical test caused or con-
19 tributed to an adverse event.

20 “(6) REQUESTS FOR ALTERNATIVE PROCESS.—
21 The Secretary may establish by regulation and im-
22 plement a program under which—

23 “(A) in vitro clinical test developers may
24 request a process for reporting adverse events

1 other than the processes set forth in this sub-
2 section; and

3 “(B) the Secretary grants or denies any
4 such request by order, notwithstanding sub-
5 chapter II of chapter 5 of title 5, United States
6 Code.

7 “(7) DEFINITIONS.—In this subsection:

8 “(A) The term ‘adverse event’ means—

9 “(i) any death or serious injury that
10 is reasonably believed to have been caused
11 by an in vitro clinical test error; or

12 “(ii) any in vitro clinical test error
13 which is more likely than not to reoccur
14 and, if the error were to reoccur, would
15 have a reasonable probability of causing
16 death or serious injury.

17 “(B) The term ‘caused by an in vitro clin-
18 ical test error’ means that an in vitro clinical
19 test error was the primary factor in the death
20 of, or serious injury to, a specific patient or
21 user.

22 “(C) The term ‘in vitro clinical test error’
23 means a clinically significant failure of an in
24 vitro clinical test to meet its performance speci-
25 fications or otherwise perform as intended, ex-

1 cept that such term excludes any such event or
2 error related to laboratory operations.

3 “(D) The term ‘permanent’ means irre-
4 versible impairment or damage to a body struc-
5 ture or function, excluding trivial impairment or
6 damage.

7 “(E) The term ‘serious injury’ means an
8 injury or illness that—

9 “(i) is life-threatening;

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

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

17 “(b) NOTIFICATION.—

18 “(1) IN GENERAL.—Except with respect to an
19 in vitro clinical test described in section 590B(l)(4),
20 the Secretary may issue such notifications or orders
21 as may be necessary to assure that adequate notifi-
22 cation is provided in an appropriate form, by the
23 persons and means best suited under the cir-
24 cumstances involved, to all health care practitioners
25 who prescribe or use an in vitro clinical test and to

1 any other person (including manufacturers, import-
2 ers, distributors, retailers, and users (including
3 home users)) who should properly receive such noti-
4 fication, if the Secretary determines that—

5 “(A) the in vitro clinical test presents an
6 unreasonable risk of substantial harm to the
7 public health when used as intended; and

8 “(B) notification under this subsection is
9 necessary to eliminate or reduce the unreason-
10 able risk of such harm and no more practicable
11 means is available under the provisions of this
12 Act (other than this section) to eliminate or re-
13 duce such risk.

14 “(2) ORDERS.—An order under this subsection
15 shall require that the individuals subject to the risk
16 with respect to which the order is to be issued be in-
17 cluded in the persons to be notified of the risk un-
18 less the Secretary determines that notice to such in-
19 dividuals would present a greater danger to the
20 health of such individuals than no such notification.
21 That notification shall describe the risk presented by
22 the test and any action which may be taken to elimi-
23 nate or reduce such risk. Before issuing an order
24 under this subsection, the Secretary shall consult

1 with the persons who are to give notice under the
2 order.

3 “(c) VOLUNTARY CORRECTIONS AND REMOVALS.—

4 “(1) IN GENERAL.—A developer or other re-
5 sponsible party may, at any time, initiate a vol-
6 untary correction or removal action with respect to
7 an in vitro clinical test.

8 “(2) NOTICE TO SECRETARY.—Not later than 7
9 calendar days after the first correction or removal
10 action undertaken by the developer or other respon-
11 sible party pursuant to paragraph (1), to reduce a
12 risk to health posed by an in vitro clinical test that
13 is in violation of this subchapter, the developer or
14 other responsible party shall submit to the Sec-
15 retary, as applicable and reasonably necessary—

16 “(A) the name, unique identifier, and other
17 similar information about the in vitro clinical
18 test;

19 “(B) the name, address, contact informa-
20 tion, and registration number of the developer
21 or other responsible party;

22 “(C) a copy of any customer notification
23 issued by the developer or other responsible
24 party;

1 “(D) a description of the problem sought
2 to be addressed by the correction or removal,
3 including a health hazard evaluation;

4 “(E) a status and summary of the devel-
5 oper or other responsible party’s internal inves-
6 tigation;

7 “(F) the number of adverse event reports
8 related to the problem sought to be addressed
9 by the correction or removal;

10 “(G) relevant in vitro clinical test labeling,
11 including instructions for use; and

12 “(H) a list of consignees.

13 “(3) CORRECTION OR REMOVAL IDENTIFIER.—
14 Not later than 7 calendar days after receipt of a no-
15 tification under paragraph (2), the Secretary shall
16 assign a unique correction or removal identifier to
17 such action and provide such identifier to the devel-
18 oper or other responsible party. The developer, Sec-
19 retary, or other responsible party shall include such
20 unique identifier on all subsequent correspondence
21 regarding the correction or removal action with the
22 Secretary, developer, health care practitioner, or any
23 user.

24 “(4) NOTICE TO USERS.—If communication of
25 a correction or removal action is necessary to protect

1 public health, such communication shall include, as
2 applicable and reasonably available—

3 “(A) the unique correction or removal
4 identifier, as assigned by the Secretary;

5 “(B) information sufficient to identify the
6 in vitro clinical test subject to the correction or
7 removal;

8 “(C) a description of the problem sought
9 to be addressed by the correction or removal,
10 including the extent of the problem;

11 “(D) a description of the potential risks to
12 patients or the public due to the problem, in-
13 cluding whether injuries or deaths have been
14 associated with the problem;

15 “(E) instructions to the patient, health
16 care practitioner, or other user, on appropriate
17 actions to be taken; and

18 “(F) contact information for obtaining ad-
19 ditional information from the developer or other
20 responsible party.

21 “(5) CLASSIFICATION OF CORRECTION OR RE-
22 MOVAL.—The Secretary shall classify a correction or
23 removal under this subsection (according to the rel-
24 ative degree of health hazard presented by the in
25 vitro clinical test being corrected or removed) within

1 30 calendar days of receiving notice pursuant to
2 paragraph (2). If the Secretary determines a notifi-
3 cation of such classification in addition to any notifi-
4 cation already provided by the developer or other re-
5 sponsible party pursuant to paragraph (4) is nec-
6 essary to protect public health, the Secretary may
7 issue such notice, and shall include in such notice
8 the unique correction or removal identifier and infor-
9 mation clarifying that such notice is intended to in-
10 form patients, health care practitioners, and other
11 users that the notice is not a second correction or
12 removal and that the notice is part of an agency
13 process for classifying an existing correction or re-
14 moval.

15 “(6) REPORT NOT AN ADMISSION.—A report or
16 other information submitted by a developer or other
17 responsible party under this subsection (and any re-
18 lease by the Secretary of that report or other infor-
19 mation) does not constitute an admission by the de-
20 veloper or other responsible party that the in vitro
21 clinical test is in violation of this subchapter or
22 caused or contributed to any injury.

23 “(7) CLOSING A CORRECTION OR REMOVAL.—
24 Not later than 45 calendar days after the developer
25 or other responsible party notifies the Secretary that

1 it has completed a correction or removal action, the
2 Secretary shall provide the developer or other re-
3 sponsible party a written statement closing the cor-
4 rection or removal action or stating the reasons the
5 Secretary cannot close the correction or removal ac-
6 tion at that time.

7 “(d) MANDATORY CORRECTIONS AND REMOVALS.—

8 “(1) IN GENERAL.—If the Secretary finds there
9 is a reasonable probability that an in vitro clinical
10 test, when used in accordance with its intended use,
11 would cause serious, adverse health consequences or
12 death, and the Secretary finds that notification
13 under this subsection is necessary to eliminate the
14 unreasonable risk of such harm and no more prac-
15 tical means is available under this Act (other than
16 this subsection) to eliminate such risk, then the Sec-
17 retary shall issue an order requiring the appropriate
18 person, as applicable, to promptly—

19 “(A) cease offering such test; and

20 “(B) notify health care practitioners and
21 other users of the test of the order and rec-
22 ommend to such practitioners and users to
23 cease offering or using such test; or

24 “(C) initiate a correction or removal of
25 such test.

1 “(2) INFORMAL HEARING.—An order under
2 paragraph (1) shall provide the person subject to the
3 order with an opportunity for an informal hearing,
4 to be held not later than 10 calendar days after the
5 date of the issuance of the order, on the actions re-
6 quired by the order and on whether the order should
7 be revised or vacated. If, after providing an oppor-
8 tunity for such a hearing, the Secretary determines
9 that inadequate grounds exist to support the actions
10 required by the order, the Secretary shall revise or
11 vacate the order.

12 “(3) AMENDMENT TO REQUIRE CORRECTION OR
13 REMOVAL.—

14 “(A) AMENDMENT.—If, after providing an
15 opportunity for an informal hearing under
16 paragraph (2), the Secretary determines that
17 an order should be amended to include a correc-
18 tion or removal of the in vitro clinical test with
19 respect to which the order was issued, the Sec-
20 retary shall, except as provided in subpara-
21 graphs (B) and (C), amend the order to require
22 a correction or removal. The Secretary shall
23 specify a timetable in which the in vitro clinical
24 test correction or removal will occur and shall
25 require periodic reports to the Secretary de-

1 scribing the progress of the correction or re-
2 moval.

3 “(B) CONTENTS.—An original or amended
4 order under paragraph (1)—

5 “(i) shall—

6 “(I) not include correction or re-
7 moval of an in vitro clinical test from
8 individuals; and

9 “(II) not include correction or re-
10 removal of an in vitro clinical test from
11 any setting if the Secretary deter-
12 mines that the risk of correcting or
13 removing such in vitro clinical test
14 from the facilities presents a greater
15 health risk than the health risk of not
16 correcting or removing the in vitro
17 clinical test from use; and

18 “(ii) may provide for notice to individ-
19 uals subject to the risks associated with
20 the use of such in vitro clinical test.

21 “(C) ASSISTANCE OF HEALTH CARE PRAC-
22 TITIONERS.—In providing the notice required
23 by subparagraph (B)(ii), the Secretary may use
24 the assistance of health care practitioners who
25 prescribed, ordered, or used such an in vitro

1 clinical test for individuals. If a significant
2 number of such individuals cannot be identified,
3 the Secretary shall notify such individuals pur-
4 suant to section 705(b).

5 “(4) CLASSIFICATION.—The Secretary shall
6 classify a correction or removal under this sub-
7 section (according to the relative degree of health
8 hazard presented by the in vitro clinical test being
9 corrected or removed) within 30 calendar days of or-
10 dering the correction or removal.

11 “(e) INAPPLICABILITY TO CERTAIN MATTERS.—

12 “(1) IN GENERAL.—The Secretary shall not
13 order a notification under subsection (b) or a correc-
14 tion or removal under subsection (d) on the basis of
15 any of the following:

16 “(A) Changes or improvements in labora-
17 tory operations.

18 “(B) Corrections or updates to patient-spe-
19 cific laboratory reports.

20 “(C) Enhancements to an in vitro clinical
21 test.

22 “(2) ENHANCEMENT.—For purposes of this
23 subsection, the term ‘enhancement’ means a change
24 to an in vitro clinical test that is not a change to

1 remedy a violation of this subchapter or associated
2 regulations enforced by the Secretary.

3 “(f) POSTMARKET SURVEILLANCE.—

4 “(1) IN GENERAL.—The Secretary may by
5 order, at the time of approval of an in vitro clinical
6 test pursuant to subsection (c), (d), or (f)(1)(A) of
7 section 590B require a developer to conduct
8 postmarket surveillance, including postmarket stud-
9 ies, for a high-risk in vitro clinical test, or a mod-
10 erate-risk in vitro clinical test described in section
11 590A(a)(3)(A), only if the Secretary determines,
12 based on valid scientific evidence, that the failure of
13 such in vitro clinical test would be reasonably likely
14 to have serious adverse health consequences. The
15 Secretary shall not, under this subsection, order
16 postmarket surveillance for an in vitro clinical test
17 to assess clinical utility.

18 “(2) SURVEILLANCE APPROVAL.—Unless a dif-
19 ferent time period is agreed to by the developer and
20 the Secretary, each developer required to conduct a
21 surveillance of an in vitro clinical test shall, within
22 30 days of receiving an order from the Secretary
23 prescribing that the developer is required under this
24 subsection to conduct such surveillance, submit, for
25 the approval of the Secretary, a plan for the re-

1 quired surveillance. The Secretary shall determine if
2 the person designated to conduct the surveillance
3 has appropriate qualifications and experience to un-
4 dertake such surveillance and if the plan will result
5 in the collection of useful data that can reveal un-
6 foreseen adverse events or other information nec-
7 essary to protect the public health. The developer
8 shall commence surveillance under this subsection
9 not later than 15 months after the day on which the
10 Secretary issues an order under this section. Any
11 such surveillance shall be completed within 3 years
12 of commencement.

13 “(3) POSTMARKET CLINICAL STUDIES.—The
14 Secretary may require the developer of an in vitro
15 clinical test to conduct a postmarket clinical study
16 under paragraph (1) only for a high-risk in vitro
17 clinical test and only if the Secretary determines
18 that no other means can provide the necessary infor-
19 mation. The authority to require such a study shall
20 not be delegated to any official or employee below
21 the level of senior management of the Center for In
22 vitro Clinical Tests.

23 “(g) MISBRANDED IN VITRO CLINICAL TESTS.—The
24 Secretary shall treat an in vitro clinical test as misbranded
25 under section 502 if the Secretary finds, based on all avail-

1 able data and information, that the in vitro clinical test
2 presents an unreasonable and substantial risk of illness
3 or injury when used as intended by its developer.

4 **“SEC. 590F. APPEALS.**

5 “(a) IN GENERAL.—The Secretary shall establish by
6 regulation an appeals process for the review of classifica-
7 tion and reclassification determinations under section
8 590A, premarket determinations under sections 590B and
9 590C, and other adverse decisions made by the Secretary
10 under this subchapter. Except as otherwise provided in
11 this subchapter, the process established by the Secretary
12 shall be consistent with the guidance entitled ‘Center for
13 Devices and Radiological Health Appeals Processes’ and
14 dated May 17, 2013.

15 “(b) TIMING FOR CERTAIN APPEALS.—With respect
16 to a premarket determination approving or disapproving
17 an application under section 590B, the applicant involved
18 or any interested person may, by petition filed on or before
19 the day that is 30 days after the date on which the Sec-
20 retary issues the order approving or disapproving such ap-
21 plication, obtain review of such determination under the
22 appeals process established pursuant to subsection (a).

23 “(c) FINAL ACTION FOR JUDICIAL REVIEW.—In all
24 cases, the process established under subsection (a) shall
25 provide for a decision constituting final action by the agen-

1 cy not later than 180 calendar days after the date on
2 which the appeal is first submitted.

3 “(d) **ADVISORY PANELS.**—The appeal process estab-
4 lished under subsection (a) shall permit the appellant to
5 request review by an advisory panel. Any such advisory
6 panel shall include persons with knowledge of in vitro clin-
7 ical tests, laboratory operations, and the use of in vitro
8 clinical tests.

9 **“SEC. 590G. PREEMPTION.**

10 “(a) **IN GENERAL.**—No State, tribal, or local govern-
11 ment (or political subdivision thereof) may establish or
12 continue in effect any requirement related to the develop-
13 ment, manufacture, labeling, distribution, sale, or use of
14 an in vitro clinical test that is different from, or in addi-
15 tion to, the requirements of this subchapter.

16 “(b) **EXCEPTIONS.**—Subsection (a) shall not be con-
17 strued to affect the authority of a State, tribal, or local
18 government—

19 “(1) to license laboratory personnel, health care
20 practitioners, or health care facilities or to regulate
21 any aspect of a health care practitioner-patient rela-
22 tionship; or

23 “(2) to enforce laws of general applicability,
24 such as zoning laws, environmental laws, labor laws,
25 and general business laws.

1 “(c) CLARIFICATION.—This section shall not be con-
2 strued to shift liability to health care practitioners or other
3 users.

4 **“SEC. 590H. APPLICABILITY OF CERTAIN PROVISIONS.**

5 “The provisions of sections 301, 303(f)(1), 304, 306,
6 501, 502, 503(a), 503(g), 506, 509, 517 , 520(c), 561,
7 562, 563, 566(b), 566(e), 702, 703, 704, 705, 721, 756,
8 770, 801, 802, 803, 1003, 1003a, and 1011 apply with
9 respect to in vitro clinical tests to the same extent and
10 in the same manner as such provisions apply with respect
11 to devices, to the extent consistent with this subchapter,
12 except as follows:

13 “(1) The following provisions do not apply with
14 respect to in vitro clinical tests: Section 301(y), sub-
15 sections (e), (f), (g), (h), and (i) of section 501, sub-
16 sections (s), (t)(2), and (t)(3) of section 502, and
17 section 510.

18 “(2) In the case of in vitro clinical tests, the
19 statement required by section 502(v) is ““Reproc-
20 essed in vitro clinical test for single use. Reprocessed
21 by ____.””.

22 “(3) In applying section 503(g)(1)(B), if the
23 Secretary determines that the primary mode of ac-
24 tion is that of an in vitro clinical test, the agency

1 center charged with premarket review of in vitro
2 clinical tests shall have primary jurisdiction.”.

3 (b) CONFORMING AMENDMENT.—Section 517(a) of
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 360g(a)) is amended—

6 (1) by striking “or” at the end of paragraph
7 (8);

8 (2) by inserting “or” at the end of paragraph
9 (9); and

10 (3) by inserting after paragraph (9) the fol-
11 lowing:

12 “(10) the issuance of a decision under section
13 590F,”.

14 (c) EMERGENCY USE OF IN VITRO CLINICAL
15 TESTS.—Section 564 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 360bbb–3) is amended—

17 (1) in subsections (a)(1) and (a)(4)(C), by in-
18 serting “in vitro clinical test,” before “or biological
19 product” each place it appears;

20 (2) in paragraph (2) of subsection (b), by add-
21 ing at the end the following:

22 “(C) CONTINUED PRODUCT AVAILABILITY
23 AFTER TERMINATION.—A manufacturer or pro-
24 vider of an in vitro clinical test with an author-
25 ization under this section may consult with the

1 Secretary for, and the Secretary may allow,
2 continued distribution and use of such test after
3 termination of the authorization if the condi-
4 tions of subsections (c)(2), (c)(3), and (c)(4)
5 continue to be satisfied.”;

6 (3) in subsection (c), in the matter before para-
7 graph (1), by inserting “(and with respect to in vitro
8 clinical tests local, State, or regional public health
9 authorities)” after “the Director of the Centers for
10 Disease Control and Prevention”;

11 (4) in subsection (e)(3)—

12 (A) in subparagraph (A), by inserting “de-
13 sign (with respect to in vitro clinical tests),” be-
14 fore “manufacture,”; and

15 (B) in subparagraph (B), by striking
16 “and” at the end;

17 (C) in subparagraph (C), by striking the
18 period at the end and inserting “; and”; and

19 (D) by adding at the end the following:

20 “(D) quality system requirements (with re-
21 spect to laboratories and laboratory operations)
22 established under section 353 of the Public
23 Health Service Act.”;

1 (5) in subsection (f)(2), by inserting “or, in the
2 case of an in vitro clinical test, for diagnosis, prog-
3 nosis, or monitoring” before “to the extent”; and

4 (6) in subsection (m)—

5 (A) in the subsection heading, by striking
6 “LABORATORY TESTS ASSOCIATED WITH DE-
7 VICES” and inserting “IN VITRO CLINICAL
8 TESTS”; and

9 (B) in paragraph (1)—

10 (i) by striking “a device” and insert-
11 ing “an in vitro clinical test”; and

12 (ii) by striking “such device” and in-
13 serting “such in vitro clinical test”.

14 (d) INSPECTIONS.—Section 704 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 374) is amended by
16 adding at the end the following:

17 “(h) INSPECTIONS BY ACCREDITED PERSONS.—

18 “(1) IN GENERAL.—The Secretary shall estab-
19 lish by regulation a process to accredit persons for
20 the purpose of conducting inspections of establish-
21 ments engaged in the design, development, valida-
22 tion, production, manufacture, preparation, propaga-
23 tion, or assembly of an in vitro clinical test. The
24 process established by the Secretary shall permit the
25 owner or operator of such an establishment to select,

1 from the list published under paragraph (4), an ac-
2 credited person to conduct such inspections.

3 “(2) ACCREDITATION CRITERIA.—The Sec-
4 retary shall publish in the Federal Register criteria
5 to accredit or deny accreditation to persons who re-
6 quest to perform the duties specified in paragraph
7 (1).

8 “(3) DISPOSITION OF REQUESTS FOR ACCREDI-
9 TATION.—The Secretary shall—

10 “(A) not later than 60 calendar days after
11 the receipt of a request for accreditation under
12 this subsection, inform the requesting person
13 whether the request is adequate for review; and

14 “(B) promptly accredit or deny accredita-
15 tion to the person.

16 “(4) LIST.—The Secretary shall—

17 “(A) publish on the Internet site of the
18 Food and Drug Administration a list of persons
19 who are accredited under this subsection; and

20 “(B) keep such list updated to ensure that
21 the identity of each accredited person, and the
22 particular activities for which the person is ac-
23 credited, is available to the public.”.

24 (e) REGULATIONS.—

1 (1) PROMULGATION.—Not later than 3 years
2 after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services, acting
4 through the Commissioner of Food and Drugs, shall
5 promulgate final regulations to carry out the amend-
6 ments made by this section.

7 (2) EFFECTIVE DATE.—

8 (A) IN GENERAL.—The regulations pro-
9 mulgated pursuant to paragraph (1) shall take
10 effect on the date that is 2 years after the date
11 of such promulgation.

12 (B) PREMARKET REQUIREMENTS.—Not-
13 withstanding subparagraph (A), with respect to
14 a manufacturer (as defined in section 7), the
15 regulations promulgated pursuant to paragraph
16 (1) to carry out sections 590A, 590B, and
17 590C of the Federal Food, Drug, and Cosmetic
18 Act, as added by subsection (a), shall take ef-
19 fect on the date that is 1 year after the date
20 of such promulgation.

21 (3) FINISHED PRODUCTS AND LABORATORY
22 TEST PROTOCOLS.—All regulations established pur-
23 suant to paragraph (1) shall account for differences
24 between finished products and laboratory test proto-
25 cols (as such terms are defined in section 201(ss) of

1 the Federal Food, Drug, and Cosmetic Act, as
2 added by section 2(a)).

3 (f) LEAST ONEROUS AND MOST EFFICIENT IMPLE-
4 MENTATION.—Any regulations promulgated for purposes
5 of implementation of subchapter J of chapter V of the
6 Federal Food, Drug, and Cosmetic Act (as added by sub-
7 section (a)), any guidances or other similar documents ex-
8 pressly authorized or required under such subchapter, and
9 any decision of the Secretary applying or implementing
10 the requirements of such subchapter shall be developed
11 and implemented in a manner that allows the regulated
12 person to satisfy the regulated person’s relevant statutory
13 obligations in the least onerous and most efficient manner
14 possible. Any such regulation, guidance, or similar docu-
15 ment shall set forth the manner in which the Secretary
16 has complied with this subsection.

17 (g) EDUCATION AND TRAINING OF AGENCY EMPLOY-
18 EES AND CONTRACTORS.—

19 (1) ESTABLISHMENT OF PLAN.—The Secretary
20 of Health and Human Services, acting through the
21 Commissioner of Food and Drugs, shall—

22 (A) publish a proposed plan for education
23 and training of employees and contractors of
24 the Food and Drug Administration and the reg-

1 ulated community on implementation of the
2 amendments made by this section;

3 (B) provide an opportunity for public com-
4 ment on such plan during a period of not less
5 than 90 calendar days;

6 (C) not later than 2 years after the date
7 of enactment of this Act, publish a final version
8 of such plan;

9 (D) ensure that initial training of employ-
10 ees and contractors under the plan is completed
11 within 1 year of the date of publishing such
12 final version; and

13 (E) offer training to the regulated commu-
14 nity as described in the plan on an ongoing
15 basis, beginning within 1 year of the date of
16 publishing such final version.

17 (2) PLAN CONTENTS.—The plan required by
18 paragraph (1) shall include—

19 (A) detailed plans for rigorous ongoing and
20 initial training of employees and contractors of
21 the Food and Drug Administration and the reg-
22 ulated community on implementation of the
23 amendments made by this section, including the
24 obligations for registration and listing, the
25 standard for review and, approval of an in vitro

1 clinical test, and the contents of a submission
2 for approval of an in vitro clinical test under
3 section 590B of the Federal Food, Drug, and
4 Cosmetic Act, as added by subsection (a);

5 (B) education of such employees and con-
6 tractors on the operation of clinical laboratories
7 and the scope of activities within such labora-
8 tories that are subject to regulation under such
9 amendments; and

10 (C) ongoing training of such employees
11 and contractors on the technology and utiliza-
12 tion of in vitro clinical tests.

13 (h) ANNUAL REPORT.—Not later than one year after
14 the date of enactment of this Act, and annually thereafter,
15 the Secretary of Health and Human Services, acting
16 through the Commissioner of Food and Drugs, shall sub-
17 mit a report to the Congress—

18 (1) describing activities that have been under-
19 taken by the Food and Drug Administration pursu-
20 ant to the amendments made by this section and
21 progress toward relevant statutory deadlines;

22 (2) explaining the ways in which such activities
23 account for the unique characteristics of in vitro
24 clinical tests and differ from the regulation of de-
25 vices; and

1 (3) explaining the ways in which such activities
2 promote patient access to new in vitro clinical tests.

3 (i) EXECUTIVE PERFORMANCE.—Timely and appro-
4 priate implementation and execution of this Act shall be
5 included in the performance evaluations of relevant Food
6 and Drug Administration executives, including members
7 of the Senior Executive Service and equivalent positions,
8 for purposes of determining any performance bonus, sal-
9 ary increase, or job advancement.

10 **SEC. 4. FDA FEES.**

11 (a) DEVELOPMENT OF USER FEES FOR IN VITRO
12 CLINICAL TESTS.—

13 (1) IN GENERAL.—Beginning not later than
14 October 1, 2018, the Secretary of Health and
15 Human Services, acting through the Commissioner
16 of Food and Drugs, shall develop recommendations
17 to present to Congress with respect to the goals, and
18 plans for meeting the goals, for the process for the
19 review of in vitro clinical test applications submitted
20 under subsections (c), (d), and (f) of section 590B
21 of the Federal Food, Drug, and Cosmetic Act (as
22 added by section 3 of this Act) for the first 7 fiscal
23 years after fiscal year 2020. In developing such rec-
24 ommendations, the Secretary shall consult with—

1 (A) the Committee on Energy and Com-
2 merce of the House of Representatives;

3 (B) the Committee on Health, Education,
4 Labor, and Pensions of the Senate;

5 (C) scientific and academic experts;

6 (D) health care professionals;

7 (E) representatives of patient and con-
8 sumer advocacy groups; and

9 (F) the regulated industry.

10 (2) PUBLIC REVIEW OF RECOMMENDATIONS.—

11 After negotiations with the regulated industry, the
12 Secretary shall—

13 (A) present the recommendations devel-
14 oped under paragraph (1) to the congressional
15 committees specified in subparagraphs (A) and
16 (B) of such paragraph;

17 (B) publish such recommendations in the
18 Federal Register;

19 (C) provide for a period of not less than 30
20 days for the public to provide written comments
21 on such recommendations;

22 (D) hold a meeting at which the public
23 may present its views on such recommenda-
24 tions; and

1 (E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 (3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than June 1, 2019, the Secretary shall
6 transmit to Congress—

7 (A) the recommendations described in
8 paragraph (1) (as revised under paragraph
9 (2)(E));

10 (B) a summary of the views and comments
11 received under paragraph (2), and any changes
12 made to the recommendations in response to
13 such views and comments.

14 (b) SENSE OF CONGRESS ON ESTABLISHMENT OF
15 USER FEE PROGRAM.—It is the sense of the Congress
16 that, based on the recommendations transmitted to Con-
17 gress by the Secretary pursuant to subsection (a)(3), Con-
18 gress should authorize a program, effective on the effective
19 date of final regulations issued under section 3(e)(2)(B)
20 of the Diagnostic Accuracy and Innovation Act, for the
21 collection of user fees relating to the submission of appli-
22 cations for the approval of in vitro clinical tests under sub-
23 sections (e), (d), and (f) of section 590B of the Federal
24 Food, Drug, and Cosmetic Act (as added by section 3 of
25 this Act).

1 (c) TRANSITIONAL PROVISIONS FOR USER FEES FOR
2 CERTAIN IN VITRO CLINICAL TESTS.—A submission for
3 approval or clearance of an in vitro clinical test (as defined
4 in section 590 of the Federal Food, Drug, and Cosmetic
5 Act (as added by section 3 of this Act)) made by a manu-
6 facturer of such test pursuant to section 6(c)(1)(A) of the
7 Diagnostic Accuracy and Innovation Act shall be subject
8 to a user fee pursuant to section 738 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 379j) in the same
10 manner and to the same extent as a submission of a pre-
11 market application, premarket report, supplement, pre-
12 market notification submission, 30-day notice, request for
13 classification information, or periodic reporting concerning
14 a class III device is subject to such a user fee.

15 (d) AUDIT.—

16 (1) IN GENERAL.—Beginning on the date that
17 is 2 years after the date on which the Secretary of
18 Health and Human Services receives the first user
19 fee applicable to a submission of an application sub-
20 mitted with respect to an in vitro clinical test (as de-
21 fined in section 590 of the Federal Food, Drug, and
22 Cosmetic Act (as added by section 3 of this Act))
23 under subsection (c), (d), or (f) of section 590B of
24 such Act (as added by such section 3)), and on a bi-
25 ennial basis thereafter until October 1, 2027, the

1 Secretary shall perform an audit of the costs of re-
2 viewing such applications under such section 590B.
3 Such an audit shall compare the costs of reviewing
4 such applications under such section 590B to the
5 amount of the user fee applicable to such applica-
6 tions.

7 (2) ALTERATION OF USER FEE.—If the audit
8 performed under paragraph (1) indicates that the
9 user fees applicable to applications described in such
10 paragraph for a year exceed 30 percent of the costs
11 of reviewing such applications, the Secretary shall
12 adjust the user fees applicable to such applications
13 so that the user fees applicable to such applications
14 for subsequent years do not exceed such percentage.

15 (3) ACCOUNTING STANDARDS.—The Secretary
16 shall perform an audit under paragraph (1) in con-
17 formance with the accounting principles, standards,
18 and requirements prescribed by the Comptroller
19 General of the United States under section 3511 of
20 title 31, United State Code, to ensure the validity of
21 any potential variability.

22 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
23 authorized to be appropriated to carry out section 3 and
24 the amendments made by such section such sums as may
25 be necessary for each of fiscal years 2018 through 2022.

1 **SEC. 5. CERTIFICATION OF LABORATORIES (CLIA).**

2 Section 353 of the Public Health Service Act (42
3 U.S.C. 263a) is amended to read as follows:

4 **“SEC. 353. CERTIFICATION OF LABORATORIES.**

5 “(a) SCOPE OF AUTHORITY; DEFINITIONS.—

6 “(1) SCOPE OF AUTHORITY.—Laboratories
7 shall be regulated by the Secretary under this sec-
8 tion. Laboratory operations shall be regulated by the
9 Secretary under this section and shall not be regu-
10 lated under the Federal Food, Drug, and Cosmetic
11 Act.

12 “(2) LIMITATIONS OF AUTHORITY.—

13 “(A) FDA REGULATION.—The design, de-
14 velopment, validation, production, manufacture,
15 preparation, propagation, and assembly of an in
16 vitro clinical test shall be regulated under sub-
17 chapter J of chapter V of the Federal Food,
18 Drug, and Cosmetic Act, and shall not be regu-
19 lated by the Secretary under this section.

20 “(B) OTHER ACTIVITIES.—The Secretary
21 shall not regulate the practice of medicine
22 under this section. The authority to so regulate
23 shall be reserved to the individual States.

24 “(3) DEFINITIONS.—In this section:

25 “(A) The term ‘certificate’ refers, as appli-
26 cable, to—

1 “(i) the documentary evidence of au-
2 thORIZATION to engage in the activities regu-
3 lated in this section required under sub-
4 section (b); or

5 “(ii) a certificate of waiver issued
6 under subsection (d)(2).

7 “(B) The term ‘in vitro clinical test’ has
8 the meaning given to that term in section
9 201(ss) of the Federal Food, Drug, and Cos-
10 metic Act.

11 “(C) The term ‘laboratory’ or ‘clinical lab-
12 oratory’ means a facility for the biological,
13 microbiological, serological, chemical, immuno-
14 hematological, hematological, biophysical,
15 cytological, pathological, or other examination
16 of materials derived from the human body for
17 the purpose of providing information for the di-
18 agnosis, prevention, or treatment of any disease
19 or impairment of, or the assessment of the
20 health of, human beings.

21 “(D)(i) The term ‘laboratory operations’
22 means the conduct of a laboratory examination
23 or other laboratory procedure on materials de-
24 rived from the human body for the purpose de-
25 scribed in subparagraph (C), including, the con-

1 duct of an in vitro clinical test and associated
2 activities not excluded by paragraph (a)(1)(B)
3 from the Secretary's authority to regulate
4 under this section, within or under the over-
5 sight of a laboratory. Such term includes the
6 following activities:

7 “(I) Developing and implementing
8 standard operating procedures.

9 “(II) Verifying laboratory perform-
10 ance of an in vitro clinical test.

11 “(III) Performing pre-analytical, ana-
12 lytical, and post-analytical processes for an
13 in vitro clinical test.

14 “(IV) Collection, transportation, dis-
15 position, and storage of patient specimens.

16 “(V) Preparing reagents or other test
17 materials which do not meet the definition
18 of a finished test product under section
19 201(ss) of the Federal Food, Drug, and
20 Cosmetic Act.

21 “(VI) Performing an in vitro clinical
22 test pursuant to the relevant standard op-
23 erating procedures for such test.

24 “(VII) Reporting the output or results
25 of an in vitro clinical test.

1 “(VIII) Validating changes to in vitro
2 clinical tests if such changes are not regu-
3 lated under subchapter J of the Federal
4 Food, Drug, and Cosmetic Act.

5 “(ii) Such term includes the preparation
6 and transfer of individual components, parts,
7 and raw materials between commonly owned
8 laboratories within the same State, if—

9 “(I) the Secretary has established by
10 regulation—

11 “(aa) applicable quality require-
12 ments that are substantially equiva-
13 lent to the comparable quality require-
14 ments under subchapter J of the Fed-
15 eral Food, Drug, and Cosmetic Act;

16 “(bb) inspection processes that
17 are substantially equivalent to the
18 comparable inspection processes under
19 such subchapter J; and

20 “(cc) enforcement processes that
21 are substantially equivalent to the
22 comparable enforcement processes
23 under such subchapter J;

24 “(II) the Secretary reviews the regula-
25 tions established pursuant to subclause (I)

1 three years after the effective date of such
2 regulations to determine whether com-
3 parable quality requirements are being im-
4 plemented as required by such clause and
5 whether the value of such requirements are
6 commensurate with the related burden;
7 and

8 “(III) as part of the review conducted
9 pursuant to subclause (II), the Secretary—

10 “(aa) holds at least one public
11 meeting;

12 “(bb) issues a draft determina-
13 tion regarding whether to maintain or
14 amend the quality requirements estab-
15 lished pursuant to subclause (I);

16 “(cc) provides for a public com-
17 ment period of 90 days on the draft
18 determination; and

19 “(dd) issues a final determina-
20 tion, with any proposed amended reg-
21 ulations, not later than four years
22 after the effective date of the regula-
23 tions established pursuant to sub-
24 clause (I).

1 “(E) The term ‘standard operating proce-
2 dures’ means with respect to an in vitro clinical
3 test, a documented set of instructions, more de-
4 tailed than the final design of such in vitro clin-
5 ical test, describing how to perform laboratory
6 operations or to comply with the applicable re-
7 quirements of this section.

8 “(b) CERTIFICATE REQUIREMENT.—No person may
9 solicit or accept materials derived from the human body
10 for laboratory examination or other laboratory procedure
11 unless there is in effect for the laboratory a certificate
12 issued by the Secretary under this section applicable to
13 the category of examinations or procedures which includes
14 such examination or procedure.

15 “(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

16 “(1) IN GENERAL.—The Secretary may issue or
17 renew a certificate for a laboratory only if the lab-
18 oratory meets the requirements of subsection (d).

19 “(2) TERM.—A certificate issued under this
20 section shall be valid for a period of 2 years or such
21 shorter period as the Secretary may establish.

22 “(d) REQUIREMENTS FOR CERTIFICATES.—

23 “(1) IN GENERAL.—A laboratory may be issued
24 a certificate or have its certificate renewed if—

1 “(A) the laboratory submits (or if the lab-
2 oratory is accredited under subsection (e), the
3 accreditation body which accredited the labora-
4 tory submits), an application—

5 “(i) in such form and manner as the
6 Secretary shall prescribe;

7 “(ii) that describes the characteristics
8 of the laboratory examinations and other
9 procedures performed by the laboratory in-
10 cluding—

11 “(I) the number and types of lab-
12 oratory examinations and other proce-
13 dures performed;

14 “(II) the methodologies for lab-
15 oratory examinations and other proce-
16 dures employed; and

17 “(III) the qualifications (edu-
18 cational background, training, and ex-
19 perience) of the personnel directing
20 and supervising the laboratory and
21 performing the laboratory examina-
22 tions and other procedures; and

23 “(iii) that contains such other infor-
24 mation as the Secretary may require to de-
25 termine compliance with this section; and

1 the laboratory agrees to provide to the Sec-
2 retary (or if the laboratory is accredited, to the
3 accreditation body which accredited it) a de-
4 scription of any change in the information sub-
5 mitted under clause (ii) not later than 6 months
6 after the change was put into effect;

7 “(B) the laboratory provides the Sec-
8 retary—

9 “(i) with satisfactory assurances that
10 the laboratory will be operated in accord-
11 ance with standards issued by the Sec-
12 retary under subsection (f); or

13 “(ii) with proof of accreditation under
14 subsection (e);

15 “(C) the laboratory agrees to permit in-
16 spections by the Secretary under subsection (g);

17 “(D) the laboratory agrees to make records
18 available and submit reports to the Secretary as
19 the Secretary may reasonably require;

20 “(E) the laboratory agrees to treat pro-
21 ficiency testing samples in the same manner as
22 it treats materials derived from the human body
23 referred to it for laboratory examinations or
24 other procedures in the ordinary course of busi-
25 ness, except that no proficiency testing sample

1 shall be intentionally referred to another labora-
2 tory for analysis as prohibited under subsection
3 (i)(4); and

4 “(F) the laboratory has in place processes
5 and policies to review and assess changes or
6 modifications to in vitro clinical tests, as re-
7 quired by paragraph (4).

8 “(2) REQUIREMENTS FOR CERTIFICATES OF
9 WAIVER.—

10 “(A) IN GENERAL.—A laboratory which
11 only performs laboratory examinations and pro-
12 cedures described in paragraph (3) shall be
13 issued a certificate of waiver or have its certifi-
14 cate of waiver renewed if—

15 “(i) the laboratory submits an appli-
16 cation—

17 “(I) in such form and manner as
18 the Secretary shall prescribe;

19 “(II) that describes the charac-
20 teristics of the laboratory examina-
21 tions and other procedures performed
22 by the laboratory, including the num-
23 ber and types of laboratory examina-
24 tions and other procedures performed,
25 the methodologies for laboratory ex-

1 aminations and other procedures em-
2 ployed, and the qualifications (edu-
3 cational background, training, and ex-
4 perience) of the personnel directing
5 and supervising the laboratory and
6 performing the laboratory examina-
7 tions and other procedures; and

8 “(III) that contains such other
9 information as the Secretary may rea-
10 sonably require to determine compli-
11 ance with this section; and

12 “(ii) the laboratory agrees to make
13 records available and submit reports to the
14 Secretary as the Secretary may require.

15 “(B) CHANGES THAT MAY AFFECT WAIVED
16 STATUS.—

17 “(i) CHANGES TO CERTAIN EXAMINA-
18 TIONS AND PROCEDURES.—If a laboratory
19 makes changes in the examinations and
20 other procedures performed by it only with
21 respect to examinations and procedures
22 which are described in paragraph (3), the
23 laboratory shall report such changes to the
24 Secretary not later than 6 months after
25 the change has been put into effect.

1 “(ii) OTHER CHANGES.—If a labora-
2 tory proposes to make changes in the ex-
3 aminations and procedures performed by it
4 such that the laboratory will perform an
5 examination or procedure not described in
6 paragraph (3), the laboratory shall report
7 such change to the Secretary before the
8 change takes effect. The laboratory shall
9 report any such change to the Secretary
10 without regard to whether such change is
11 a modification subject to premarket ap-
12 proval under section 590B(n) of the Fed-
13 eral Food, Drug, and Cosmetic Act. If any
14 such change is a modification subject to
15 premarket approval under such section
16 590B(n), the laboratory shall obtain such
17 approval, if required, before putting the
18 modification into effect.

19 “(iii) HIGH COMPLEXITY.—In the
20 case of any modification by a laboratory to
21 an examination or procedure described in
22 paragraph (3) that causes the examination
23 or procedure to have high complexity, the
24 examination or procedure shall be subject
25 to the requirements under this section for

1 high complexity examinations and proce-
2 dures.

3 “(C) EFFECT.—Subsections (g) and (h)
4 shall not apply to a laboratory to which a cer-
5 tificate of waiver has been issued.

6 “(3) EXAMINATIONS AND PROCEDURES.—

7 “(A) IN GENERAL.—The examinations and
8 procedures identified in paragraph (2) are lab-
9 oratory examinations and procedures that have
10 been approved by the Food and Drug Adminis-
11 tration for home use or that, as determined by
12 the Secretary, are simple laboratory examina-
13 tions and procedures that have an insignificant
14 risk of an erroneous result, including those
15 that—

16 “(i) employ methodologies that are so
17 simple and accurate as to render the likeli-
18 hood of erroneous results by the user neg-
19 ligible; or

20 “(ii) the Secretary has determined
21 pose no unreasonable risk of harm to the
22 patient if performed incorrectly.

23 “(B) DEFINITION.—In this paragraph, the
24 phrase ‘accurate as to render the likelihood of
25 erroneous results by the user negligible’ means,

1 with respect to an in vitro clinical test, that the
2 accuracy achieved by individuals qualified to
3 perform a laboratory examination or procedure
4 in a laboratory holding a certificate of waiver
5 under paragraph (2) is equivalent to the accu-
6 racy achieved by individuals qualified to per-
7 form a laboratory examination or procedure in
8 a laboratory certified under paragraph (1), as
9 shown by evidence that directly compares such
10 accuracy or evaluates such agreement of re-
11 sults.

12 “(e) ACCREDITATION.—

13 “(1) IN GENERAL.—A laboratory may be ac-
14 credited for purposes of obtaining a certificate if the
15 laboratory—

16 “(A) meets the requirements of this section
17 and meets the standards of an approved accred-
18 itation body; and

19 “(B) authorizes the accreditation body to
20 submit to the Secretary (or such State agency
21 as the Secretary may designate) such records or
22 other information as the Secretary may require.

23 “(2) APPROVAL OF ACCREDITATION BODIES.—

24 “(A) IN GENERAL.—The Secretary may
25 approve a private organization, to be an accred-

1 itation body for the accreditation of laboratories

2 if—

3 “(i) the accreditation body—

4 “(I) has in place effective conflict
5 of interest provisions;

6 “(II) uses inspectors trained to
7 use and apply the standards issued by
8 the Secretary under subsection (f) and
9 in the application of other require-
10 ments of this section;

11 “(III) uses inspectors who are
12 qualified to evaluate the methodolo-
13 gies used by the laboratories in per-
14 forming laboratory examinations and
15 other procedures; and

16 “(IV) maintains appropriate
17 records;

18 “(ii) the accreditation body agrees to
19 inspect a laboratory for purposes of accred-
20 itation with such frequency as may be de-
21 termined by the Secretary;

22 “(iii) the legally binding standards ap-
23 plied by the body in determining whether
24 or not to accredit a laboratory are the

1 standards issued by the Secretary under
2 subsection (f);

3 “(iv) there is adequate provision for
4 assuring that the standards issued by the
5 Secretary under subsection (f) and other
6 applicable statutory and regulatory re-
7 quirements continue to be met by the lab-
8 oratory;

9 “(v) in the case of any laboratory ac-
10 credited by the body which has had its ac-
11 creditation denied, suspended, withdrawn,
12 or revoked or which has had any other ac-
13 tion taken against it by the accrediting
14 body, the accrediting body agrees to sub-
15 mit to the Secretary the name of such lab-
16 oratory within 30 days of the action taken;
17 and

18 “(vi) if the accreditation body has its
19 approval withdrawn by the Secretary, the
20 body agrees to notify each laboratory ac-
21 credited by the body of the withdrawal
22 within 10 days of the withdrawal.

23 “(B) CRITERIA AND PROCEDURES.—The
24 Secretary shall promulgate criteria and proce-
25 dures for approving an accreditation body and

1 for withdrawing such approval if the Secretary
2 determines that the accreditation body does not
3 meet the requirements of subparagraph (A).

4 “(C) EFFECT OF WITHDRAWAL OF AP-
5 PROVAL.—If the Secretary withdraws the ap-
6 proval of an accreditation body under subpara-
7 graph (B), the certificate of any laboratory ac-
8 credited by the body shall continue in effect for
9 60 calendar days after the laboratory receives
10 notification of the withdrawal of the approval,
11 except that the Secretary may extend such pe-
12 riod for a laboratory if the Secretary determines
13 that the laboratory submitted an application for
14 accreditation or a certificate in a timely manner
15 after receipt of the notification of the with-
16 drawal of approval.

17 “(D) EVALUATIONS.—The Secretary shall,
18 beginning one year after the date on which the
19 criteria and procedures are promulgated under
20 subparagraph (B), evaluate annually the per-
21 formance of each approved accreditation body
22 by—

23 “(i) inspecting under subsection (g) a
24 sufficient number of the laboratories ac-
25 credited by such body to allow a reasonable

1 estimate of the performance of such body;

2 and

3 “(ii) such other means as the Sec-
4 retary determines appropriate.

5 “(E) REPORT.—The Secretary shall , be-
6 ginning 2 years after the date of the enactment
7 of the Diagnostic Accuracy and Innovation Act,
8 annually prepare and submit to Congress a re-
9 port describing—

10 “(i) the implementation of this section
11 during the previous year; and

12 “(ii) the results of the evaluation con-
13 ducted under subparagraph (D) for the
14 year covered by the report.

15 “(3) WITHDRAWAL OR REVOCATION OF LAB-
16 ORATORY ACCREDITATION.—If an accreditation body
17 withdraws or revokes the accreditation of a labora-
18 tory, the certificate of the laboratory shall continue
19 in effect—

20 “(A) for 45 calendar days after the labora-
21 tory receives notice of the withdrawal or revoca-
22 tion of the accreditation; or

23 “(B) until the effective date of any action
24 taken by the Secretary under subsection (j).

1 “(4) UPDATED STANDARDS.—Beginning no
2 later than the effective date of the standards under
3 subsection (f), the regulations for carrying out such
4 standards, and other applicable requirements, ap-
5 proved accreditation bodies shall ensure that—

6 “(A) the inspectors of such bodies are
7 trained with respect to, and the processes of
8 such bodies are updated in accordance with,
9 such requirements or regulations; and

10 “(B) any inspection or other review of a
11 laboratory by the approved accreditation body
12 for purposes of accreditation includes a review
13 and assessment of—

14 “(i) compliance by the laboratory with
15 such requirements and regulations; and

16 “(ii) whether sufficient processes, poli-
17 cies, organization, and training systems
18 are in place to demonstrate reasonable as-
19 surance of future compliance with such re-
20 quirements and regulations.

21 “(f) STANDARDS.—

22 “(1) IN GENERAL.—The Secretary shall issue
23 standards to assure consistent performance by lab-
24 oratories issued a certificate under this section of ac-
25 curate and reliable laboratory examinations and

1 other procedures. Such standards shall require each
2 laboratory issued a certificate under this section—

3 “(A) to maintain a quality management
4 system for all phases of the total testing proc-
5 ess within, or under the oversight of, the lab-
6 oratory (consisting of the pre-analytic, analytic,
7 and post-analytic processes) and general labora-
8 tory systems adequate and appropriate for the
9 validity and reliability of the laboratory exami-
10 nations and other procedures of the laboratory
11 and to meet requirements relating to the proper
12 collection, transportation, and storage of speci-
13 mens and the reporting of results;

14 “(B) to maintain records, equipment, and
15 facilities necessary for the proper and effective
16 operation of the laboratory;

17 “(C) in performing and carrying out its
18 laboratory examinations and other procedures,
19 to use only personnel meeting such qualifica-
20 tions as the Secretary may establish for the di-
21 rection, supervision, and performance of exami-
22 nations and procedures within the laboratory,
23 which qualifications shall take into consider-
24 ation competency, training, experience, job per-
25 formance, and education and which qualifica-

1 tions shall, as appropriate, be different on the
2 basis of the type of examinations and proce-
3 dures being performed by the laboratory and
4 the risks and consequences of erroneous results
5 associated with such examinations and proce-
6 dures;

7 “(D) to qualify under a proficiency testing
8 program meeting the standards established by
9 the Secretary under paragraph (3);

10 “(E) to have in place procedures assessing
11 the impact of changes in laboratory operations,
12 equipment, or material on the accuracy and re-
13 liability of the examinations and other proce-
14 dures of the laboratory;

15 “(F) to have in place quality systems to
16 assess the ability of incoming materials and
17 equipment to meet their intended purposes;

18 “(G) to meet such other requirements as
19 the Secretary reasonably determines necessary
20 to assure consistent performance by such lab-
21 oratories of accurate and reliable laboratory ex-
22 aminations and procedures; and

23 “(H) to have in place processes and poli-
24 cies to review and assess modifications to in

1 vitro clinical tests in accordance with paragraph
2 (7).

3 “(2) CONSIDERATIONS.—In developing the
4 standards to be issued under paragraph (1), the Sec-
5 retary shall, within the flexibility provided under
6 subparagraphs (A) through (H) of paragraph (1),
7 take into consideration—

8 “(A) the examinations and procedures per-
9 formed and the methodologies employed;

10 “(B) the degree of independent judgment
11 involved;

12 “(C) the amount of interpretation involved;

13 “(D) the difficulty of the calculations in-
14 volved;

15 “(E) the calibration and quality control re-
16 quirements of the instruments used;

17 “(F) the type of training required to oper-
18 ate the instruments used in the methodology;

19 “(G) the regulations issued by the Sec-
20 retary to carry out subchapter J of chapter V
21 of the Federal Food, Drug, and Cosmetic Act,
22 in order to avoid duplicative requirements; and

23 “(H) such other factors as the Secretary
24 considers relevant.

25 “(3) PROFICIENCY TESTING PROGRAM.—

1 “(A) IN GENERAL.—The Secretary shall
2 establish standards for the proficiency testing
3 programs for laboratories issued a certificate
4 under this section which are conducted by the
5 Secretary, conducted by an organization ap-
6 proved under subparagraph (C), or conducted
7 by an approved accrediting body. The standards
8 shall require that a laboratory issued a certifi-
9 cate under this section be tested for each exam-
10 ination and procedure conducted within a cat-
11 egory of examinations or procedures for which
12 it has received a certificate, except for examina-
13 tions and procedures for which the Secretary
14 has determined that a proficiency test cannot
15 reasonably be developed. The testing shall be
16 conducted on a quarterly basis, except where
17 the Secretary determines for technical and sci-
18 entific reasons that a particular examination or
19 procedure may be tested less frequently (but
20 not less often than twice per year). Such stand-
21 ards shall include standards for proficiency test-
22 ing programs for any new specialties and sub-
23 specialties identified under paragraph
24 (5)(A)(ii).

1 “(B) CRITERIA.—The standards estab-
2 lished under subparagraph (A) shall include
3 uniform criteria for acceptable performance
4 under a proficiency testing program, based on
5 the available technology and the clinical rel-
6 evance of the laboratory examination or other
7 procedure subject to such program. The criteria
8 shall be established for all examinations and
9 procedures and shall be uniform for each exam-
10 ination and procedure. The standards shall also
11 include a system for grading proficiency testing
12 performance to determine whether a laboratory
13 has performed acceptably for a particular quar-
14 ter and acceptably for a particular examination
15 or procedure or category of examination or pro-
16 cedure over a period of successive quarters.

17 “(C) APPROVED PROFICIENCY TESTING
18 PROGRAMS.—For the purpose of administering
19 proficiency testing programs which meet the
20 standards established under subparagraph (A),
21 the Secretary shall approve a proficiency testing
22 program offered by a private organization or a
23 State if the program meets the standards estab-
24 lished under subparagraph (A) and the organi-
25 zation or State provides technical assistance to

1 laboratories seeking to qualify under the pro-
2 gram. The Secretary shall evaluate each pro-
3 gram approved under this subparagraph annu-
4 ally to determine if the program continues to
5 meet the standards established under subpara-
6 graph (A) and shall withdraw the approval of
7 any program that no longer meets such stand-
8 ards, as specified in subsection (e).

9 “(D) ONSITE TESTING.—The Secretary
10 shall perform, or shall direct a program ap-
11 proved under subparagraph (C) to perform, on-
12 site proficiency testing to assure compliance
13 with the standards under this section, in ac-
14 cordance with paragraph (5). The Secretary
15 shall perform, on an onsite or other basis, pro-
16 ficiency testing to evaluate the performance of
17 a proficiency testing program approved under
18 subparagraph (C) and to assure quality per-
19 formance by a laboratory.

20 “(E) TRAINING, TECHNICAL ASSISTANCE,
21 AND ENHANCED PROFICIENCY TESTING.—The
22 Secretary may, in lieu of or in addition to ac-
23 tions authorized under subsection (i), (j), or
24 (k), require any laboratory which fails to per-
25 form acceptably on an individual examination

1 and procedure or a category of examinations
2 and procedures—

3 “(i) to undertake training and to ob-
4 tain the necessary technical assistance to
5 meet the requirements of the proficiency
6 testing program;

7 “(ii) to enroll in a program of en-
8 hanced proficiency testing; or

9 “(iii) to undertake any combination of
10 the training, technical assistance, or test-
11 ing described in clauses (i) and (ii).

12 “(F) TESTING RESULTS.—The Secretary
13 shall establish a system to make the results of
14 the proficiency testing programs subject to the
15 standards established by the Secretary under
16 subparagraph (A) available, on a reasonable
17 basis, upon request of any person. The Sec-
18 retary shall include with results made available
19 under this subparagraph such explanatory in-
20 formation as may be appropriate to assist in
21 the interpretation of such results.

22 “(4) NATIONAL STANDARDS FOR QUALITY AS-
23 SURANCE IN CYTOLOGY SERVICES.—

24 “(A) ESTABLISHMENT.—The Secretary
25 shall establish national standards for quality as-

1 surance in cytology services designed to assure
2 consistent performance by laboratories of accu-
3 rate and reliable cytological services.

4 “(B) STANDARDS.—The standards estab-
5 lished under subparagraph (A) shall include—

6 “(i) the maximum number of cytology
7 slides that any individual may screen in a
8 24-hour period;

9 “(ii) requirements that a clinical lab-
10 oratory maintain a record of—

11 “(I) the number of cytology
12 slides screened during each 24-hour
13 period by each individual who exam-
14 ines cytology slides for the laboratory;
15 and

16 “(II) the number of hours de-
17 voted during each 24-hour period to
18 screening cytology slides by such indi-
19 vidual;

20 “(iii) criteria for requiring rescreening
21 of cytological preparations, such as—

22 “(I) random rescreening of cytol-
23 ogy specimens determined to be in the
24 benign category;

1 “(II) focused rescreening of such
2 preparations in high-risk groups; and

3 “(III) for each abnormal
4 cytological result, rescreening of all
5 prior cytological specimens for the pa-
6 tient, if available;

7 “(iv) periodic confirmation and eval-
8 uation of the proficiency of individuals in-
9 volved in screening or interpreting
10 cytological preparations, including an-
11 nounced and unannounced onsite pro-
12 ficiency testing of such individuals, with
13 such testing to take place, to the extent
14 practicable, under normal working condi-
15 tions;

16 “(v) procedures for detecting inad-
17 equately prepared slides, for assuring that
18 no cytological diagnosis is rendered on
19 such slides, and for notifying referring
20 physicians of such slides;

21 “(vi) requirements that all cytological
22 screening be done on the premises of a lab-
23 oratory that is certified under this section;

24 “(vii) requirements for the retention
25 of cytology slides by laboratories for such

1 periods of time as the Secretary considers
2 appropriate; and

3 “(viii) standards requiring periodic in-
4 spection of cytology services by persons ca-
5 pable of evaluating the quality of cytology
6 services.

7 “(5) UNIFORMITY; SPECIALTIES AND SUB-
8 SPECIALTIES; ERRORS; HARMONIZATION.—

9 “(A) IN GENERAL.—The Secretary shall
10 ensure that the standards under this sub-
11 section—

12 “(i) provide nationally uniform stand-
13 ards for the performance of laboratory op-
14 erations;

15 “(ii) include—

16 “(I) standards for specialty and
17 subspecialty testing, including other
18 specialty and subspecialty testing not
19 specifically included as of the date of
20 enactment of the Diagnostic Accuracy
21 and Innovation Act in existing regula-
22 tions and standards; and

23 “(II) periodic updates of such
24 standards;

1 “(iii) include common standards for
2 the identification, investigation, and as-
3 sessment of laboratory errors and for the
4 corrective and preventive actions appro-
5 priate to address such errors;

6 “(iv) include enhanced quality require-
7 ments for preparation of reagents for use
8 not as a finished product but as a compo-
9 nent, part, or raw material of an in vitro
10 clinical test performed by the same facility,
11 and for preparation and transfer of indi-
12 vidual components, parts, and raw mate-
13 rials between commonly owned laboratories
14 within the same State, to ensure consistent
15 reagent preparation and quality control of
16 the reagent; and

17 “(v) to the extent possible, be har-
18 monized, in cooperation with the Food and
19 Drug Administration and the Centers for
20 Medicare & Medicaid Services, with other
21 existing standards and best practices, in-
22 cluding the accreditation standards of
23 widely recognized professional organiza-
24 tions and the terms, definitions, and stand-

1 ards under section 590E of the Federal
2 Food, Drug, and Cosmetic Act.

3 “(B) QUALITY SYSTEM PROCESSES.—The
4 standards under this subsection shall include
5 quality processes for—

6 “(i) management responsibility and
7 auditing;

8 “(ii) document controls;

9 “(iii) purchasing controls;

10 “(iv) laboratory processes, operations
11 and controls;

12 “(v) corrective and preventive actions;

13 “(vi) records; and

14 “(vii) servicing and maintenance.

15 “(C) MODERNIZED REGULATIONS.—Not
16 later than the day that is 3 years after the date
17 of enactment of the Diagnostic Accuracy and
18 Innovation Act, the Secretary shall issue final
19 regulations to implement this paragraph.

20 “(D) RULE OF CONSTRUCTION.—Nothing
21 in subparagraph (A) shall be construed to pro-
22 hibit an approved accreditation body from es-
23 tablishing and applying standards equal to or
24 more stringent than the standards established

1 by the Secretary under this section for purposes
2 of accreditation.

3 “(E) EFFECTIVE DATE.—The final regula-
4 tions required to be issued under subparagraph
5 (C) shall take effect on the date that is 2 years
6 after the date of issuance of such final regula-
7 tions. On and after such effective date—

8 “(i) the Secretary may issue or renew
9 a certificate for a laboratory under this
10 section only if the laboratory is in compli-
11 ance with such regulations; and

12 “(ii) each laboratory required to be
13 certified under this section shall comply
14 with such regulations.

15 “(6) ADVISORY PANEL.—In proposing and fi-
16 nalizing regulations under paragraph (5), the Sec-
17 retary shall utilize the Clinical Laboratory Improve-
18 ment Advisory Committee or such other advisory
19 panel, as determined appropriate by the Secretary,
20 to provide input into the development and content of
21 such regulations. Such advisory panel shall include,
22 at a minimum, representatives of laboratories, lab-
23 oratory operations experts, health care professionals,
24 professional societies, patient groups, laboratory test

1 developers, regulatory and quality experts, and pub-
2 lic health experts.

3 “(7) MODIFICATIONS TO IN VITRO CLINICAL
4 TESTS.—

5 “(A) PROCESSES AND POLICIES.—A lab-
6 oratory shall have in place processes and poli-
7 cies to review and assess changes to in vitro
8 clinical tests prior to the implementation of
9 such a change. Such a review and assessment
10 shall be designed to determine whether the pro-
11 posed change is a modification subject to sub-
12 chapter J of chapter V of the Federal Food,
13 Drug, and Cosmetic Act and, if so, whether
14 that modification results in a meaningful clin-
15 ical impact or changes the intended use of the
16 in vitro clinical test so as to be subject to pre-
17 market approval or listing under section
18 590B(n) of such Act.

19 “(B) PREMARKET APPROVAL OR LIST-
20 ING.—If the proposed modification has a mean-
21 ingful clinical impact or changes the intended
22 use of the in vitro clinical test so as to be sub-
23 ject to premarket approval or listing under sec-
24 tion 590B(n) of the Federal Food, Drug, and
25 Cosmetic Act, the laboratory—

1 “(i) shall obtain an approval pursuant
2 to section 590B of the Federal Food,
3 Drug, and Cosmetic Act or, if such an ap-
4 proval is not required, shall list such modi-
5 fication pursuant to section 590B(e) of the
6 Federal Food, Drug, and Cosmetic Act;
7 and

8 “(ii) shall not implement such modi-
9 fication until such approval is obtained or
10 listing occurs, as applicable, unless other-
11 wise authorized to do so.

12 “(C) EXCLUSIONS.—Amendments,
13 changes, corrections, or updates to a patient
14 specific laboratory test report—

15 “(i) shall not be considered a modi-
16 fication that requires review under section
17 590B(n) of the Federal Food, Drug, and
18 Cosmetic Act; and

19 “(ii) shall not be treated—

20 “(I) as labeling under the Fed-
21 eral Food, Drug, and Cosmetic Act;
22 or

23 “(II) as establishing an intended
24 use for purposes of such Act.

25 “(g) INSPECTIONS.—

1 “(1) IN GENERAL.—The Secretary may, on an
2 announced or unannounced basis, enter and inspect,
3 during regular hours of operation, laboratories sub-
4 ject to the requirements of this section. In con-
5 ducting such inspections, the Secretary shall have
6 access to all facilities, equipment, materials, records,
7 and information that the Secretary determines have
8 a bearing on whether the laboratory is being oper-
9 ated in accordance with this section. As part of such
10 an inspection the Secretary may copy any such ma-
11 terial or require it to be submitted to the Secretary.
12 An inspection under this paragraph may be made
13 only upon presenting identification to the owner, op-
14 erator, or agent in charge of the laboratory being in-
15 spected.

16 “(2) COMPLIANCE WITH REQUIREMENTS AND
17 STANDARDS.—The Secretary shall conduct inspec-
18 tions of laboratories under paragraph (1) to deter-
19 mine their compliance with the requirements of sub-
20 section (d) and the standards issued under sub-
21 section (f). Inspections of laboratories not accredited
22 under subsection (e) shall be conducted on a biennial
23 basis or with such other frequency as the Secretary
24 determines to be necessary to assure compliance
25 with such requirements and standards. Inspections

1 of laboratories accredited under subsection (e) shall
2 be conducted on such basis as the Secretary deter-
3 mines is necessary to assure compliance with such
4 requirements and standards.

5 “(3) SCOPE OF INSPECTIONS.—Any inspections
6 conducted pursuant to this section shall be limited
7 to laboratory operations and related issues and shall
8 not include any inspection related to activities regu-
9 lated under subchapter J of chapter V of the Fed-
10 eral Food, Drug, and Cosmetic Act.

11 “(h) INTERMEDIATE SANCTIONS.—

12 “(1) IN GENERAL.—If the Secretary determines
13 that a laboratory which has been issued a certificate
14 under this section no longer substantially meets the
15 requirements for the issuance of a certificate, the
16 Secretary may impose intermediate sanctions in lieu
17 of the actions authorized by subsection (i).

18 “(2) TYPES OF SANCTIONS.—The intermediate
19 sanctions which may be imposed under paragraph
20 (1) shall consist of—

21 “(A) directed plans of correction;

22 “(B) civil money penalties in an amount
23 not to exceed \$10,000 for each violation listed
24 in subsection (i)(1) or for each day of substan-
25 tial noncompliance with the requirements;

1 “(C) payment for the costs of onsite moni-
2 toring; or

3 “(D) any combination of the actions de-
4 scribed in subparagraphs (A), (B), and (C).

5 “(3) PROCEDURES.—The Secretary shall de-
6 velop and implement procedures with respect to
7 when and how each of the intermediate sanctions is
8 to be imposed under paragraph (1). Such procedures
9 shall provide for notice to the laboratory and a rea-
10 sonable opportunity to respond to the proposed sanc-
11 tion and appropriate procedures for appealing deter-
12 minations relating to the imposition of intermediate
13 sanctions.

14 “(i) SUSPENSION, REVOCATION, AND LIMITATION.—

15 “(1) IN GENERAL.—Except as provided in para-
16 graph (2), the certificate of a laboratory issued
17 under this section may be suspended, revoked, or
18 limited if the Secretary finds, after reasonable notice
19 and opportunity for hearing to the owner or operator
20 of the laboratory, that such owner or operator or
21 any employee of the laboratory—

22 “(A) has been guilty of misrepresentation
23 in obtaining the certificate;

24 “(B) has performed or represented the lab-
25 oratory as entitled to perform a laboratory ex-

1 amination or other procedure which is not with-
2 in a category of laboratory examinations or
3 other procedures authorized in the certificate;

4 “(C) has failed to comply with the require-
5 ments of subsection (d) or the standards pre-
6 scribed by the Secretary under subsection (f);

7 “(D) has failed to comply with reasonable
8 requests of the Secretary for—

9 “(i) any information or materials; or

10 “(ii) work on materials;

11 that the Secretary concludes is necessary to de-
12 termine the laboratory’s continued eligibility for
13 its certificate or continued compliance with the
14 Secretary’s standards under subsection (f);

15 “(E) has refused a reasonable request of
16 the Secretary, or any Federal officer or em-
17 ployee duly designated by the Secretary, for
18 permission to inspect the laboratory and its op-
19 erations and pertinent records during the hours
20 the laboratory is in operation;

21 “(F) has violated or aided and abetted in
22 the violation of any provisions of this section; or

23 “(G) has not complied with an inter-
24 mediate sanction imposed under subsection (h).

1 “(2) ACTION BEFORE A HEARING.—If the Sec-
2 retary determines that—

3 “(A) the failure of a laboratory to comply
4 with the standards of the Secretary under sub-
5 section (f) presents an imminent and serious
6 risk to human health; or

7 “(B) a laboratory has engaged in an action
8 described in subparagraph (D) or (E) of para-
9 graph (1);

10 the Secretary may suspend or limit the certificate of
11 the laboratory before holding a hearing under para-
12 graph (1) regarding such failure or refusal. The op-
13 portunity for a hearing shall be provided no later
14 than 60 calendar days from the effective date of the
15 suspension or limitation. A suspension or limitation
16 under this paragraph shall stay in effect until the
17 decision of the Secretary made after the hearing
18 under paragraph (1).

19 “(3) INELIGIBILITY TO OWN OR OPERATE LAB-
20 ORATORIES AFTER REVOCATION.—No person who
21 has owned or operated a laboratory which has had
22 its certificate revoked may, within 2 years of the rev-
23 ocation of the certificate, own or operate a labora-
24 tory for which a certificate has been issued under
25 this section, except that if the revocation occurs pur-

1 suant to paragraph (4) the Secretary may substitute
2 intermediate sanctions under subsection (h) instead
3 of the 2-year prohibition against ownership or oper-
4 ation which would otherwise apply under this para-
5 graph. The certificate of a laboratory which has been
6 excluded from participation under the Medicare pro-
7 gram under title XVIII of the Social Security Act
8 because of actions relating to the quality of the lab-
9 oratory shall be suspended for the period the labora-
10 tory is so excluded.

11 “(4) IMPROPER REFERRALS.—

12 “(A) IN GENERAL.—Any laboratory that
13 the Secretary determines intentionally refers its
14 proficiency testing samples to another labora-
15 tory for analysis may have its certificate re-
16 voked for at least one year and shall be subject
17 to appropriate fines and penalties as provided
18 for in subsection (h).

19 “(B) DEFINITION.—In this paragraph, the
20 term ‘intentionally refers’ means refers with spe-
21 cific intent to circumvent the proficiency testing
22 requirements of this section.

23 “(j) INJUNCTIONS.—Whenever the Secretary has rea-
24 son to believe that continuation of any activity by a labora-
25 tory would constitute a significant hazard to the public

1 health the Secretary may bring suit in the district court
2 of the United States for the district in which such labora-
3 tory is situated to enjoin continuation of such activity.
4 Upon proper showing, a temporary injunction or restrain-
5 ing order against continuation of such activity pending
6 issuance of a final order under this subsection shall be
7 granted without bond by such court.

8 “(k) JUDICIAL REVIEW.—

9 “(1) PETITION.—Any laboratory which has had
10 an intermediate sanction imposed under subsection
11 (h) or has had its certificate suspended, revoked, or
12 limited under subsection (i) may, at any time within
13 60 calendar days after the date the action of the
14 Secretary under subsection (i) or (h) becomes final,
15 file a petition with the United States court of ap-
16 peals for the circuit wherein the laboratory has its
17 principal place of business for judicial review of such
18 action. As soon as practicable after receipt of the pe-
19 tition, the clerk of the court shall transmit a copy
20 of the petition to the Secretary or other officer des-
21 ignated by the Secretary for that purpose. As soon
22 as practicable after receipt of the copy, the Sec-
23 retary shall file in the court the record on which the
24 action of the Secretary is based, as provided in sec-
25 tion 2112 of title 28, United States Code.

1 “(2) ADDITIONAL EVIDENCE.—If the petitioner
2 applies to the court for leave to adduce additional
3 evidence, and shows to the satisfaction of the court
4 that such additional evidence is material and that
5 there were reasonable grounds for the failure to ad-
6 duce such evidence in the proceeding before the Sec-
7 retary, the court may order such additional evidence
8 (and evidence in rebuttal of such additional evi-
9 dence) to be taken before the Secretary, and to be
10 adduced upon the hearing in such manner and upon
11 such terms and conditions as the court may deem
12 proper. The Secretary may modify the findings of
13 the Secretary as to the facts, or make new findings,
14 by reason of the additional evidence so taken, and
15 the Secretary shall file such modified or new find-
16 ings, and the recommendations of the Secretary, if
17 any, for the modification or setting aside of his
18 original action, with the return of such additional
19 evidence.

20 “(3) JUDGMENT OF COURT.—Upon the filing of
21 the petition referred to in paragraph (1), the court
22 shall have jurisdiction to affirm the action, or to set
23 it aside in whole or in part, temporarily or perma-
24 nently. The findings of the Secretary as to the facts,

1 if supported by substantial evidence, shall be conclu-
2 sive.

3 “(4) FINALITY OF JUDGMENT.—The judgment
4 of the court affirming or setting aside, in whole or
5 in part, any such action of the Secretary shall be
6 final, subject to review by the Supreme Court of the
7 United States upon certiorari or certification as pro-
8 vided in section 1254 of title 28, United States
9 Code.

10 “(l) SANCTIONS.—Any person who intentionally vio-
11 lates any requirement of this section shall be imprisoned
12 for not more than one year or fined under title 18, United
13 States Code, or both, except that if the conviction is for
14 a second or subsequent violation of such a requirement
15 such person shall be imprisoned for not more than 3 years
16 or fined in accordance with title 18, United States Code,
17 or both.

18 “(m) FEES.—

19 “(1) CERTIFICATE FEES.—The Secretary shall
20 require payment of fees for the issuance and renewal
21 of certificates, except that the Secretary shall only
22 require a nominal fee for the issuance and renewal
23 of certificates of waiver.

24 “(2) ADDITIONAL FEES.—The Secretary shall
25 require the payment of fees for inspections of labora-

1 tories which are not accredited and for the cost of
2 performing proficiency testing on laboratories which
3 do not participate in proficiency testing programs
4 approved under subsection (f)(3)(C).

5 “(3) CRITERIA.—

6 “(A) FEES UNDER PARAGRAPH (1).—Fees
7 imposed under paragraph (1) shall be sufficient
8 to cover the general costs of administering this
9 section, including evaluating and monitoring
10 proficiency testing programs approved under
11 subsection (f) and accrediting bodies and imple-
12 menting and monitoring compliance with the re-
13 quirements of this section.

14 “(B) FEES UNDER PARAGRAPH (2).—Fees
15 imposed under paragraph (2) shall be sufficient
16 to cover the cost of the Secretary in carrying
17 out the inspections and proficiency testing de-
18 scribed in paragraph (2).

19 “(C) FEES IMPOSED UNDER PARAGRAPHS
20 (1) AND (2).—Fees imposed under paragraphs
21 (1) and (2) shall vary by group or classification
22 of laboratory, based on such considerations as
23 the Secretary determines are relevant, which
24 may include the dollar volume and scope of the
25 testing being performed by the laboratories.

1 “(n) INFORMATION.—On April 1, 1990, and annually
2 thereafter, the Secretary shall compile and make available
3 to physicians and the general public information, based
4 on the previous calendar year, which the Secretary deter-
5 mines is useful in evaluating the performance of a labora-
6 tory, including—

7 “(1) a list of laboratories which have been con-
8 victed under Federal or State laws relating to fraud
9 and abuse, false billings, or kickbacks;

10 “(2) a list of laboratories—

11 “(A) which have had their certificates re-
12 voked, suspended, or limited under subsection
13 (i); or

14 “(B) which have been the subject of a
15 sanction under subsection (l);

16 together with a statement of the reasons for the rev-
17 ocation, suspension, limitation, or sanction;

18 “(3) a list of laboratories subject to inter-
19 mediate sanctions under subsection (h) together with
20 a statement of the reasons for the sanctions;

21 “(4) a list of laboratories whose accreditation
22 has been withdrawn or revoked together with a
23 statement of the reasons for the withdrawal or rev-
24 ocation;

1 “(5) a list of laboratories against which the
2 Secretary has taken action under subsection (j) to-
3 gether with a statement of the reasons for such ac-
4 tion; and

5 “(6) a list of laboratories which have been ex-
6 cluded from participation under title XVIII or XIX
7 of the Social Security Act.

8 The information to be compiled under paragraphs (1)
9 through (6) shall be information for the calendar year pre-
10 ceding the date the information is to be made available
11 to the public and shall be accompanied by such explana-
12 tory information as may be appropriate to assist in the
13 interpretation of the information compiled under such
14 paragraphs.

15 “(o) DELEGATION.—In carrying out this section, the
16 Secretary may, pursuant to agreement, use the services
17 or facilities of any Federal or State or local public agency
18 or nonprofit private organization, and may pay therefor
19 in advance or by way of reimbursement, and in such in-
20 stallments, as the Secretary may determine.

21 “(p) STATE LAWS.—

22 “(1) IN GENERAL.—Except as provided in para-
23 graph (2), no State, tribal or local government (or
24 political subdivision thereof) may establish or con-
25 tinue in effect with respect to a laboratory, a clinical

1 laboratory, or laboratory operations any requirement
2 which is different from, or in addition to, any re-
3 quirement applicable under this section to such lab-
4 oratory, clinical laboratory, or laboratory operations.

5 “(2) EXCEPTIONS.—Paragraph (1) shall not be
6 construed to affect the authority of a State, tribal,
7 or local government—

8 “(A) to license or regulate the terms of li-
9 censure of laboratory personnel, health care
10 practitioners, or health care facilities or to reg-
11 ulate any aspect of a health care practitioner-
12 patient relationship; or

13 “(B) to enforce laws of general applica-
14 bility, such as zoning laws, environmental laws,
15 labor laws, and general business laws.

16 “(3) CLARIFICATION.—This section shall not be
17 construed to shift liability to health care practi-
18 tioners.

19 “(q) CONSULTATIONS.—In carrying out this section,
20 the Secretary shall consult with appropriate private orga-
21 nizations and public agencies, including the Food and
22 Drug Administration.”.

23 **SEC. 6. TRANSITIONAL PROVISIONS.**

24 (a) CLASSIFICATION.—With respect to an in vitro
25 clinical test that is sought to be first offered after the date

1 of enactment of this Act, but before the effective date of
2 regulations implementing section 590A of the Federal
3 Food, Drug, and Cosmetic Act, as added by section 3 of
4 this Act, the Secretary shall, by regulation—

5 (1) classify such in vitro clinical test as a low-
6 risk, moderate-risk, or high-risk in vitro clinical test
7 pursuant to such section 590A; and

8 (2) classify any finished product pursuant to
9 section 513 of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360c).

11 (b) QUALITY REQUIREMENTS.—

12 (1) MANUFACTURERS.—A manufacturer of an
13 in vitro clinical test—

14 (A) prior to the date of promulgation of
15 final regulations under section 3(e), shall, with
16 respect to such in vitro clinical test, comply
17 with the quality system requirements applicable
18 to devices under the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 301 et seq.), including
20 part 820 of title 21, Code of Federal Regula-
21 tions, as in effect on the date of enactment of
22 this Act; and

23 (B) on or after the date of promulgation of
24 final regulations under section 3(e) and before
25 the effective date of such regulations under sec-

1 tion 3(e)(2)(A), shall, with respect to such in
2 vitro clinical test, comply with, at the election
3 of the manufacturer—

4 (i) the quality system requirements
5 described in subparagraph (A); or

6 (ii) the quality requirements under
7 section 590D of the Federal Food, Drug,
8 and Cosmetic Act, as added by section
9 3(a).

10 (2) LABORATORY DEVELOPERS.—A laboratory
11 developer of an in vitro clinical test, with respect to
12 activities other than laboratory operations—

13 (A) prior to the date of promulgation of
14 final regulations under section 3(e), shall, with
15 respect to such in vitro clinical test, comply
16 with any applicable quality requirements under
17 section 353 of the Public Health and Service
18 Act (42 U.S.C. 263a), as in effect on the day
19 before the date of enactment of this Act; and

20 (B) on or after the date of promulgation of
21 final regulations under section 3(e) and before
22 the effective date of such regulations under sec-
23 tion 3(e)(2)(A), shall, with respect to such in
24 vitro clinical test, comply with, at the election
25 of the laboratory developer—

1 (i) any applicable quality requirements
2 under section 353 of the Public Health
3 and Service Act (42 U.S.C. 263a), as in ef-
4 fect on the day before the date of enact-
5 ment of this Act; or

6 (ii) the quality requirements under
7 section 590D of the Federal Food, Drug,
8 and Cosmetic Act, as added by section
9 3(a).

10 (c) SUBMISSION REQUIREMENTS.—

11 (1) MANUFACTURERS.—A manufacturer of an
12 in vitro clinical test—

13 (A) with respect to an in vitro clinical test
14 first offered prior to the effective date of final
15 regulations under section 3(e)(2)(B), shall com-
16 ply with the approval process under section 515
17 of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360e), the clearance process under
19 section 510(k) of such Act (21 U.S.C. 360(k)),
20 the de novo process under section 513(f)(2) of
21 such Act (21 U.S.C. 360c(f)(2)), or the listing
22 process under section 510(j) of such Act (21
23 U.S.C. 360(j)), as applicable, in effect on the
24 date of enactment of this Act; and

1 (B) with respect to an in vitro clinical test
2 first in use on or after the effective date of final
3 regulations under section 3(e)(2)(B), shall com-
4 ply with the premarket submission requirements
5 of sections 590A, 590B, and 590D of the Fed-
6 eral Food, Drug, and Cosmetic Act, as added
7 by section 3(a).

8 (2) LABORATORIES.—

9 (A) With respect to an in vitro clinical test
10 first offered on or after the date that is 90 cal-
11 endar days prior to the date of enactment of
12 this Act, a laboratory developer of such in vitro
13 clinical test shall—

14 (i) comply with any applicable pre-
15 market requirements pursuant to section
16 353 of the Public Health and Service Act
17 (42 U.S.C. 263a), as in effect on the day
18 before the date of enactment of this Act;
19 or

20 (ii) comply with the premarket sub-
21 mission requirements of sections 590A,
22 590B, and 590D of the Federal Food,
23 Drug, and Cosmetic Act, as added by sec-
24 tion 3(a).

1 (B) If a laboratory developer elects to com-
2 ply with the premarket requirements specified
3 in subparagraph (A)(i), the laboratory developer
4 shall submit to the Secretary postmarket data
5 establishing a reasonable assurance that the in
6 vitro clinical test is analytically valid and clini-
7 cally valid. Such data shall be provided not
8 later than 3 years after the promulgation of
9 final regulations under section 3(e) and shall be
10 subject to fees pursuant to section 4.

11 (C) If a laboratory developer elects to com-
12 ply with the premarket submission requirements
13 specified in subparagraph (A)(ii), the laboratory
14 developer may immediately offer the in vitro
15 clinical test for use but—

16 (i) not later than the two years after
17 the promulgation of final regulations under
18 section 3(e), the laboratory developer shall
19 comply with such premarket submission re-
20 quirements; and

21 (ii) the corresponding application, no-
22 tification, or listing for the in vitro clinical
23 test shall not be subject to fees pursuant
24 to section 4.

25 (d) POSTMARKET REQUIREMENTS.—

1 (1) MANUFACTURERS.—A manufacturer of an
2 in vitro clinical test—

3 (A) prior to the date of promulgation of
4 final regulations under section 3(e), shall, with
5 respect to such in vitro clinical test, comply
6 with the postmarket requirements applicable to
7 devices under the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 301 et seq.), including
9 part 803 of title 21, Code of Federal Regula-
10 tions, as in effect on the date of enactment of
11 this Act; and

12 (B) on or after the date of promulgation of
13 final regulations under section 3(e) and before
14 the effective date of such regulations under sec-
15 tion 3(e)(2)(A), shall, with respect to such in
16 vitro clinical test, comply with, at the election
17 of the manufacturer—

18 (i) the postmarket requirements appli-
19 cable to devices under the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 301 et
21 seq.), including part 803 of title 21, Code
22 of Federal Regulations, as in effect on the
23 date of enactment of this Act; or

24 (ii) the postmarket requirements
25 under section 590E of the Federal Food,

1 Drug, and Cosmetic Act, as added by sec-
2 tion 3(a).

3 (2) LABORATORY DEVELOPERS.—A laboratory
4 developer of an in vitro clinical test, with respect to
5 activities governed by this Act and the amendments
6 made by this Act other than laboratory operations—

7 (A) prior to the date of promulgation of
8 final regulations under section 3(e), shall, with
9 respect to such in vitro clinical test, comply
10 with any applicable postmarket requirements
11 under section 353 of the Public Health and
12 Service Act (42 U.S.C. 263a), as in effect on
13 the day before the date of enactment of this
14 Act; and

15 (B) on or after the date of promulgation of
16 final regulations under section 3(e) and before
17 the effective date of such regulations under sec-
18 tion 3(e)(2)(A), shall, with respect to such in
19 vitro clinical test, comply with, at the election
20 of the laboratory developer—

21 (i) any applicable postmarket require-
22 ments under section 353 of the Public
23 Health and Service Act (42 U.S.C. 263a),
24 as in effect on the day before the date of
25 enactment of this Act; or

1 (ii) the postmarket requirements
2 under section 590E of the Federal Food,
3 Drug, and Cosmetic Act, as added by sec-
4 tion 3(a).

5 (e) DEFINITIONS.—In this section:

6 (1) The term “developer” has the meaning
7 given to such term in section 590 of the Federal
8 Food, Drug, and Cosmetic Act, as added by section
9 3(a).

10 (2) The term “device” has the meaning given to
11 such term in section 201 of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 321).

13 (3) The term “finished product” has the mean-
14 ing given to such term in section 201(ss) of the Fed-
15 eral Food, Drug, and Cosmetic Act, as added by sec-
16 tion 2.

17 (4) The term “in vitro clinical test” has the
18 meaning given to such term in section 201(ss) of the
19 Federal Food, Drug, and Cosmetic Act, as added by
20 section 2.

21 (5) The term “laboratory developer” means a
22 laboratory that is the developer of—

23 (A) an in vitro clinical test first offered
24 prior to the date that is 90 calendar days prior
25 to the date of enactment of this Act for which

1 the Secretary did not require an approval under
2 section 515 of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 360e), a clearance
4 under section 510(k) of such Act (21 U.S.C.
5 360(k)), or notification under section 510(j) of
6 such Act (21 U.S.C. 360(j)) or otherwise as-
7 serted enforcement discretion with regard to
8 such sections; or

9 (B) an in vitro clinical test first offered on
10 or after the day that is 90 calendar days prior
11 to the date of enactment of this Act for which,
12 prior to such day, the Secretary would not have
13 required an approval under such section 515, a
14 clearance under such section 510(k), or notifi-
15 cation under such section 510(j) or otherwise
16 would have asserted enforcement discretion with
17 regard to such sections.

18 (6) The term “manufacturer” means the devel-
19 oper of an in vitro clinical test other than a labora-
20 tory developer.