

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 4421
OFFERED BY M . _____**

Page 36, after line 21, add the following:

1 **TITLE III—VERIFYING ACCU-**
2 **RATE LEADING-EDGE IVCT**
3 **DEVELOPMENT**

4 **SEC. 301. DEFINITIONS.**

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

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

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

13 “(A) identifying or diagnosing a disease or con-
14 dition;

15 “(B) providing information for diagnosing,
16 screening, measuring, detecting, predicting,
17 prognosing, analyzing, or monitoring a disease or
18 condition, including by making a determination of
19 an individual’s state of health; or

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

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

4 “(A) a test kit;

5 “(B) a test system;

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

7 “(D) an instrument (as defined in section
8 587(11));

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

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

14 “(i) is a component or part of another in
15 vitro clinical test or analyzes, processes, or in-
16 terprets a signal or pattern from another in
17 vitro clinical test; and

18 “(ii) does not analyze, process, or interpret
19 a signal, pattern, or medical image from a de-
20 vice; and

21 “(G) subject to subparagraph (3), a component
22 or part of a test kit, a test system, a test protocol
23 or laboratory test protocol, an instrument, a speci-
24 men receptacle, or software described in subpara-

1 graph (F), whether alone or in combination, includ-
2 ing reagents, calibrators, and controls.

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

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

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

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

20 (2) by adding at the end of paragraph (g) the
21 following:

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

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

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

7 (1) by striking “(1) The term ‘biological prod-
8 uct’ means” and inserting “(1)(A) The term ‘biologi-
9 cal product’ means”; and

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

11 “(B) The term ‘biological product’ does not in-
12 clude an in vitro clinical test as defined in section
13 201(ss) of the Federal Food, Drug, and Cosmetic
14 Act.”.

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

19 **SEC. 302. REGULATION OF IN VITRO CLINICAL TESTS.**

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

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

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

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

4 **“SEC. 587. DEFINITIONS.**

5 “In this subchapter:

6 “(1) ANALYTICAL VALIDITY.—The term ‘ana-
7 lytical validity’ means, with respect to an in vitro
8 clinical test, the ability of the in vitro clinical test,
9 to identify, measure, detect, calculate, or analyze (or
10 assist in such identification, measurement, detection,
11 calculation, or analysis of) one or more analytes, bio-
12 markers, substances, or other targets intended to be
13 identified, measured, detected, calculated, or ana-
14 lyzed by the test.

15 “(2) APPLICABLE STANDARD.—The term ‘ap-
16 plicable standard’, with respect to an in vitro clinical
17 test, means a reasonable assurance of analytical and
18 clinical validity for its indications for use, and a rea-
19 sonable assurance of safety for individuals who come
20 into contact with such in vitro clinical test, except
21 that such term, with respect to specimen receptacles
22 and test instruments, means a reasonable assurance
23 of analytical validity for its indications for use and
24 safety for individuals who come into contact with
25 such specimen receptacle or test instrument.

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

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

9 “(5) COMPONENT OR PART.—The term ‘compo-
10 nent or part’ means a substance, piece, part, raw
11 material, software, firmware, labeling, or assembly,
12 including reagents, that is intended to be included as
13 an aspect of an in vitro clinical test described in sec-
14 tion 201(ss)(1).

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

17 “(A) designing, validating, producing,
18 manufacturing, remanufacturing, labeling, ad-
19 vertising, propagating, importing, or assembling
20 an in vitro clinical test;

21 “(B) modifying an in vitro clinical test, in-
22 cluding modifying the indications for use of the
23 in vitro clinical test, or modifying an article to
24 be an in vitro clinical test; or

1 “(C) establishing a test system as de-
2 scribed or included in a test protocol developed
3 by another entity unless such test protocol is
4 listed as an in vitro clinical test in the com-
5 prehensive test information system established
6 under section 587T by that other entity.

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

11 “(A) is certified by the Secretary under
12 section 353 of the Public Health Service Act;
13 and

14 “(B) assembles for use solely within that
15 laboratory, without otherwise developing, an in
16 vitro clinical test appropriately listed in the
17 comprehensive test information system estab-
18 lished under section 587T by a different person.

19 “(8) FIRST-OF-A-KIND.—The term ‘first-of-a-
20 kind’, with respect to an in vitro clinical test, means
21 that such test has any novel combination of the ele-
22 ments specified in paragraph (10) that differs from
23 in vitro clinical tests that already are legally avail-
24 able in the United States, except for such tests of-

1 ferred under section 587C(a)(3), 587C(a)(4), or
2 587G.

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

8 “(A)(i) is reasonably likely to result in se-
9 rious or irreversible harm or death to a patient
10 or patients, or would otherwise cause serious
11 harm to the public health; or

12 “(ii) is reasonably likely to result in the
13 absence, significant delay, or discontinuation of
14 life-supporting or life-sustaining medical treat-
15 ment; and

16 “(B) mitigating measures are not able to
17 be established and applied to prevent, mitigate,
18 or detect the inaccurate result, or otherwise suf-
19 ficiently mitigate the risk resulting from an un-
20 detected inaccurate result described in subpara-
21 graph (A), such that the test would be mod-
22 erate-risk or low-risk.

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

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

4 “(B) Test method.

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

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

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

14 “(11) INSTRUMENT.—

15 “(A) IN GENERAL.—The term ‘instrument’
16 means an analytical or pre-analytical instru-
17 ment.

18 “(B) ANALYTIC INSTRUMENT.—The term
19 ‘analytic instrument’ means an in vitro clinical
20 test that is hardware intended by the developer
21 to be used with one or more other in vitro clin-
22 ical tests to generate a clinical test result, in-
23 cluding software used to effectuate the
24 functionality of the hardware.

1 “(C) PRE-ANALYTICAL INSTRUMENT.—The
2 term ‘pre-analytical instrument’ means an in
3 vitro clinical test that is hardware intended by
4 the developer solely to generate an output for
5 use exclusively with one or more analytical in-
6 struments as defined in subparagraph (B) and
7 which does not itself generate a clinical test re-
8 sult. Such term may include software used to
9 effectuate the hardware’s functionality.

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

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

17 “(B) have the same indications for use and
18 capabilities;

19 “(C) share the same measurement prin-
20 ciples, detection methods, and reaction condi-
21 tions, as applicable; and

22 “(D) produce the same or similar analyt-
23 ical results from samples of the same specimen
24 type or types.

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

3 “(A) means the conduct of a laboratory ex-
4 amination or other laboratory procedure on ma-
5 terials derived from the human body, including
6 the conduct of an in vitro clinical test and asso-
7 ciated activities, that is—

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

10 “(ii) not related to the design, analyt-
11 ical validation, or clinical validation of an
12 in vitro clinical test; and

13 “(B) includes—

14 “(i) performing pre-analytical and
15 post-analytical processes for an in vitro
16 clinical test;

17 “(ii) standard operating procedures
18 and the conduct thereof; and

19 “(iii) preparing reagents or other test
20 materials that do not meet the criteria for
21 being an in vitro clinical test for clinical
22 use.

23 “(14) LOW-RISK.—The term ‘low-risk’, with re-
24 spect to an in vitro clinical test or category of in
25 vitro clinical tests, means that an undetected inac-

1 curate result from such in vitro clinical test, or such
2 category of in vitro clinical tests, when used as in-
3 tended—

4 “(A) would cause only minimal or imme-
5 diately reversible harm, and would lead to only
6 a remote risk of adverse patient impact or ad-
7 verse public health impact; or

8 “(B) sufficient mitigating measures are
9 able to be established and applied such that the
10 in vitro clinical test meets the standard de-
11 scribed in subparagraph (A).

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

14 “(A) means controls, standards, and other
15 requirements that the Secretary determines,
16 based on evidence, are necessary—

17 “(i) for an in vitro clinical test, or a
18 category of in vitro clinical tests, to meet
19 the applicable standard; or

20 “(ii) to mitigate the risk of harm en-
21 suing from an undetected inaccurate result
22 or misinterpretation of a result; and

23 “(B) may include, as required by the Sec-
24 retary, as appropriate, applicable requirements
25 regarding labeling, conformance to performance

1 standards and consensus standards, perform-
2 ance testing, submission of clinical data, adver-
3 tising, website posting of information, clinical
4 studies, postmarket surveillance, user com-
5 prehension studies, training, and confirmatory
6 laboratory, clinical findings, the history of the
7 developer, the role of a health professional in
8 the testing process, such as integration of the
9 testing laboratory into the direct medical care
10 of the patient, including direct interaction be-
11 tween the testing laboratory and treating physi-
12 cian, or testing.

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

16 “(A) means a test or category of tests that
17 is not high-risk under the criteria under para-
18 graph (9) or low-risk under the criteria under
19 paragraph (14); and

20 “(B) may include a test or category of
21 tests that, when used as intended, meet the cri-
22 teria specified in paragraph (9)(A) for high-
23 risk, but for which one or more mitigating
24 measures are able to be established and applied
25 to prevent, mitigate, or detect an inaccurate re-

1 sult or otherwise sufficiently mitigate the risk
2 resulting from an undetected inaccurate result,
3 but are not sufficient such that the test is low-
4 risk under the criteria in paragraph (14).

5 “(17) SPECIMEN RECEPTACLE.—The term
6 ‘specimen receptacle’ means an in vitro clinical test
7 intended for taking, collecting, holding, storing, or
8 transporting of specimens derived from the human
9 body or for preparation, analysis, or in vitro clinical
10 examination for purposes described in section
11 201(ss)(1).

12 “(18) TECHNOLOGY.—The term ‘technology’—
13 “(A) means a set of control mechanisms,
14 energy sources, or operating principles—

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

17 “(ii) for which design and develop-
18 ment (including analytical and clinical vali-
19 dation, as applicable) of the tests would be
20 addressed in a similar manner or through
21 similar procedures; and

22 “(B) may include clot detection, colori-
23 metric (non-immunoassay), electrochemical
24 (non-immunoassay), enzymatic (non-
25 immunoassay), flow cytometry, fluorometry

1 (non-immunoassay), immunoassay, mass spec-
2 trometry or chromatography, microbial culture,
3 next generation sequencing, nephelometric or
4 turbidimetric (non-immunoassay), singleplex or
5 multiplex non-NGS nucleic acid analysis, slide-
6 based technology, spectroscopy, and any other
7 technology, as the Secretary determines appro-
8 priate.

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

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

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

15 “(i) has been generated and evaluated
16 by persons qualified by training or experi-
17 ence to do so, using procedures generally
18 accepted by other persons so qualified; and

19 “(ii) forms an appropriate basis for
20 concluding by qualified experts whether the
21 applicable standard has been met by the in
22 vitro clinical test; and

23 “(B) may include evidence described in
24 subparagraph (A) consisting of—

25 “(i) peer-reviewed literature;

- 1 “(ii) clinical guidelines;
- 2 “(iii) reports of significant human ex-
- 3 perience with an in vitro clinical test;
- 4 “(iv) bench studies;
- 5 “(v) case studies or histories;
- 6 “(vi) clinical data;
- 7 “(vii) consensus standards;
- 8 “(viii) reference standards;
- 9 “(ix) data registries;
- 10 “(x) postmarket data;
- 11 “(xi) real world data;
- 12 “(xii) clinical trials; and
- 13 “(xiii) data collected in countries
- 14 other than the United States if such data
- 15 are demonstrated to be appropriate for the
- 16 purpose of making a regulatory determina-
- 17 tion under this subchapter.

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

19 “(a) IN GENERAL.—No person shall introduce or de-

20 liver for introduction into interstate commerce any in vitro

21 clinical test, unless—

22 “(1) an approval of an application filed pursu-

23 ant to subsection (a) or (b) of section 587B is effec-

24 tive with respect to such in vitro clinical test;

1 “(2) the in vitro clinical test is offered under a
2 technology certification order under section
3 587D(b)(1); or

4 “(3) the test is exempt under sections 587C or
5 587G from the requirements of section 587B.

6 “(b) TRANSFER OR SALE OF IN VITRO CLINICAL
7 TESTS.—

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

20 “(2) TRANSFER OR SALE OF PREMARKET AP-
21 PROVAL.—

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

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

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

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

18 “(3) TRANSFER OR SALE OF TECHNOLOGY CER-
19 TIFICATION.—

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

24 “(i) is an eligible person under section
25 587D(a)(2); and

1 “(ii) maintains, upon such transfer or
2 sale, test design and quality requirements,
3 processes and procedures under the scope
4 of technology certification, and scope of the
5 technology certification identified in the
6 applicable technology certification order.

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

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

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

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

12 **“SEC. 587B. PREMARKET REVIEW.**

13 “(a) APPLICATION.—

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

17 “(2) TRANSPARENCY AND PREDICTABILITY.—If
18 a developer files a premarket application under this
19 section and provides any additional documentation
20 required under section 587D, the in vitro clinical
21 test that is the subject of the premarket application
22 may be utilized as the representative in vitro clinical
23 test reviewed by the Secretary to support a tech-
24 nology certification order under section 587D.

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

4 “(A) General information regarding the in
5 vitro clinical test, including—

6 “(i) the name and address of the ap-
7 plicant;

8 “(ii) the table of contents for the ap-
9 plication and the identification of the infor-
10 mation the applicant claims as trade secret
11 or confidential commercial or financial in-
12 formation;

13 “(iii) a description of the test’s design
14 and intended use, including the indications
15 for use; and

16 “(iv) a description regarding test
17 function and performance characteristics.

18 “(B) A summary of the data and informa-
19 tion in the application for the in vitro clinical
20 test, including—

21 “(i) a brief description of the foreign
22 and domestic marketing history of the test,
23 if any, including a list of all countries in
24 which the test has been marketed and a
25 list of all countries in which the test has

1 been withdrawn from the market for any
2 reason related to the ability of the in vitro
3 clinical test to meet the applicable stand-
4 ard, if known by the applicant;

5 “(ii) a description of benefit and risk
6 considerations related to the in vitro clin-
7 ical test, including a description of any ap-
8 plicable adverse effects of the test on
9 health and how such adverse effects have
10 been, or will be, mitigated;

11 “(iii) a risk assessment of the test;
12 and

13 “(iv) a description of how the data
14 and information in the application con-
15 stitute valid scientific evidence and support
16 a showing that the test meets the applica-
17 ble standard under section 587(2).

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

21 “(D) A bibliography of applicable pub-
22 lished reports and a description of any studies
23 conducted, including any unpublished studies
24 related to such test, that are known or that
25 should reasonably be known to the applicant,

1 and a description of data and information rel-
2 evant to the evaluation of whether the test
3 meets the applicable standard.

4 “(E) Applicable information regarding the
5 methods used in, and the facilities or controls
6 used for, the development of the test to dem-
7 onstrate compliance with the applicable quality
8 requirements under section 587K.

9 “(F) Information demonstrating compli-
10 ance with any relevant and applicable—

11 “(i) mitigating measures under sec-
12 tion 587E; and

13 “(ii) standards established or recog-
14 nized under section 514 prior to the date
15 of enactment of the VALID Act of 2023,
16 or, after applicable standards are estab-
17 lished or recognized under section 587R,
18 with such standards.

19 “(G) Valid scientific evidence to support
20 that the test meets the applicable standard,
21 which shall include—

22 “(i) summary information for all sup-
23 porting validation studies performed, in-
24 cluding a description of the objective of the
25 study, a description of the experimental de-

1 sign of the study, a description of any limi-
2 tations of the study, a brief description of
3 how the data were collected and analyzed,
4 a brief description of the results of each
5 study, and conclusions drawn from each
6 study;

7 “(ii) raw data for each study, which
8 may include, as applicable, tabulations of
9 data and results; and

10 “(iii) for nonclinical laboratory studies
11 involving the test, if applicable, a state-
12 ment that studies were conducted in com-
13 pliance with applicable good laboratory
14 practices.

15 “(H) To the extent the application seeks
16 authorization to make modifications to the test
17 within the scope of the approval that are not
18 otherwise permitted without premarket review
19 under this subchapter, a proposed change pro-
20 tocol that includes validation procedures and
21 acceptance criteria for anticipated modifications
22 that could be made to the test within the scope
23 of the approval.

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

1 “(J) Such other data or information as the
2 Secretary may require in accordance with the
3 least burdensome requirements under section
4 587AA(c).

5 “(4) REGULATION FOR PREMARKET AND AB-
6 BREVIAED PREMARKET APPLICATIONS.—Not later
7 than 3 years after the date of enactment of the
8 VALID Act of 2023, the Secretary shall promulgate
9 final regulations detailing the information to be pro-
10 vided in a premarket application and abbreviated
11 premarket application under this section.

12 “(5) REFUSE TO FILE A PREMARKET OR AB-
13 BREVIAED PREMARKET APPLICATION.—The Sec-
14 retary may refuse to file an application under this
15 section only for lack of completeness or legibility of
16 the application. If, after receipt of an application
17 under this section, the Secretary refuses to file such
18 an application, the Secretary shall provide to the de-
19 veloper, within 45 calendar days of receipt of such
20 application submitted under this subsection or with-
21 in 30 calendar days of receipt of an application sub-
22 mitted under subsection (b), a description of the rea-
23 son for such refusal, and identify the information re-
24 quired, if any, to allow for the filing of the applica-
25 tion.

1 “(6) SUBSTANTIVE REVIEW FOR DEFICIENT AP-
2 PLICATION.—If, after receipt of an application under
3 this section, the Secretary determines that any por-
4 tion of such application is materially deficient, the
5 Secretary shall provide to the applicant a description
6 of such material deficiencies and the information re-
7 quired to resolve such deficiencies.

8 “(7) INSPECTIONS.—With respect to an appli-
9 cation under paragraph (1), preapproval inspections
10 authorized by an employee of the Food and Drug
11 Administration or a person accredited under section
12 587Q need not occur unless requested by the Sec-
13 retary.

14 “(b) ABBREVIATED PREMARKET REVIEW.—

15 “(1) IN GENERAL.—Any developer may file
16 with the Secretary an application for abbreviated
17 premarket approval for—

18 “(A) an instrument;

19 “(B) a specimen receptacle;

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

22 “(D) an in vitro clinical test that is deter-
23 mined by the Secretary to be eligible for abbrevi-
24 ated premarket review under section
25 587F(a)(1)(B).

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

3 “(A) the information required for applica-
4 tions submitted under subsection (a)(3), except
5 that applications under paragraph (1) need not
6 include—

7 “(i) quality requirement information;

8 or

9 “(ii) raw data, unless requested in
10 writing by the Secretary, in accordance
11 with the least burdensome requirements
12 under section 587AA(c), and with super-
13 visory review and concurrence prior to
14 issuance of such request; and

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

20 “(3) SAFETY INFORMATION.—The developer of
21 an in vitro clinical test specimen receptacle reviewed
22 under this subsection shall maintain safety informa-
23 tion for such specimen receptacle.

24 “(4) INSPECTIONS.—With respect to an appli-
25 cation under paragraph (1), preapproval inspections

1 shall not be required unless requested in writing by
2 the Secretary, after supervisory review and concur-
3 rence, because such inspection is considered nec-
4 essary to complete the review.

5 “(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—

6 “(1) IN GENERAL.—A developer of an instru-
7 ment family shall file with the Secretary an applica-
8 tion for premarket approval of one version of an in-
9 strument under this subsection. Any modified
10 versions of the instrument that generate a new in-
11 strument within the same instrument family shall be
12 exempt from premarket review requirements of this
13 section, provided that the developer of such instru-
14 ment or instrument family—

15 “(A) maintains documentation that the
16 new instrument is part of the instrument fam-
17 ily, as defined in section 587;

18 “(B) performs, documents, and maintains
19 a risk assessment (as described in subsection
20 (a)(3)(B)(iii)) of the new instrument compared
21 to the instrument approved under subsection
22 (b) and no new risks are identified;

23 “(C) performs, documents, and maintains
24 validation and verification activities for the new
25 instrument;

1 “(D) makes such documentation available
2 to the Secretary upon request; and

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

5 “(2) TEST KITS AND TEST PROTOCOLS.—With
6 regard to a test kit or test protocol that is approved
7 under this section for use on an approved instru-
8 ment or an instrument exempt from premarket re-
9 view, including an instrument within an instrument
10 family under this section, a submission under this
11 section shall not be required for such test kit or test
12 protocol in order for it to be used on a new instru-
13 ment within its instrument family, provided that—

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

16 “(i) change the claims for the test kit
17 or test protocol, except as applicable,
18 claims regarding an instrument or instru-
19 ments that can be used with such test kit
20 or test protocol;

21 “(ii) adversely affect performance of
22 the test kit or test protocol; or

23 “(iii) cause the test kit or test pro-
24 tocol to no longer conform with perform-
25 ance standards required under section

1 587R or comply with any applicable miti-
2 gating measures under section 587E, con-
3 ditions of approval under subsection
4 (e)(2)(B), or restrictions under section
5 587O;

6 “(B) the test developer does not identify
7 any new risks for the test kit or test protocol
8 when using the new instrument after con-
9 ducting a risk assessment;

10 “(C) the test developer validates the use of
11 the new instrument with the test kit or test
12 protocol and maintains validation documenta-
13 tion;

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

16 “(i) in settings for which a certificate
17 of waiver is in effect under section 353 of
18 the Public Health Service Act;

19 “(ii) without a prescription;

20 “(iii) at home; or

21 “(iv) in testing donors, donations, and
22 recipients of blood, blood components,
23 human cells, tissues, cellular-based prod-
24 ucts, or tissue-based products;

1 “(E) the test developer makes the docu-
2 mentation described under subparagraph (C)
3 available to the Secretary upon request; and

4 “(F) the test developer updates the listing
5 information for the test kit or test protocol, as
6 applicable.

7 “(d) AMENDMENTS TO AN APPLICATION.—An appli-
8 cant shall amend an application submitted under sub-
9 section (a), (b), or (f) if the applicant becomes aware of
10 information that could reasonably affect an evaluation
11 under subsection (e) of whether the approval standard has
12 been met.

13 “(e) ACTION ON AN APPLICATION FOR PREMARKET
14 APPROVAL.—

15 “(1) REVIEW.—

16 “(A) DISPOSITION.—As promptly as pos-
17 sible, but not later than 90 calendar days after
18 an application under subsection (a) is accepted
19 for submission (unless the Secretary determines
20 that an extension is necessary to review one or
21 more major amendments to the application), or
22 not later than 60 calendar days after an appli-
23 cation under subsection (b) is accepted for sub-
24 mission or a supplemental application under
25 subsection (f) is accepted for submission, the

1 Secretary, after considering any applicable re-
2 port and recommendations pursuant to advisory
3 committees under section 587H, shall issue an
4 order approving the application, unless the Sec-
5 retary finds that the grounds for approval in
6 paragraph (2) are not met.

7 “(B) RELIANCE ON PROPOSED LABEL-
8 ING.—In determining whether to approve or
9 deny an application under paragraph (1), the
10 Secretary shall rely on the indications for use
11 included in the proposed labeling, provided that
12 such labeling is not false or misleading based on
13 a fair evaluation of all material facts.

14 “(2) APPROVAL OF AN APPLICATION.—

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

20 “(i) the applicant is in compliance
21 with applicable quality requirements in sec-
22 tion 587K;

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

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

5 “(iv) the applicant permits, if re-
6 quested, authorized employees of the Food
7 and Drug Administration and persons ac-
8 credited under section 587Q an oppor-
9 tunity to inspect pursuant to section 704;

10 “(v) the test conforms with any appli-
11 cable performance standards required
12 under section 587R and any applicable
13 mitigating measures under section 587E;

14 “(vi) all nonclinical laboratory studies
15 and clinical investigations involving human
16 subjects that are described in the applica-
17 tion were conducted in a manner that
18 meets the applicable requirements of this
19 subchapter; and

20 “(vii) other data and information the
21 Secretary may require under subsection
22 (a)(3)(J) support approval.

23 “(B) CONDITIONS OF APPROVAL.—An
24 order approving an application pursuant to this
25 section may require reasonable conditions of ap-

1 proval for the in vitro clinical test, which may
2 include conformance with applicable mitigating
3 measures under section 587E, restrictions
4 under section 587O, and performance standards
5 under section 587R.

6 “(C) PUBLICATION.—The Secretary shall
7 publish an order for each application approved
8 pursuant to this paragraph on the public
9 website of the Food and Drug Administration
10 and make publicly available a summary of the
11 data used to approve such application. In mak-
12 ing the order and summary publicly available,
13 the Secretary shall not disclose any information
14 that—

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

20 “(ii) could compromise national secu-
21 rity.

22 “(3) REVIEW OF DENIALS.—An applicant
23 whose application submitted under this section has
24 been denied approval under this subsection may, by
25 petition filed not more than 60 calendar days after

1 the date on which the applicant receives notice of
2 such denial, obtain review of the denial in accord-
3 ance with section 587P.

4 “(f) SUPPLEMENTS TO AN APPROVED APPLICA-
5 TION.—

6 “(1) RISK ANALYSIS.—Prior to implementing
7 any modification to an in vitro clinical test, the hold-
8 er of the application approved under subsection (e)
9 for such test shall perform risk analyses in accord-
10 ance with this subsection, unless such modification is
11 included in the change protocol submitted by the ap-
12 plicant and approved under this section or exempt
13 under section 587C.

14 “(2) SUPPLEMENT REQUIREMENT.—

15 “(A) IN GENERAL.—If the holder of an ap-
16 plication of an approved in vitro clinical test
17 makes a modification to such in vitro clinical
18 test, except as provided in subparagraph (C), or
19 otherwise specified by the Secretary, the holder
20 of the application approved under subsection (e)
21 for an in vitro clinical test shall submit a sup-
22 plemental application to the Secretary. The
23 holder of the application may not implement
24 such modification to the in vitro clinical test
25 until such supplemental application is approved.

1 The information required in a supplemental ap-
2 plication is limited to what is needed to support
3 the change.

4 “(B) CHANGE PROTOCOLS.—The holder of
5 an approved application may submit under this
6 paragraph a supplemental application to modify
7 the change protocol for a test or to request a
8 change protocol for a test.

9 “(C) EXCEPTIONS.—Notwithstanding sub-
10 paragraphs (A) and (B), and so long as the
11 holder of an approved application submitted
12 under subsection (a) or (b) for an in vitro clin-
13 ical test does not add a manufacturing site, or
14 change activities at an existing manufacturing
15 site, with respect to the test, the holder of an
16 approved application may, without submission
17 of a supplemental application, implement the
18 following modifications to the test:

19 “(i) Modifications in accordance with
20 an approved change protocol under sub-
21 section (a)(3)(H).

22 “(ii) Modifications that are exempt
23 under section 587C(a)(6).

24 “(iii) Labeling changes that are ap-
25 propriate to address a safety concern, ex-

1 cept such labeling changes that include any
2 of the following remain subject to subpara-
3 graph (A):

4 “(I) A change to the indications
5 for use of the test.

6 “(II) A change to the perform-
7 ance claims made with respect to the
8 test.

9 “(III) A change that adversely
10 affects performance of the test.

11 “(D) REPORTING FOR CERTAIN MODIFICA-
12 TIONS MADE PURSUANT TO A CHANGE PRO-
13 TOCOL.—The holder of an application approved
14 under subsection (e), with an approved change
15 protocol under subsection (a)(2)(H) for such in
16 vitro clinical test shall—

17 “(i) report any modification to such
18 test made pursuant to such change pro-
19 tocol approved under subsection (a)(3)(H)
20 in a submission under section
21 587J(c)(2)(B); and

22 “(ii) include in such report—

23 “(I) a description of the modi-
24 fication;

1 “(II) the rationale for imple-
2 menting such modification; and

3 “(III) as applicable, a summary
4 of the evidence supporting that the
5 test, as modified, meets the applicable
6 standard, complies with performance
7 standards required under section
8 587Q, and complies with any miti-
9 gating measures established under
10 section 587E and any restrictions
11 under section 587O.

12 “(E) REPORTING FOR CERTAIN SAFETY
13 RELATED LABELING CHANGES.—The holder of
14 the application for an in vitro clinical test ap-
15 proved under subsection (e) shall—

16 “(i) report to the Secretary any modi-
17 fication to the test described in subpara-
18 graph (C)(iii) not more than 30 days after
19 the date on which the test, with the modi-
20 fication, is introduced into interstate com-
21 merce; and

22 “(ii) include in the report—

23 “(I) a description of the change
24 or changes;

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

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

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

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

10 “(i) a description of the modification;

11 “(ii) data relevant to the modification
12 to demonstrate that the applicable stand-
13 ard is met, not to exceed data require-
14 ments for the original submission;

15 “(iii) acceptance criteria; and

16 “(iv) any revised labeling; and

17 “(B) for manufacturing site changes—

18 “(i) the information listed in subpara-
19 graph (A); and

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

1 “(4) ADDITIONAL DATA.—The Secretary may
2 require, when necessary, data to evaluate a modifica-
3 tion to an in vitro clinical test that is in addition to
4 the data otherwise required under the preceding
5 paragraphs if the data request is in accordance with
6 the least burdensome requirements under section
7 587AA(c).

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

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

16 “(A) the data demonstrate that the modi-
17 fied in vitro clinical test meets the applicable
18 standard; and

19 “(B) the holder of the application approved
20 under subsection (e) for the test has dem-
21 onstrated compliance with applicable quality
22 and inspection requirements, as applicable and
23 appropriate.

24 “(7) PUBLICATION.—The Secretary shall pub-
25 lish on the public website of the Food and Drug Ad-

1 ministration notice of any order approving a supple-
2 ment under this subsection provided that doing so
3 does not disclose any information that—

4 “(A) is trade secret or confidential com-
5 mercial or financial information; or

6 “(B) could compromise national security.

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

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

15 “(1) ORDER WITHDRAWING APPROVAL.—

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

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

1 “(ii) there is a reasonable likelihood
2 that the test would cause death or serious
3 adverse health consequences, including by
4 causing the absence, significant delay, or
5 discontinuation of life-saving or life sus-
6 taining medical treatment;

7 “(iii) the holder of the approved appli-
8 cation—

9 “(I) has failed to, or repeatedly
10 or deliberately failed to, maintain
11 records to make reports, as required
12 under section 587M;

13 “(II) has refused to permit ac-
14 cess to, or copying or verification of
15 such records, as required under sec-
16 tion 704;

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

19 “(IV) has not complied with any
20 mitigating measure required under
21 section 587E or restriction under sec-
22 tion 587O; or

23 “(iv) the labeling of such in vitro clin-
24 ical test, based on a fair evaluation of all
25 material facts, is false or misleading in any

1 particular and was not corrected within a
2 reasonable time after receipt of written no-
3 tice from the Secretary of such fact.

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

9 “(C) PUBLICATION.—The Secretary shall
10 publish any order under subparagraph (A) on
11 the public website of the Food and Drug Ad-
12 ministration provided that doing so does not
13 disclose—

14 “(i) any information that is trade se-
15 cret or confidential commercial or financial
16 information; or

17 “(ii) any other information that the
18 Secretary determines, if published, could
19 compromise national security.

20 “(2) ORDER OF TEMPORARY SUSPENSION.—If,
21 after providing due notice and an opportunity for an
22 informal hearing to the holder of an approved appli-
23 cation for an in vitro clinical test under this section,
24 the Secretary determines, based on scientific evi-
25 dence, that there is a reasonable likelihood that the

1 in vitro clinical test would cause death or serious ad-
2 verse health consequences, such as by causing the
3 absence, significant delay, or discontinuation of life-
4 saving or life-sustaining medical treatment, the Sec-
5 retary shall, by order, temporarily suspend the ap-
6 proval of the application. If the Secretary issues
7 such an order, the Secretary shall proceed expedi-
8 tiously under paragraph (1) to withdraw approval of
9 such application.

10 “(3) APPEAL WITHDRAWING APPROVAL AND
11 ORDERS OF TEMPORARY SUSPENSIONS.—An order of
12 withdrawal or an order of temporary suspension may
13 be appealed under 587P.

14 **“SEC. 587C. EXEMPTIONS.**

15 “(a) IN GENERAL.—The following in vitro clinical
16 tests are exempt from premarket review under section
17 587B, and may be lawfully offered subject to other appli-
18 cable requirements of this Act:

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

20 “(A) EXEMPTION.—An in vitro clinical
21 test is exempt from premarket review under
22 section 587B and may be lawfully offered sub-
23 ject to the other applicable requirements of this
24 Act, if the developer of the in vitro clinical
25 test—

1 “(i) maintains documentation dem-
2 onstrating that the test meets and con-
3 tinues to meet the criteria set forth in sub-
4 paragraph (B); and

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

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

10 “(i)(I)(aa) was offered for clinical use
11 prior to the date of enactment of the
12 VALID Act of 2023; and

13 “(bb) immediately prior to such date
14 of enactment was exempt pursuant to sub-
15 section (l) or (m)(2) of section 510 from
16 the requirements for submission of a re-
17 port under section 510(k); or

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

20 “(bb) is not an instrument; and

21 “(cc) falls within a category of tests
22 that was exempt from the requirements for
23 submission of a report under section
24 510(k) as of such date of enactment (in-

1 cluding class II devices and excluding class
2 I devices described in section 510(l));

3 “(ii) meets the applicable standard as
4 described in section 587(2);

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

7 “(iv) is not likely to cause or con-
8 tribute to serious adverse health con-
9 sequences.

10 “(C) EFFECT ON SPECIAL CONTROLS.—

11 For any in vitro clinical test, or category of in
12 vitro clinical tests, that is exempt from pre-
13 market review based on the criteria in subpara-
14 graph (B), any special control that applied to a
15 device within a predecessor category imme-
16 diately prior to the date of enactment of the
17 VALID Act of 2023 shall be deemed a miti-
18 gating measure applicable under section 587E
19 to an in vitro clinical test within the successor
20 category, except to the extent such mitigating
21 measure is withdrawn or changed in accordance
22 with section 587E.

23 “(D) NEAR-PATIENT TESTING.—Not later
24 than 1 year after the date of enactment of the
25 VALID Act of 2023, the Secretary shall issue

1 draft guidance indicating categories of tests
2 that shall be exempt from premarket review
3 under section 587B when offered for near-pa-
4 tient testing (point of care), which were not ex-
5 empt from submission of a report under section
6 510(k) pursuant to subsection (l) or (m)(2) of
7 section 510 and regulations imposing limita-
8 tions on exemption for in vitro devices intended
9 for near-patient testing (point of care).

10 “(2) LOW-RISK TESTS.—

11 “(A) EXEMPTION.—An in vitro clinical
12 test is exempt from premarket review under
13 section 587B and may be lawfully offered sub-
14 ject to the other applicable requirements of this
15 Act, including section 587J(b), if such test
16 meets the definition of low-risk under section
17 587 and if the developer of the test—

18 “(i) maintains documentation dem-
19 onstrating that the in vitro clinical test
20 meets and continues to meet the criteria
21 set forth in subparagraph (B); and

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

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

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

6 “(ii) the labeling and advertising are
7 not false or misleading;

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

11 “(iv) the in vitro clinical test falls
12 within a category of tests listed as de-
13 scribed in subparagraph (C).

14 “(C) LIST OF LOW-RISK TESTS.—

15 “(i) IN GENERAL.—The Secretary
16 shall maintain, and make publicly available
17 on the website of the Food and Drug Ad-
18 ministration, a list of in vitro clinical tests,
19 and categories of in vitro clinical tests,
20 that are low-risk in vitro clinical tests for
21 purposes of the exemption under this para-
22 graph.

23 “(ii) INCLUSION.—The list under
24 clause (i) shall consist of—

1 “(I) all in vitro clinical tests and
2 categories of in vitro clinical tests that
3 are exempt from premarket review
4 pursuant to paragraph (1) or this
5 paragraph; and

6 “(II) all in vitro clinical tests and
7 categories of in vitro clinical tests that
8 are designated by the Secretary pur-
9 suant to subparagraph (D) as low-risk
10 for purposes of this paragraph.

11 “(D) DESIGNATION OF TESTS AND CAT-
12 EGORIES.—Without regard to subchapter II of
13 chapter 5 of title 5, United States Code, the
14 Secretary may designate, in addition to the
15 tests and categories described in subparagraph
16 (C)(i), additional in vitro clinical tests, and cat-
17 egories of in vitro clinical tests, as low-risk in
18 vitro clinical tests for purposes of the exemption
19 under this paragraph. The Secretary may make
20 such a designation on the Secretary’s own ini-
21 tiative or in response to a request by a devel-
22 oper pursuant to subsection (a) or (b) of section
23 587F. In making such a designation for a test
24 or category of tests, the Secretary shall con-
25 sider—

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

3 “(ii) the existence of and ability to de-
4 velop mitigating measures sufficient for
5 such test category to meet the low-risk
6 standard; and

7 “(iii) such other factors as the Sec-
8 retary determines to be appropriate for the
9 protection of the public health.

10 “(3) HUMANITARIAN TEST EXEMPTION.—

11 “(A) IN GENERAL.—An in vitro clinical
12 test that meets the criteria under subparagraph
13 (B) is exempt from premarket review under sec-
14 tion 587B and may be lawfully offered subject
15 to the other applicable requirements of this sub-
16 chapter, if the developer of the test—

17 “(i) maintains documentation (which
18 may include literature citations in special-
19 ized medical journals, textbooks, special-
20 ized medical society proceedings, and gov-
21 ernmental statistics publications, or, if no
22 such studies or literature citations exist,
23 credible conclusions from appropriate re-
24 search or surveys) demonstrating that such

1 test meets and continues to meet the cri-
2 teria described in this subsection; and

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

5 “(B) CRITERIA FOR EXEMPTION.—An in
6 vitro clinical test is exempt as described in sub-
7 paragraph (A) if—

8 “(i) the in vitro clinical test is in-
9 tended by the developer for use for a diag-
10 nostic purpose for—

11 “(I) a noncontagious disease or
12 condition that affects not more than
13 10,000 (or such other higher number
14 determined by the Secretary) individ-
15 uals in the United States per year; or

16 “(II) a contagious disease or con-
17 dition that affects not more than
18 1,500 individuals in the United States
19 per year;

20 “(ii) the in vitro clinical test meets
21 the applicable standard described in sec-
22 tion 587(2);

23 “(iii) the labeling and advertising for
24 the in vitro clinical test are not false or
25 misleading;

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

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

6 “(C) EXCEPTION FOR CERTAIN TESTS.—

7 An in vitro clinical test intended to inform the
8 use of a specific individual or specific type of bi-
9 ological product, drug, or device shall be eligible
10 for an exemption from premarket review under
11 this subsection only if, the developer submits a
12 request under section 587F(e) for informal
13 feedback and the Secretary determines that
14 such in vitro clinical test is eligible for an ex-
15 emption from premarket review under this sub-
16 section.

17 “(4) CUSTOM TESTS AND LOW-VOLUME
18 TESTS.—An in vitro clinical test is exempt from pre-
19 market review under section 587B, quality require-
20 ments under section 587K, and listing requirements
21 under section 587J, and may be lawfully offered
22 subject to the other applicable requirements of this
23 Act, if—

24 “(A) such in vitro clinical test—

1 “(i) is a test protocol performed for
2 not more than 5 patients per year (or such
3 other higher number determined by the
4 Secretary), in a laboratory certified by the
5 Secretary under section 353 of the Public
6 Health Service Act that—

7 “(I) meets the requirements to
8 perform tests of high-complexity in
9 which the test protocol was developed;
10 or

11 “(II) meets the requirements to
12 perform tests of high-complexity with-
13 in the same corporate organization
14 and having common ownership by the
15 same parent corporation as the lab-
16 oratory in which such test protocol
17 was developed; or

18 “(ii) is an in vitro clinical test devel-
19 oped to diagnose a unique pathology or
20 physical condition of a specific patient or
21 patients (including an in vitro clinical test
22 modified for such purpose), upon the pre-
23 scription or order of a health care practi-
24 tioner licensed to prescribe or order such
25 test, or a health care professional or other

1 specially qualified person designated under
2 regulations to prescribe or order such test,
3 for which no other in vitro clinical test is
4 commercially available in the United
5 States, and is—

6 “(I) not intended for use with re-
7 spect to more than 5 (or such other
8 higher number determined by the Sec-
9 retary) other patients; and

10 “(II) not included in any test
11 menu or template test report or other
12 promotional materials, and is not oth-
13 erwise advertised; and

14 “(B) the developer of the in vitro clinical
15 test—

16 “(i) maintains documentation dem-
17 onstrating that such test meets the appli-
18 cable criteria described in subparagraph
19 (A);

20 “(ii) makes such documentation, such
21 as a prescription order requesting the cus-
22 tom test for an individual patient, available
23 to the Secretary upon request; and

24 “(iii) informs the Secretary, on an an-
25 nual basis, in a manner prescribed by the

1 Secretary by guidance, that such test was
2 offered.

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

8 “(6) MODIFIED TESTS.—

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

12 “(i) the modification is made by—

13 “(I) the developer that obtained
14 premarket approval for the unmodi-
15 fied version of the test under section
16 587B; or

17 “(II) a clinical laboratory cer-
18 tified by the Secretary under section
19 353 of the Public Health Service Act
20 that meets the requirements for per-
21 forming high complexity testing, to a
22 lawfully offered in vitro clinical test,
23 including another developer’s lawfully
24 offered in vitro clinical test, excluding
25 investigational in vitro clinical tests

1 offered under section 587S, and the
2 modified test is performed—

3 “(aa) in the same clinical
4 laboratory in which it was devel-
5 oped for which a certification is
6 still in effect under section 353
7 that meets the requirements to
8 perform tests of high complexity;

9 “(bb) by another clinical lab-
10 oratory for which a certificate is
11 in effect under section 353 that
12 meets the requirements to per-
13 form tests of high complexity, is
14 within the same corporate organi-
15 zation, and has common owner-
16 ship by the same parent corpora-
17 tion as the laboratory in which
18 the test was developed; or

19 “(cc) by a clinical laboratory
20 for which a certificate is in effect
21 under section 353 that meets the
22 requirements to perform tests of
23 high complexity and is within a
24 public health laboratory network
25 coordinated or managed by the

1 Centers for Disease Control and
2 Prevention, if the test was devel-
3 oped by the Centers for Disease
4 Control and Prevention or an-
5 other laboratory within such pub-
6 lic health laboratory network;

7 “(ii) the modification does not—

8 “(I) constitute a significant
9 change to the indications for use, ex-
10 cept for changes to a specimen type,
11 as specified in the guidance issued
12 under subparagraph (E);

13 “(II) cause the test to no longer
14 comply with applicable mitigating
15 measures under section 587E or re-
16 strictions under section 587O;

17 “(III) significantly change per-
18 formance claims or significantly and
19 adversely change performance, unless
20 provided for under an approved
21 change protocol under section
22 587B(a)(3)(H); or

23 “(IV) constitute an adverse
24 change in the safety of the in vitro
25 clinical test for individuals who come

1 in contact with the in vitro clinical
2 test;

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

5 “(iv) the labeling and advertising are
6 not false or misleading; and

7 “(v) the test is not likely to cause or
8 contribute to serious adverse health con-
9 sequences.

10 “(B) CERTAIN MODIFICATIONS.—A modi-
11 fication to extend specimen stability is exempt
12 from premarket review under section 587B if
13 the modified test meets the requirements in
14 clauses (ii) through (v) of subparagraph (A).

15 “(C) MODIFICATIONS UNDER A CHANGE
16 PROTOCOL.—Notwithstanding subparagraph
17 (A), a modification made under a change pro-
18 tocol pursuant to subsection (a)(2)(H) of sec-
19 tion 587B is exempt from review under such
20 section.

21 “(D) DOCUMENTATION.—A person who
22 modifies an in vitro clinical test in a manner
23 that is a modification described in this para-
24 graph shall—

1 “(i) document the modification that
2 was made and the basis for determining
3 that the modification, considering the
4 changes individually and collectively, is a
5 type of modification described in subpara-
6 graph (A), (B), or (C); and

7 “(ii) provide such documentation to
8 the Secretary upon request or inspection.

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

19 “(b) MANUAL TESTS.—

20 “(1) EXEMPTION.—An in vitro clinical test is
21 exempt from all requirements of this subchapter if
22 the output of such in vitro clinical test is the result
23 of direct, manual observation, without the use of
24 automated instrumentation or software for inter-

1 mediate or final interpretation, by a qualified labora-
2 tory professional, and such in vitro clinical test—

3 “(A) is developed and used within a single
4 clinical laboratory for which a certificate is in
5 effect under section 353 of the Public Health
6 Service Act that meets the requirements under
7 section 353 for performing high-complexity test-
8 ing;

9 “(B) is not a specimen receptacle, instru-
10 ment, or an in vitro clinical test that includes
11 an instrument or specimen receptacle that is
12 not approved under or exempt from section
13 587B;

14 “(C) is not a high-risk test, or is a high-
15 risk test that the Secretary has determined
16 meets at least one condition in paragraph (2)
17 and is otherwise appropriate for this exemption;
18 and

19 “(D) is not intended for testing donors,
20 donations, or recipients of blood, blood compo-
21 nents, human cells, tissues, cellular-based prod-
22 ucts, or tissue-based products.

23 “(2) HIGH-RISK TEST LIMITATION OR CONDI-
24 TION.—A high-risk test may be exempt under para-

1 graph (1) from the requirements of this subchapter
2 only if—

3 “(A) no components or parts of such test,
4 including any reagent, is introduced into inter-
5 state commerce under the exemption under sub-
6 section (e), and any article for taking or deriv-
7 ing specimens from the human body used in
8 conjunction with the test remains subject to the
9 requirements of this subchapter; or

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

13 “(c) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

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

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

23 “(d) GENERAL LABORATORY EQUIPMENT.—As set
24 forth in section 201(ss)(3)(C), general purposes laboratory

1 equipment is not an in vitro clinical tests and is not sub-
2 ject to the requirements of this subchapter.

3 “(e) COMPONENTS AND PARTS.—

4 “(1) IN GENERAL.—Subject to paragraph (2), a
5 component or part described in section
6 201(ss)(2)(G) is—

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

10 “(B) subject to the requirements of this
11 subchapter and regulated based on its risk
12 when used as intended by the developer, not-
13 withstanding its subsequent use by a developer
14 as a component, part, or raw material of an-
15 other in vitro clinical test.

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

23 “(3) FURTHER DEVELOPMENT.—A component,
24 part, or raw material (as described in paragraph

1 (1) is intended for further development (for pur-
2 poses of such paragraph) if—

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

5 “(B) in the case of such a test that is in-
6 troduced or delivered for introduction into
7 interstate commerce after the date of enactment
8 of the VALID Act of 2023, the labeling of such
9 test bears the following statement: ‘This prod-
10 uct is intended solely for further development of
11 an in vitro clinical test and is exempt from
12 FDA regulation. This product must be evalu-
13 ated by the in vitro clinical test developer if it
14 is used with or in the development of an in vitro
15 clinical test.’.

16 “(f) GENERAL EXEMPTION AUTHORITY.—The Sec-
17 retary may, by order published in the Federal Register
18 following notice and an opportunity for comment, exempt
19 a class of persons from any section under this subchapter
20 upon a finding that such exemption is appropriate for the
21 protection of the public health and other relevant consider-
22 ations.

23 “(g) OTHER EXEMPTIONS.—An in vitro clinical test
24 that is intended solely for use in forensic analysis or law
25 enforcement activity is exempt from the requirements of

1 this subchapter. An in vitro clinical test that is intended
2 for use in making clinical decisions for individual patients,
3 or whose individually identifiable results may be reported
4 back to an individual patient or the patient’s health care
5 provider, even if also intended for forensic analysis or law
6 enforcement purposes, is not intended solely for forensic
7 analysis or law enforcement for purposes of this sub-
8 section.

9 “(h) REVOCATION.—

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

19 “(2) PROCESS.—Any action under paragraph
20 (1) shall be made by publication of a notice of such
21 proposed action on the website of the Food and
22 Drug Administration, the consideration of comments
23 to a public docket on such proposal, and publication
24 of a final action on such website within 60 calendar
25 days of the close of the comment period posted to

1 such public docket, notwithstanding subchapter II of
2 chapter 5 of title 5, United States Code.

3 “(i) PRE-ANALYTICAL INSTRUMENT.—A pre-analyt-
4 ical instrument is exempt from premarket review under
5 section 587B and may be lawfully offered subject to the
6 other applicable requirements of this Act, if either of the
7 following applies:

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

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

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

24 “(a) DEFINITIONS.—In this section:

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

4 “(A) a component or part of an in vitro
5 clinical test as described in section
6 201(ss)(2)(G) unless it is a component or part
7 and is regulated based on its own risk under
8 section 587C(e)(1)(B) or as part of an other-
9 wise eligible in vitro clinical test;

10 “(B) an instrument under section
11 201(ss)(2)(D) or an in vitro clinical test that
12 includes an instrument that is subject to section
13 587B, but is not approved under, or exempt
14 from, section 587B;

15 “(C) a specimen receptacle under section
16 201(ss)(2)(E) or an in vitro clinical test that
17 includes a specimen receptacle that is subject to
18 section 587B, but is not approved under, or ex-
19 empt from, section 587B;

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

1 “(E) high-risk;

2 “(F) a combination product, unless such
3 test has been determined to be eligible to be in-
4 troduced into interstate commerce under a tech-
5 nology certification order pursuant to the regu-
6 latory pathway designation process described in
7 section 587F, or as described in subsection (k),
8 and the drug or biological product constituent
9 part complies with the requirements of section
10 503(g) applicable to the drug or biological prod-
11 uct; or

12 “(G) a first-of-a-kind in vitro clinical test,
13 unless such test has been determined to be eli-
14 gible to be introduced into interstate commerce
15 under a technology certification order pursuant
16 to the regulatory pathway designation process
17 described in section 587F, or as described in
18 subsection (k).

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

22 “(A) is a laboratory subject to section 353
23 of the Public Health Service Act and does not
24 have in effect a certificate applicable to the cat-

1 egory of laboratory examination or other proce-
2 dure;

3 “(B) was a laboratory, or an owner or op-
4 erator or any employee of a laboratory, found
5 to have committed a significant violation of sec-
6 tion 353 of the Public Health Service Act that
7 resulted in a suspended, revoked, or limited cer-
8 tificate within the 2-year period preceding the
9 date of the submission of the application for a
10 technology certificate under subsection (c) and
11 such violation has not been resolved; or

12 “(C) has been found to have submitted in-
13 formation to the Secretary, or otherwise dis-
14 seminated information, that—

15 “(i) made false or misleading state-
16 ments relevant to the requirements of this
17 subchapter; or

18 “(ii) violated any requirement of this
19 Act, where such violation exposed individ-
20 uals to serious risk of illness, injury, or
21 death, unless—

22 “(I) such violation has been re-
23 solved; or

24 “(II) such violation is not perti-
25 nent to any in vitro clinical test within

1 the scope of the technology certifi-
2 cation that such developer seeks.

3 “(b) APPLICABILITY.—

4 “(1) IN GENERAL.—An in vitro clinical test is
5 not subject to section 587B and may be introduced
6 into interstate commerce if the in vitro clinical
7 test—

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

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

10 “(C) falls within the scope of a technology
11 certification order issued under this section and
12 that is in effect;

13 “(D) complies with the conditions of the
14 technology certification order, including with
15 applicable mitigating measures under section
16 587E, restrictions under section 587O, and per-
17 formance standards under section 587R; and

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

20 “(2) SCOPE.—

21 “(A) IN GENERAL.—Subject to subpara-
22 graph (B), the scope of a technology certifi-
23 cation order issued under this section shall
24 apply to one or more technologies with multiple
25 in vitro clinical tests utilizing a technology that

1 does not significantly differ in control mecha-
2 nisms, energy sources, or operating principles
3 and for which development, including design,
4 and analytical and clinical validation, of the in
5 vitro clinical tests would be addressed through
6 similar procedures, and be no broader than—

7 “(i) a single technology type; or

8 “(ii) a fixed combination of tech-
9 nologies.

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

23 “(c) APPLICATION FOR TECHNOLOGY CERTIFI-
24 CATION.—

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

5 “(2) CONTENT OF APPLICATION.—A developer
6 that submits an application for a technology certifi-
7 cation shall include all necessary information to
8 make a showing that all eligible in vitro clinical tests
9 developed within the scope of the technology certifi-
10 cation order will meet the applicable standard, in-
11 cluding—

12 “(A) the name and address of the devel-
13 oper;

14 “(B) a table of contents for the application
15 and the identification of the information the de-
16 veloper claims as trade secret or confidential
17 commercial or financial information;

18 “(C) the signature of the individual filing
19 the application or an authorized representative;

20 “(D) a statement identifying the scope of
21 the proposed technology certification intended
22 to be introduced into interstate commerce under
23 the application;

1 “(E) information establishing that the de-
2 veloper submitting the application is an eligible
3 person;

4 “(F) quality procedures showing that eligi-
5 ble in vitro clinical tests covered under the tech-
6 nology certification will conform to the applica-
7 ble quality requirements of section 587K with
8 respect to—

9 “(i) design controls, including related
10 purchasing controls and acceptance activi-
11 ties;

12 “(ii) complaint investigation, adverse
13 event reporting, and corrections and re-
14 movals; and

15 “(iii) process validation, as applicable;

16 “(G) procedures for analytical and clinical
17 validation, including all procedures for valida-
18 tion, verification, and acceptance criteria, and
19 an explanation as to how such procedures, when
20 used, provide a showing that eligible in vitro
21 clinical tests within the proposed scope of the
22 technology certification order are analytically
23 and clinically valid;

24 “(H) procedures that provide a showing
25 that in vitro clinical tests covered by the pro-

1 posed scope of the technology certification order
2 will be safe for individuals who come into con-
3 tact with in vitro clinical tests covered by such
4 order;

5 “(I) a proposed listing submission under
6 section 587J(b) for in vitro clinical tests that
7 the developer intends to introduce into inter-
8 state commerce upon receiving a technology cer-
9 tification order, which shall not be construed to
10 limit the developer from introducing additional
11 tests not included in such submission under the
12 same technology certification order;

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

15 “(i) a test within the scope of the
16 technology certification application with
17 the appropriate analytical complexity at
18 the time of the submission of the applica-
19 tion under this section to serve as the rep-
20 resentative test;

21 “(ii) the information specified in sub-
22 section (a) or (b) of section 587B, as ap-
23 plicable, for the representative in vitro clin-
24 ical test or tests, unless the Secretary de-

1 termines that such information is not nec-
2 essary;

3 “(iii) a summary of a risk assessment
4 of the in vitro clinical test;

5 “(iv) an explanation of the choice of
6 the representative in vitro clinical test or
7 tests for the technology certification appli-
8 cation and how such test adequately dem-
9 onstrates the range of procedures that the
10 developer includes in the application under
11 subparagraphs (F), (G), (H), and (I); and

12 “(v) a brief explanation of the ways in
13 which the procedures included in the appli-
14 cation under subparagraphs (F), (G), (H),
15 and (I) have been applied to the represent-
16 ative in vitro clinical test or tests; and

17 “(K) such other information necessary to
18 make a determination on a technology certifi-
19 cation application as the Secretary may deter-
20 mine necessary.

21 “(3) REFERENCE TO EXISTING APPLICA-
22 TIONS.—With respect to the content requirements in
23 the technology certification application described in
24 paragraph (2), a developer may incorporate by ref-

1 erence any content of an application previously sub-
2 mitted by the developer.

3 “(d) ACTION ON AN APPLICATION FOR TECHNOLOGY
4 CERTIFICATION.—

5 “(1) SECRETARY RESPONSE.—

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

10 “(i) if the Secretary finds that all of
11 the grounds in paragraph (3) are met,
12 issue a technology certification order
13 granting the application, which—

14 “(I) may include reasonable con-
15 ditions of certification; and

16 “(II) shall specify the scope of
17 the technology certification; or

18 “(ii) deny the application, if the Sec-
19 retary finds (and sets forth the basis of
20 such finding as part of or accompanying
21 such denial) that one or more grounds for
22 granting the application specified in para-
23 graph (3) are not met.

24 “(B) EXTENSION.—The timeline described
25 in subparagraph (A) may be extended by mu-

1 tual agreement between the Secretary and the
2 applicant.

3 “(2) DEFICIENT APPLICATIONS.—

4 “(A) IN GENERAL.—If, after receipt of an
5 application under this section, the Secretary de-
6 termines that any portion of such application is
7 deficient, the Secretary, not later than 60 days
8 after receipt of such application, shall provide
9 to the applicant a description of such defi-
10 ciencies and identify the information required to
11 resolve such deficiencies.

12 “(B) CONVERTING TO PREMARKET APPLI-
13 CATIONS.—When responding to the deficiency
14 letter, the developer may convert the application
15 for technology certification under subsection (c)
16 into a premarket application under section
17 587B.

18 “(3) TECHNOLOGY CERTIFICATION ORDER.—
19 The Secretary shall issue an order granting a tech-
20 nology certification under this section if, on the
21 basis of the information submitted to the Secretary
22 as part of the application and any other information
23 with respect to such applicant, the Secretary finds
24 that—

1 “(A) there is a showing that in vitro clin-
2 ical tests within the scope of the technology cer-
3 tification order will meet the applicable stand-
4 ard;

5 “(B) the methods used in, and the facili-
6 ties or controls used for, the development of eli-
7 gible in vitro clinical tests covered by the pro-
8 posed scope of the technology certification con-
9 form to the applicable requirements of section
10 587K with respect to—

11 “(i) design controls, including related
12 purchasing controls and acceptance activi-
13 ties;

14 “(ii) complaint investigation, adverse
15 event reporting, and corrections and re-
16 movals; and

17 “(iii) process validation, as applicable;

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

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

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

1 “(i) meet the applicable standard; and

2 “(ii) reasonably represent the range of
3 procedures required to be submitted in the
4 application;

5 “(F) the applicant has agreed to permit,
6 upon request, authorized employees of the Food
7 and Drug Administration or persons accredited,
8 or recognized under this Act, an opportunity to
9 inspect at a reasonable time and in a reason-
10 able manner the facilities and all pertinent
11 equipment, finished and unfinished materials,
12 containers, and labeling therein, including all
13 things (including records, files, papers, and con-
14 trols) bearing on whether an in vitro clinical
15 test is adulterated, misbranded, or otherwise in
16 violation of this Act, and permits such author-
17 ized employees or persons accredited under this
18 Act to view and to copy and verify all records
19 pertinent to the application and the in vitro
20 clinical test; and

21 “(G) based on other data and information
22 the Secretary may require under subsection
23 (c)(2)(K), the Secretary finds that such data
24 and information support granting a technology
25 certification order.

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

5 “(e) SUPPLEMENTS.—

6 “(1) SUPPLEMENTAL APPLICATIONS.—

7 “(A) IN GENERAL.—With respect to any of
8 the following changes related to a technology
9 certification order, a supplemental application
10 to a technology certification order shall be sub-
11 mitted by the holder of the technology certifi-
12 cation order describing such proposed changes,
13 and the in vitro clinical test with such changes
14 may not be introduced into interstate commerce
15 until a technology certification order for such
16 supplemental application is granted:

17 “(i) Any significant change to the pro-
18 cedures provided in support of the applica-
19 tion for technology certification submitted
20 under subparagraph (G) or (H) of sub-
21 section (c)(2).

22 “(ii) Any significant change to the
23 procedures provided in support of the ap-
24 plication for technology certification sub-

1 mitted under subparagraph (F) of sub-
2 section (c)(2).

3 “(B) SECRETARY ACTION ON SUPPLE-
4 MENTAL APPLICATIONS.—Any action by the
5 Secretary on a supplemental application shall
6 be in accordance with subsection (d), and any
7 order resulting from such supplement shall be
8 treated as an amendment to a technology cer-
9 tification order.

10 “(2) CONTENT OF APPLICATION.—

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

14 “(i) contain all necessary information
15 to make a showing that any in vitro clin-
16 ical test affected by such change that is
17 within the scope of the technology certifi-
18 cation order will meet the applicable stand-
19 ard; and

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

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

1 “(i) a description of the change, in-
2 cluding a rationale for implementing such
3 change;

4 “(ii) a description of how the change
5 was evaluated;

6 “(iii) data from a representative in
7 vitro clinical test or tests that supports a
8 showing that, in using the modified proce-
9 dure or procedures, all eligible in vitro clin-
10 ical tests within the scope of the tech-
11 nology certification will meet the applicable
12 standard;

13 “(iv) as applicable, information to
14 demonstrate that the modified procedure
15 or procedures submitted under subsection
16 (c)(2)(F) continue to conform to applicable
17 requirements under section 587K; and

18 “(v) any other information requested
19 by the Secretary.

20 “(3) CHANGES IN RESPONSE TO A PUBLIC
21 HEALTH RISK.—

22 “(A) IN GENERAL.—If the holder of a
23 technology certification makes a change to an
24 in vitro clinical test or tests to address a poten-
25 tial risk to public health by adding a new speci-

1 fication or test method, such holder may imme-
2 diately implement such change and shall submit
3 a notification for such change to the Secretary
4 within 30 days.

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

7 “(i) a summary of the relevant
8 change;

9 “(ii) the rationale for implementing
10 such change;

11 “(iii)(I) if such a change necessitates
12 a change to the procedures reviewed as
13 part of the granted technology certification
14 order, the modified procedures; or

15 “(II) if the procedures were not
16 changed, an explanation as to why they
17 were not changed; and

18 “(iv) if such a change necessitates a
19 change to the procedures reviewed as part
20 of the granted technology certification
21 order, data from a representative in vitro
22 clinical test or tests that support a showing
23 that, in using the modified procedures, all
24 eligible in vitro clinical tests within the

1 scope of the technology certification will
2 meet the applicable standard.

3 “(f) TEMPORARY HOLD.—

4 “(1) IN GENERAL.—Subject to the process
5 specified in paragraph (2), and based on one or
6 more findings under paragraph (4), the Secretary
7 may issue a temporary hold prohibiting any holder
8 of a technology certification order issued under this
9 section from introducing into interstate commerce
10 an in vitro clinical test that was not previously the
11 subject of a listing under section 587J. The tem-
12 porary hold shall identify the grounds for the tem-
13 porary hold under paragraph (4) and the rationale
14 for such finding.

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

23 “(3) WRITTEN REQUESTS.—Any written re-
24 quest to the Secretary from the holder of a tech-
25 nology certification order that a temporary hold

1 under paragraph (1) be removed shall receive a deci-
2 sion, in writing and specifying the reasons therefore,
3 within 90 days after receipt of such request. Any
4 such request shall include information to support the
5 removal of the temporary hold.

6 “(4) GROUNDS FOR TEMPORARY HOLD.—The
7 Secretary may initiate a temporary hold under this
8 subsection upon a finding that the holder of a tech-
9 nology certification order—

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

13 “(B) offers one or more in vitro clinical
14 tests with advertising or labeling that is false or
15 misleading;

16 “(C) has reported a correction or removal
17 of an in vitro clinical test that is offered under
18 a technology certification order under this sec-
19 tion and has failed to demonstrate that the
20 issue or issues causing the correction or re-
21 moval does not adversely impact the ability of
22 other in vitro clinical tests offered under the
23 same technology certification order to meet the
24 applicable standard; or

1 “(D) has introduced into interstate com-
2 merce an in vitro clinical test under a tech-
3 nology certification order and such test is adul-
4 terated or misbranded, based on a determina-
5 tion by the Secretary, and has failed to dem-
6 onstrate that the issue or issues causing the
7 adulteration or misbranding does not adversely
8 impact the ability of other in vitro clinical tests
9 offered under the same technology certification
10 granted under this section to meet the applica-
11 ble standard.

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

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

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

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

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

5 “(h) REPORTS TO CONGRESS.—

6 “(1) IN GENERAL.—Not later than 1 year after
7 the effective date of the VALID Act of 2023, and
8 annually thereafter for the next 4 years, the Sec-
9 retary shall submit to the Committee on Health,
10 Education, Labor, and Pensions of the Senate and
11 the Committee on Energy and Commerce of the
12 House of Representatives, and make publicly avail-
13 able, including through posting on the website of the
14 Food and Drug Administration, a report containing
15 the information described in paragraph (2).

16 “(2) CONTENT.—

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

19 “(i) the total number of applications
20 for technology certifications filed, issued,
21 withdrawn, and denied;

22 “(ii) the total number of technology
23 certification orders the Secretary put on
24 temporary hold under subsection (h) and

1 the number of technology certification or-
2 ders withdrawn under subsection (i);

3 “(iii) the types of technologies for
4 which the Secretary issued technology cer-
5 tification orders;

6 “(iv) the total number of holders of
7 technology certification orders that are in
8 effect; and

9 “(v) the total number of in vitro clin-
10 ical test categories that required premarket
11 review under section 587B that were reded-
12 icated as eligible in vitro clinical tests
13 under this section.

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

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

22 “(i) PUBLIC MEETING AND INPUT.—

23 “(1) PUBLIC DOCKET.—Not later than 30 days
24 after the date of enactment of the VALID Act of
25 2023, the Secretary shall establish a public docket to

1 receive comments concerning recommendations for
2 implementation of this section, including criteria and
3 procedures for subsections (c) through (h). The pub-
4 lic docket shall remain open for at least 1 year after
5 the establishment of the public docket.

6 “(2) PUBLIC MEETING.—Not later than 180
7 days after the date of enactment of the VALID Act
8 of 2023, the Secretary shall convene a public meet-
9 ing to which stakeholders from organizations rep-
10 resenting patients and consumers, academia, and the
11 in vitro clinical test industry are invited to discuss
12 the technology certification process including appli-
13 cation requirements, inspections, alignment with
14 third-party accreditors, and the definition of the
15 term ‘technology’ under section 587.

16 “(j) REGULATIONS.—The Secretary shall issue regu-
17 lations regarding the technology certification process, in-
18 cluding describing criteria or procedures relating to tech-
19 nology certification under this section, which shall be sub-
20 ject to public comment for a minimum of 60 days from
21 issuance prior to finalizing such regulations after consid-
22 ering the comments received. The regulation shall include
23 an outline of the application process, opportunities to meet
24 with officials of the Food and Drug Administration, and
25 plans to streamline inspections.

1 “(k) NOTIFICATION.—

2 “(1) IN GENERAL.—Notwithstanding subsection
3 (a)(1), a first-of-a-kind in vitro clinical test or a
4 combination product that meets the definition of a
5 moderate-risk test under section 587 may be intro-
6 duced into interstate commerce under a technology
7 certification order that has been issued by the Sec-
8 retary, subject to other applicable requirements if—

9 “(A) the developer provides notification to
10 the Secretary 60 days prior to introducing such
11 tests into interstate commerce that includes in-
12 formation demonstrating that the test is mod-
13 erate-risk and within the scope of the applicable
14 technology certification order; and

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

18 “(2) NOTIFICATION FROM SECRETARY.—The
19 Secretary shall issue a notification to the developer
20 that such test may not be introduced into interstate
21 commerce under such order if the Secretary deter-
22 mines that—

23 “(A) such test—

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

1 “(ii) is not eligible to be introduced
2 into interstate commerce under any of sub-
3 paragraphs (A) through (E) of subsection
4 (a)(1); or

5 “(iii) is not eligible to be introduced
6 into interstate commerce under the ref-
7 erenced technology certification order
8 issued by the Secretary because it is not
9 within the scope of the technology certifi-
10 cation order under subsection (b)(2); or

11 “(B) based on the information included in
12 the notification submitted by the developer pur-
13 suant to this subsection, there is insufficient in-
14 formation for the Secretary to make the deter-
15 minations described in clauses (i), (ii), and (iii)
16 of subparagraph (A).

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

18 “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

19 “(1) ESTABLISHING, CHANGING, OR WITH-
20 DRAWING.—

21 “(A) ESTABLISHMENT.—The Secretary
22 may establish and require, on the basis of evi-
23 dence, mitigating measures for any in vitro clin-
24 ical test or category of in vitro clinical tests
25 with the same indications for use that is intro-

1 duced or delivered for introduction into inter-
2 state commerce after the Secretary establishes
3 any such mitigating measures.

4 “(B) METHODS OF ESTABLISHMENT.—The
5 Secretary may establish mitigating measures—

6 “(i) under the process set forth in
7 subparagraph (D);

8 “(ii) as provided under section 587F;
9 or

10 “(iii) through a premarket approval or
11 technology certification order, which may
12 establish mitigating measures for an indi-
13 vidual in vitro clinical test or a category of
14 in vitro clinical tests.

15 “(C) METHODS OF CHANGE OR WITH-
16 DRAWAL.—The Secretary may change or with-
17 draw mitigating measures—

18 “(i) under the process set forth in
19 subparagraph (D); or

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

21 “(D) PROCESS FOR ESTABLISHMENT,
22 CHANGE, OR WITHDRAWAL.—Notwithstanding
23 subchapter II of chapter 5 of title 5, United
24 States Code, the Secretary may, upon the ini-
25 tiative of the Secretary or upon petition of an

1 interested person, establish, change, or with-
2 draw mitigating measures for an in vitro clin-
3 ical test or category of in vitro clinical tests
4 by—

5 “(i) publishing a proposed order in
6 the Federal Register;

7 “(ii) providing an opportunity for
8 public comment for a period of not less
9 than 30 60 calendar days; and

10 “(iii) after consideration of any com-
11 ments submitted, publishing a final order
12 in the Federal Register that responds to
13 the comments submitted, and which shall
14 include a reasonable transition period.

15 “(E) EFFECT OF MITIGATING MEASURES
16 ON GRANDFATHERED TESTS.—A mitigating
17 measure shall not be required by the Secretary
18 for an in vitro clinical test subject to section
19 587G(a).

20 “(2) IN VITRO CLINICAL TESTS PREVIOUSLY
21 CLEARED OR EXEMPT AS DEVICES WITH SPECIAL
22 CONTROLS.—

23 “(A) IN GENERAL.—Any special controls
24 applicable to an in vitro clinical test previously
25 cleared or exempt under section 510(k), or clas-

1 sified under section 513(f)(2) prior to date of
2 enactment of the VALID Act of 2023, including
3 any such special controls established during the
4 period beginning on the date of enactment of
5 the VALID Act of 2023 and ending on the ef-
6 fective date of such Act (as described in section
7 5(b) of such Act)—

8 “(i) shall continue to apply to such in
9 vitro clinical test after such effective date;
10 and

11 “(ii) are deemed to be mitigating
12 measures as of the effective date specified
13 in section 5(a)(1)(A) of the VALID Act of
14 2023.

15 “(B) CHANGES.—Notwithstanding sub-
16 paragraph (A), the Secretary may establish,
17 change, or withdraw mitigating measures for
18 such tests or category of tests using the proce-
19 dures under paragraph (1).

20 “(b) DOCUMENTATION.—

21 “(1) IN VITRO CLINICAL TESTS SUBJECT TO
22 PREMARKET REVIEW.—The developer of an in vitro
23 clinical test subject to premarket review under sec-
24 tion 587B and to which mitigating measures apply
25 shall maintain documentation in accordance with the

1 applicable quality requirements under section 587K
2 and make such documentation available to the Sec-
3 retary upon request or inspection.

4 “(2) OTHER TESTS.—The developer of an in
5 vitro clinical test that is offered under a technology
6 certification order or other exemption from pre-
7 market review under section 587B and to which
8 mitigating measures apply shall—

9 “(A) maintain documentation in accord-
10 ance with the applicable quality requirements
11 under section 587K demonstrating that such
12 mitigating measures continue to be met fol-
13 lowing a test modification by the developer;

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

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

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

20 “(a) PATHWAY DETERMINATIONS.—

21 “(1) IN GENERAL.—After considering available
22 evidence with respect to an in vitro clinical test or
23 category of in vitro clinical tests with the same in-
24 tended use, including the identification, establish-
25 ment under paragraph (4), and implementation of

1 mitigating measures under section 587E, as appro-
2 priate, the Secretary may, upon the initiative of the
3 Secretary or upon request of a developer, determine
4 that—

5 “(A) such in vitro clinical test is high-risk
6 and subject to premarket review under section
7 587B;

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

13 “(C) such in vitro clinical test, including a
14 first-of-a-kind test is low-risk or otherwise ex-
15 empt from premarket review under section
16 587B.

17 “(2) REQUESTS.—

18 “(A) SUBMISSIONS BY DEVELOPERS.—

19 “(i) ABBREVIATED PREMARKET RE-
20 VIEW; TECHNOLOGY CERTIFICATION.—A
21 developer submitting a request that the
22 Secretary make a determination as de-
23 scribed in paragraph (1)(B) shall submit
24 information to support that the in vitro
25 clinical test is moderate-risk or propose

1 mitigating measures, if applicable, that
2 would support such a determination.

3 “(ii) LOW-RISK; EXEMPT FROM PRE-
4 MARKET REVIEW.—A developer submitting
5 a request that the Secretary make a deter-
6 mination as described in paragraph (1)(C)
7 shall submit information that the in vitro
8 clinical test is low-risk, or otherwise appro-
9 priate for exemption from premarket re-
10 view under section 587B and propose miti-
11 gating measures, if applicable, that would
12 support such a determination.

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

21 “(3) SUFFICIENCY OF MITIGATING MEAS-
22 URES.—When determining whether mitigating meas-
23 ures for an in vitro clinical test, or category of in
24 vitro clinical tests, are sufficient to make such test

1 moderate-risk or low-risk, the Secretary shall take
2 into account the following:

3 “(A) The degree to which the technology
4 for the intended use of the in vitro clinical test
5 is well-characterized, taking into consideration
6 factors that include one or more of the fol-
7 lowing:

8 “(i) Peer-reviewed literature.

9 “(ii) Practice guidelines.

10 “(iii) Consensus standards.

11 “(iv) Recognized standards of care.

12 “(v) Use of such technology, including
13 historical use.

14 “(vi) Multiple scientific publications
15 by different authors.

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

18 “(viii) Real world evidence.

19 “(B) Whether the criteria for performance
20 of the test are well-established to be sufficient
21 for the intended use.

22 “(C) The clinical circumstances under
23 which the in vitro clinical test is used, including
24 whether the in vitro clinical test is the sole de-
25 terminate for the diagnosis or treatment of the

1 targeted disease, and the availability of other
2 tests (such as confirmatory or adjunctive tests)
3 or relevant material standards.

4 “(D) Whether such mitigating measures
5 sufficiently mitigate the risk of harm such that
6 the test or category of tests is moderate-risk or
7 low-risk.

8 “(4) PROCESS.—

9 “(A) IN GENERAL.—For a test that is not
10 first-of-a-kind, any action under paragraph (1)
11 shall be made by publication of a notice of such
12 proposed action on the website of the Food and
13 Drug Administration, the consideration of com-
14 ments to a public docket on such proposal, and
15 publication of a final action on such website
16 within 60 calendar days of the close of the com-
17 ment period posted to such public docket, not-
18 withstanding subchapter II of chapter 5 of title
19 5, United States Code.

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

23 “(i) Any determination that the test is
24 subject to premarket approval or abbrevi-
25 ated premarket review under subpara-

1 graph (A) or (B) of paragraph (1) shall be
2 published on the website of the Food and
3 Drug Administration, notwithstanding sub-
4 clause II of chapter 5 of title 5, United
5 States Code, only after the in vitro clinical
6 test is approved under section 587B. Until
7 that time, the determination shall not be
8 binding on other in vitro clinical tests.

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

15 “(5) NO EFFECT ON GRANDFATHERING DETER-
16 MINATIONS.—A determination under paragraph (1)
17 shall have no effect on the applicability of section
18 587G to an in vitro clinical tests.

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

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

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

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

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

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

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

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

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

24 “(A) if a meeting is requested—

1 “(i) within 60 calendar days after
2 such receipt, or within such time period as
3 may be agreed to by the developer, meet or
4 confer with the developer submitting the
5 request; and

6 “(ii) within 15 calendar days after
7 such meeting or conference, provide to the
8 developer a written record or response de-
9 scribing the issues discussed and conclu-
10 sions reached in the meeting or conference;
11 and

12 “(B) if written feedback is requested, pro-
13 vide feedback to the requestor within 75 days
14 after such receipt.

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

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

19 “(1) the test was first offered for clinical use,
20 and was not intended solely for investigational use,
21 not later than 45 days after the date of enactment
22 of the VALID Act of 2023;

23 “(2) the test was developed by a clinical labora-
24 tory for which a certificate was in effect under sec-
25 tion 353 of the Public Health Service Act that meets

1 the requirements for performing tests of high com-
2 plexity;

3 “(3) the test is performed—

4 “(A) in the same clinical laboratory in
5 which the test was developed for which a certifi-
6 cation is still in effect under section 353 of the
7 Public Health Service Act that meets the re-
8 quirements to perform tests of high complexity;

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

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

1 public health laboratory network coordinated or
2 managed by the Centers for Disease Control
3 and Prevention;

4 “(4) the test does not have in effect an ap-
5 proval under section 515, a clearance under section
6 510(k), an authorization under section 513(f)(2), or
7 an exemption under section 520(m), or licensure
8 under section 351 of the Public Health Service Act;

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

14 “(6) when used as an investigational in vitro
15 clinical test, such test complies with section 587S, as
16 applicable;

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

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

1 “(A) has been approved, cleared, or au-
2 thorized by the Secretary for home specimen
3 collection and the collection is performed pursu-
4 ant to the approved, cleared, or authorized la-
5 beling, including any indication for use as pre-
6 scription use or over-the-counter use, or

7 “(B) is exempt from premarket review and
8 its use is consistent with applicable limitations
9 on the exemption;

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

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

17 “(11) the developer of the test—

18 “(A) maintains documentation dem-
19 onstrating that the test meets and continues to
20 meet the criteria set forth in this subsection;
21 and

22 “(B) makes such documentation available
23 to the Secretary upon request.

24 “(b) EXEMPTIONS APPLICABLE TO GRAND-
25 FATHERED TESTS.—An in vitro clinical test that meets

1 the criteria specified in subsection (a) is exempt from pre-
2 market review under 587B, labeling requirements under
3 587L, and test design requirements and quality require-
4 ments under 587K, and may be lawfully offered subject
5 to the other applicable requirements of this Act.

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

12 “(1) documents each such modification and
13 maintains documentation of the basis for such deter-
14 mination;

15 “(2) provides such documentation relating to
16 the change to the Secretary upon request or inspec-
17 tion; and

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

21 “(d) REQUEST FOR INFORMATION.—

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

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

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

7 “(C) It is probable that such in vitro clin-
8 ical test will cause serious adverse health con-
9 sequences.

10 “(2) PROCESS.—

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

20 “(B) DEADLINE FOR SUBMITTING INFOR-
21 MATION.—Not later than 45 days after receiv-
22 ing a request for information under subpara-
23 graph (A)—

24 “(i) the developer of an in vitro clin-
25 ical test—

1 “(I) may seek a teleconference
2 prior to the submission of information
3 under subclause (II) to discuss the
4 Secretary’s request; and

5 “(II) shall submit the informa-
6 tion requested pursuant to subpara-
7 graph (A), and may include in such
8 submission a request for a teleconfer-
9 ence; and

10 “(ii) the Secretary shall—

11 “(I) schedule a teleconference re-
12 quested under clause (i)(I); and

13 “(II) hold a teleconference if re-
14 quested within 10 days of the Sec-
15 retary’s receipt of the information
16 submitted under clause (i)(II).

17 “(C) REVIEW DEADLINE.—Upon receiving
18 a submission under subparagraph (B), the Sec-
19 retary shall—

20 “(i) review the submitted information
21 within 45 calendar days of such receipt,
22 which may include communication with the
23 developer; and

24 “(ii) determine whether the criteria
25 listed in paragraph (1) apply to the in

1 vitro clinical test and communicate such
2 determination to the developer as described
3 in subparagraph (D).

4 “(D) COMMUNICATION AND RESULTS OF
5 DETERMINATION.—The Secretary shall notify
6 the developer, in writing, of the Secretary’s de-
7 termination under subparagraph (C), as follows:

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

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

1 “(I) the Secretary shall notify the
2 developer of such a determination and
3 allow the developer to seek a tele-
4 conference to discuss the finding;

5 “(II) the developer shall submit
6 information demonstrating resolution
7 of the determination within 15 days of
8 receiving such notification; and

9 “(III) the Secretary shall make a
10 determination within 30 days of the
11 receipt of such submission of informa-
12 tion as to whether the criteria under
13 paragraph (1) continue to apply to the
14 test and, if through such determina-
15 tion the Secretary determines that—

16 “(aa) none of the criteria
17 listed in paragraph (1) apply to
18 the test, such test shall be ex-
19 empt from relevant requirements
20 of the subchapter as set forth in
21 subsection (b), subject to applica-
22 ble limitations; or

23 “(bb) one or more of the cri-
24 teria listed in paragraph (1)
25 apply to the in vitro clinical test,

1 such test is not exempt as set
2 forth in this section and shall not
3 be offered unless approved under
4 section 587B, or, upon a deter-
5 mination by the Secretary pursu-
6 ant to section 587F, offered
7 under a technology certification
8 order under section 587D or of-
9 fered as a low-risk test.

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

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

22 “(a) IN GENERAL.—The Secretary may establish ad-
23 visory committees or use advisory committee panels of ex-
24 perts established before the date of enactment of the
25 VALID Act of 2023 (including a device classification

1 panel under section 513) for the purposes of providing ex-
2 pert scientific advice and making recommendations related
3 to—

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

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

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

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

17 “(5) such other purposes as the Secretary de-
18 termines appropriate.

19 “(b) APPOINTMENTS.—

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

1 individuals with, to the extent feasible, scientific exper-
2 tise in the development of such in vitro clinical tests,
3 laboratory operations, and the use of in vitro clinical
4 tests. The Secretary shall designate one member of
5 each committee to serve as chair.

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

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

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

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

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

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

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

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

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

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

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

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

5 “(a) IN GENERAL.—The purpose of this section is
6 to encourage the Secretary, and provide the Secretary with
7 sufficient authority, to apply efficient and flexible ap-
8 proaches to expedite the development of, and prioritize the
9 review of, in vitro clinical tests that represent break-
10 through technologies.

11 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
12 shall establish a program to expedite the development of,
13 and provide for the priority review of, in vitro clinical
14 tests.

15 “(c) ELIGIBILITY.—The program developed under
16 subsection (b) shall be available for any in vitro clinical
17 test that—

18 “(1) provides or enables more effective treat-
19 ment or diagnosis of life-threatening or irreversibly
20 debilitating human disease or conditions; and

21 “(2) is a test—

22 “(A) that represents a breakthrough tech-
23 nology;

24 “(B) for which no approved alternative in
25 vitro clinical test exists, including no in vitro

1 clinical test offered under a technology certifi-
2 cation order;

3 “(C) that offers a clinically meaningful ad-
4 vantage over existing alternative in vitro clinical
5 tests that are approved (including in vitro clin-
6 ical tests offered under a technology certifi-
7 cation order), including the potential to reduce
8 or eliminate the need for hospitalization, im-
9 prove patient quality of life, facilitate patients’
10 ability to manage their own care (such as
11 through self-directed personal assistance), or es-
12 tablish long-term clinical efficiencies; or

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

15 “(d) DESIGNATION.—

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

1 “(2) DETERMINATION.—Not later than 60 cal-
2 endar days after the receipt of a request under para-
3 graph (1), the Secretary shall determine whether the
4 in vitro clinical test that is the subject of the request
5 meets the criteria described in subsection (c). If the
6 Secretary determines that the test meets the criteria,
7 the Secretary shall designate the test for expedited
8 development and priority review.

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

13 “(4) WITHDRAWAL.—

14 “(A) IN GENERAL.—The designation of an
15 in vitro clinical test under this subsection is
16 deemed to be withdrawn, and such in vitro clin-
17 ical test shall no longer be eligible for designa-
18 tion under this section, if an application for ap-
19 proval for such test under section 587B or
20 587D is denied. Such test shall be eligible for
21 breakthrough designation upon a new request
22 for such designation.

23 “(B) EXCEPTION.—The Secretary may not
24 withdraw a designation granted under this sub-
25 section based on the subsequent approval or

1 technology certification of another in vitro clin-
2 ical test that—

3 “(i) is designated under this section;

4 or

5 “(ii) was given priority review under
6 section 515B.

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

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

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

22 “(2) provide a template for request under sub-
23 section (d);

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

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

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

9 “(1) the criteria and standards for evaluating
10 an application pursuant to section 587B or 587D,
11 including the recognition of valid scientific evidence
12 as described in section 587(20) and consideration
13 and application of the least burdensome means de-
14 scribed under section 587AA(e);

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

17 “(3) the authority of the Secretary to act on an
18 application pursuant to section 587B before comple-
19 tion of an establishment inspection, as the Secretary
20 determines appropriate; or

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

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

24 “(a) REGISTRATION REQUIREMENT.—

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

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

13 “(B) submit an initial registration con-
14 taining the information required under subpara-
15 graph (A)—

16 “(i) in accordance with the timelines
17 for submission under subsection (c), if the
18 establishment is engaged in any activity
19 described in subsection (b)(1) on the effec-
20 tive date of this section, unless the Sec-
21 retary establishes by guidance a date later
22 than such date for all or a category of such
23 establishments; or

24 “(ii) not later than 30 days prior to
25 engaging in any activity described in sub-

1 section (b)(1), if the establishment is not
2 engaged in any activity described in this
3 paragraph on the effective date of this sec-
4 tion.

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

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

17 “(b) LISTING INFORMATION FOR IN VITRO CLINICAL
18 TESTS.—

19 “(1) IN GENERAL.—Each person who—

20 “(A) is a developer; and

21 “(B) introduces or proposes to begin the
22 introduction or delivery for introduction into
23 interstate commerce through an exemption
24 under subsection (a)(1), (a)(2), (a)(3), or (g) of
25 section 587C or section 587G or through the

1 filing of an application under section 587B or
2 section 587D,
3 shall submit a listing to the Secretary containing the
4 information described in paragraph (2), or (4), as
5 applicable, in accordance with the applicable sched-
6 ule described under subsection (c). Such listing shall
7 be prepared in such form and manner as the Sec-
8 retary may specify in guidance. Listing information
9 shall be submitted through the comprehensive test
10 information system in accordance with section 587T,
11 as appropriate.

12 “(2) SUBMISSIONS.—Each developer submitting
13 a listing under paragraph (1) shall electronically
14 submit to the comprehensive test information system
15 described in section 587T the following information,
16 as applicable, for each in vitro clinical test for which
17 such person is a developer in the form and manner
18 prescribed by the Secretary, taking into account the
19 least burdensome requirements under section
20 587AA(c):

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

23 “(B) Contact information for the official
24 correspondent for the listing.

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

4 “(D) The certificate number for any lab-
5 oratory certified by the Secretary under section
6 353 of the Public Health Service Act that
7 meets the requirements to perform high-com-
8 plexity testing and that is the developer of the
9 in vitro clinical test, and the certificate number
10 under such section for any laboratory that is
11 performing the test, is within the same cor-
12 porate organization, and has common ownership
13 by the same parent corporation.

14 “(E) Whether the in vitro clinical test is,
15 as applicable, offered as a test approved under
16 section 587B, offered under a granted tech-
17 nology certification order, or offered as an ex-
18 empt in vitro clinical test under section 587C or
19 587G.

20 “(F) Indications for use information under
21 section 587(10).

22 “(G) A brief summary of the analytical
23 and clinical performance of the in vitro clinical
24 test, and as applicable, the lot release criteria.

1 “(H) A brief description of conformance
2 with any applicable mitigating measures, re-
3 strictions, and standards.

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

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

13 “(4) GRANDFATHERED TESTS.—A developer of-
14 fering a test that is a grandfathered in vitro clinical
15 test under section 587G(a) shall submit listing infor-
16 mation required under subparagraphs (A) through
17 (F) of paragraph (2), and may submit a statement
18 of the performance specifications for such in vitro
19 clinical tests.

20 “(5) EXEMPT TESTS.—A developer of an in
21 vitro clinical test who introduces or proposes to
22 begin the introduction or delivery for introduction
23 into interstate commerce that is otherwise exempt
24 from the requirement to submit listing information

1 pursuant to an exemption under section 587C may
2 submit listing information under this subsection.

3 “(c) TIMELINES FOR SUBMISSION OF LISTING IN-
4 FORMATION.—

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

8 “(A) For an in vitro clinical test that was
9 listed as a device under section 510(j) prior to
10 the effective date of this section, a person shall
11 maintain a device listing under section 510
12 until such time as the system for submitting
13 the listing information required under sub-
14 section (b) becomes available and thereafter
15 shall submit the listing information not later
16 than the later of 1 year after the system for
17 submitting the listing under this section be-
18 comes available or the effective date of this sec-
19 tion.

20 “(B) For an in vitro clinical test that is
21 subject to grandfathering under section
22 587G(a) a person shall submit the listing infor-
23 mation required under subsection (b)(4) within
24 10 calendar days of offering the test after the
25 effective date of this section.

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

5 “(i) For an in vitro clinical test that
6 is not exempt from premarket approval
7 under section 587B, a person shall submit
8 the required listing information, prior to
9 offering the in vitro clinical test and not
10 later than 30 business days after the date
11 of approval of the premarket approval ap-
12 plication.

13 “(ii) For an in vitro clinical test that
14 is exempt from premarket review under
15 section 587C, the required listing informa-
16 tion shall be submitted prior to offering
17 the in vitro clinical test.

18 “(2) UPDATES.—

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

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

6 “(d) PUBLIC AVAILABILITY OF LISTING INFORMA-
7 TION.—

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

12 “(2) CONFIDENTIALITY.—Listing information
13 for an in vitro clinical test that is subject to pre-
14 market approval or technology certification shall re-
15 main confidential until such date as the in vitro clin-
16 ical test receives the applicable premarket approval
17 or the developer receives a technology certification
18 order and for subsequent tests introduced under a
19 technology certification order until their introduc-
20 tion.

21 “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY
22 REQUIREMENTS.—The public listing requirements of
23 this subsection shall not apply to any registration
24 and listing information submitted under subsection

1 (a) or (b), if the Secretary determines that such in-
2 formation—

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

5 “(B) if posted, could compromise national
6 security.

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

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

12 “(a) APPLICABILITY.—

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

17 “(2) CERTIFIED LABORATORY REQUIRE-
18 MENTS.—A developer shall establish and maintain
19 quality requirement under subsection (b)(2) or
20 (b)(3), as applicable, if such developer is a clinical
21 laboratory certified by the Secretary under section
22 353 of the Public Health Service Act that—

23 “(A) is certified to perform high-com-
24 plexity testing;

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

3 “(i) within the laboratory certified by
4 the Secretary under such section 353 in
5 which such test was developed; or

6 “(ii) within another laboratory cer-
7 tified by the Secretary under such section
8 353 if such laboratory is—

9 “(I) within the same corporate
10 organization and has common owner-
11 ship by the same parent corporation
12 as the laboratory in which the test
13 was developed; or

14 “(II) within a public health lab-
15 oratory network coordinated or man-
16 aged by the Centers for Disease Con-
17 trol and Prevention, if the test is de-
18 veloped by a public health laboratory
19 or the Centers for Disease Control
20 and Prevention; and

21 “(C) does not manufacture, produce, or
22 distribute in vitro clinical tests other than lab-
23 oratory test protocols.

24 “(3) REGULATIONS.—The Secretary shall pro-
25 mulgate quality system regulations implementing

1 this section. In promulgating such regulations under
2 this section, the Secretary shall consider whether,
3 and to what extent, international harmonization is
4 appropriate.

5 “(4) QUALITY SYSTEMS FOR HYBRID DEVEL-
6 OPERS OF BOTH LABORATORY TEST PROTOCOLS AND
7 OTHER IN VITRO CLINICAL TESTS.—An entity that
8 develops both laboratory test protocols and other in
9 vitro clinical tests shall comply with subsection
10 (b)(1) for activities related to the development of
11 any in vitro clinical test that is not a laboratory test
12 protocol and with subsection (b)(2) or (b)(3), as ap-
13 plicable, for activities related to the development of
14 any laboratory test protocol.

15 “(b) QUALITY REQUIREMENTS.—

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

18 “(A) avoid duplication of regulations and
19 guidance under section 353 of the Public
20 Health Service Act, such that laboratories
21 would not be subject to conflicting regulatory
22 obligations with respect to the same activity;

23 “(B) not apply to laboratory operations;
24 and

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

- 4 “(i) management responsibilities;
5 “(ii) quality audits;
6 “(iii) personnel;
7 “(iv) design controls;
8 “(v) document controls;
9 “(vi) purchasing controls;
10 “(vii) identification and traceability;
11 “(viii) production and process con-
12 trols;
13 “(ix) acceptance activities;
14 “(x) nonconforming in vitro clinical
15 tests;
16 “(xi) corrective and preventive action;
17 “(xii) labeling and packaging controls;
18 “(xiii) handling, storage, distribution,
19 and installation;
20 “(xiv) complaints and records;
21 “(xv) servicing; and
22 “(xvi) statistical techniques.

23 “(2) EXCEPTION FOR LABORATORY TEST PRO-
24 TOCOLS.—Developers that are developing test proto-
25 cols for use as described in subsection (a)(2)(B)(i)

1 are exempt from the requirements under paragraph
2 (1)(C) except for the requirements described in
3 clauses (iv), (ix), (xi), and (xiv) of such paragraph.

4 “(3) QUALITY REQUIREMENTS FOR CERTAIN
5 LABORATORIES DISTRIBUTING LABORATORY TEST
6 PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC
7 HEALTH NETWORKS.—Quality requirements applica-
8 ble to the developer who is distributing a laboratory
9 test protocol as described in subsection (a)(2)(B)(ii)
10 shall consist of the following:

11 “(A) Clauses (iv), (ix), (xi), (xiv), (xii) of
12 paragraph (1)(B).

13 “(B) The requirement to maintain records
14 of the laboratories to which the laboratory test
15 protocol is distributed.

16 “(c) REGULATIONS.—In implementing quality re-
17 quirements for test developers that participate in inter-
18 national audit programs under this section, the Secretary
19 shall—

20 “(1) for purposes of facilitating international
21 harmonization, consider whether the developer par-
22 ticipates in an international audit program in which
23 the United States participates and recognizes com-
24 pliance with, or conformance to, such standards rec-
25 ognized by the Secretary; and

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

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

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

11 “(b) LABELS.—

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

16 “(2) REGULATIONS.—The label of an in vitro
17 clinical test shall state the name and place of busi-
18 ness of its developer and meet the requirements set
19 forth in regulations promulgated in accordance with
20 this section.

21 “(c) LABELING.—

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

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

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

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

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

11 “(B) information to facilitate reporting an
12 adverse event;

13 “(C) information regarding accessing the
14 performance summary data displayed in the
15 listing database for the test;

16 “(D) the indications for use of the in vitro
17 clinical test; and

18 “(E) any warnings, contraindications, or
19 limitations.

20 “(3) PUBLIC AVAILABILITY OF INFORMATION.—

21 The Secretary shall make all of the information de-
22 scribed in paragraph (2) with respect to each in
23 vitro clinical test available to the public, as applica-
24 ble, in accordance with section 587T, except to the

1 extent that the Secretary determines that such infor-
2 mation—

3 “(A) is trade secret or confidential com-
4 mercial or financial information; or

5 “(B) if posted, could compromise national
6 security.

7 “(4) ADDITIONAL REQUIREMENTS.—Labeling
8 for an in vitro clinical test used for
9 immunohematology testing shall meet the applicable
10 requirements set forth in part 660 of title 21, Code
11 of Federal Regulations (or any successor regula-
12 tions), related to the labeling of blood grouping re-
13 agents, reagent red blood cells, and anti-human
14 globulin.

15 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-
16 MENTS.—

17 “(1) IN GENERAL.—

18 “(A) IN GENERAL.—With respect to an in
19 vitro clinical test that meets the criteria of sub-
20 paragraph (B), the ‘state in one place’ regula-
21 tions under section 809.10(b) of title 21, Code
22 of Federal Regulations (or any successor regu-
23 lations) may be satisfied by the laboratory post-
24 ing such information on its website or in mul-

1 tiple documents, if such documents are main-
2 tained and accessible in one place.

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

6 “(i) developed by a laboratory cer-
7 tified by the Secretary under section 353
8 of the Public Health Service Act that
9 meets the requirements to perform tests of
10 high-complexity; and

11 “(ii) performed in—

12 “(I) the same laboratory in which
13 such test was developed; or

14 “(II) by another laboratory cer-
15 tified by the Secretary under section
16 353 of the Public Health Service Act
17 that—

18 “(aa) meets the require-
19 ments to perform tests of high
20 complexity; and

21 “(bb) is under common own-
22 ership and control as the labora-
23 tory that developed the test.

24 “(2) TEST INSTRUMENT LABELING.—Unless
25 the instrument is the entire test system, the labeling

1 for an instrument is not required to bear the infor-
2 mation indicated in paragraphs (3), (4), (5), (7),
3 (8), (9), (10), (11), (12), and (13) of section
4 809.10(b) of title 21, Code of Federal Regulations
5 (or any successor regulations).

6 “(3) REAGENT LABELING.—For purposes of
7 compliance with subsection (c)(1), the labeling for a
8 reagent intended for use as a replacement in an in
9 vitro clinical test may be limited to that information
10 necessary to identify the reagent adequately and to
11 describe its proper use in the test.

12 “(4) INVESTIGATIONAL USE.—A shipment or
13 other delivery of an in vitro clinical test for inves-
14 tigational use pursuant to section 587S shall be ex-
15 empt from the labeling requirements of subsections
16 (b) and (c)(1) and from any standard promulgated
17 through regulations, except as required under sec-
18 tion 353 of the Public Health Service Act or section
19 587R of this Act.

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

1 “(6) OVER-THE-COUNTER TEST SPECIMEN RE-
2 CEPTACLE LABELING.—The labeling for over-the-
3 counter test specimen receptacles for drugs of abuse
4 testing shall bear the name and place of business of
5 the developer included in the registration under sec-
6 tion 587J and any information specified in applica-
7 ble regulations promulgated under this section, in
8 language appropriate for the intended users.

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

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

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

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

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

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

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

15 “(1) have caused or contributed to a patient or
16 user death; or

17 “(2) present an imminent threat to public
18 health.

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

1 “(d) DEFINITIONS.—For the purposes of this sec-
2 tion—

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

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

9 “(A) a significant delay in a diagnosis that
10 results in the absence, delay, or discontinuation
11 of critical medical treatment or that irreversibly
12 or seriously and negatively alters the course of
13 a disease or condition; or

14 “(B) an injury that—

15 “(i) is life threatening;

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

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

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

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

2 “(a) REGULATIONS.—The Secretary shall promulgate
3 regulations, or amend existing regulations, as appropriate,
4 to implement this section.

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

6 “(1) IN GENERAL.—Each in vitro clinical test
7 developer shall report to the Secretary any correc-
8 tion or removal of an in vitro clinical test under-
9 taken by such developer if the correction or removal
10 was undertaken—

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

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

16 “(2) EXCEPTION FOR IN VITRO CLINICAL TESTS
17 OFFERED UNDER A TECHNOLOGY CERTIFICATION
18 ORDER.—For any eligible test offered under a tech-
19 nology certification order under section 587D, a cor-
20 rection and removal report for any correction or re-
21 moval of an in vitro clinical test should demonstrate
22 that the issue or issues causing the correction or re-
23 moval do not adversely impact the ability of other in
24 vitro clinical tests offered under the same technology
25 certification order to meet the applicable standard.

1 “(c) **TIMING.**—A developer shall submit any report
2 required under this subsection to the Secretary within 15
3 business days of initiating such correction or removal.

4 “(d) **RECORDKEEPING.**—A developer of an in vitro
5 clinical test that undertakes a correction or removal of an
6 in vitro clinical test which is not required to be reported
7 under this subsection shall keep a record of such correc-
8 tion or removal.

9 “(e) **RECALL COMMUNICATIONS.**—Upon the report-
10 ing of a correction or removal by the developer—

11 “(1) the Secretary shall classify such correction
12 or removal under this section within 45 calendar
13 days; and

14 “(2) not later than 70 calendar days after the
15 developer or other responsible party notifies the Sec-
16 retary that it has completed a recall action, the Sec-
17 retary shall provide the developer or other respon-
18 sible party with a written statement closing the re-
19 call action or stating the reasons the Secretary can-
20 not close the recall at that time.

21 **“SEC. 5870. RESTRICTED IN VITRO CLINICAL TESTS.**

22 “(a) **APPLICABILITY.**—

23 “(1) **IN GENERAL.**—For the types of in vitro
24 clinical tests described in paragraph (3), the Sec-
25 retary may require, in issuing an approval of an in

1 vitro clinical test under section 587B, granting a
2 technology certification order under section 587D, or
3 in issuing a determination under section 587F(a), or
4 by issuing a regulation, that such test, or category
5 of tests, be restricted to sale, distribution, or use
6 upon such conditions as the Secretary may prescribe
7 under paragraph (2).

8 “(2) CONDITIONS.— The Secretary may pre-
9 scribe conditions under this section, based on avail-
10 able evidence, with respect to an in vitro clinical test
11 described in paragraph (3), that are determined to
12 be needed due to the potential for harmful effect of
13 such test (including any resulting absence, signifi-
14 cant delay, or discontinuation of appropriate medical
15 treatment), and are necessary to ensure that the test
16 meets the applicable standard.

17 “(3) IN VITRO CLINICAL TESTS SUBJECT TO
18 RESTRICTIONS.—The restrictions or conditions au-
19 thorized under this section may be applied by the
20 Secretary to any high-risk or moderate-risk in vitro
21 clinical test, prescription home-use in vitro clinical
22 test, direct-to-consumer in vitro clinical test, or over-
23 the-counter in vitro clinical test.

24 “(b) LABELING AND ADVERTISING OF A RESTRICTED
25 IN VITRO CLINICAL TEST.—The labeling and advertising

1 of an in vitro clinical test to which restrictions apply under
2 subsection (a) shall bear such appropriate statements of
3 the restrictions as the Secretary may prescribe in an ap-
4 proval under section 587B, an order under section 587D,
5 a determination under section 587F(a), or in regulation,
6 as applicable.

7 “(c) **DEVICE RESTRICTIONS.**—An in vitro clinical
8 test that was offered as a restricted device prior to the
9 date of enactment of this subchapter—

10 “(1) shall continue to comply with the applica-
11 ble restrictions under section 515 or section 520(e)
12 until this subchapter takes effect; and

13 “(2) except for in vitro clinical tests required to
14 meet the requirements of section 809.30 of title 21,
15 Code of Federal Regulations prior to the effective
16 date of this subchapter specified in section
17 5(a)(1)(A) of the VALID Act of 2023, such restric-
18 tions described in paragraph (1) shall be deemed to
19 be restrictions under this subchapter as of such ef-
20 fective date.

21 **“SEC. 587P. APPEALS.**

22 “(a) **SIGNIFICANT DECISION.**—

23 “(1) **IN GENERAL.**—The Secretary shall—

24 “(A) maintain a substantive summary of
25 the scientific and regulatory rationale for any

1 significant decision of the Food and Drug Ad-
2 ministration pursuant to section 587F, regard-
3 ing—

4 “(i) the submission of an application
5 for, or a review of, an in vitro clinical test
6 under section 587B or section 587D;

7 “(ii) an exemption under section
8 587C; or

9 “(iii) any requirements for mitigation
10 measures to an in vitro clinical test or cat-
11 egory of in vitro clinical tests; and

12 “(B) include in such summaries docu-
13 mentation of significant controversies or dif-
14 ferences of opinion and the resolution of such
15 controversies or differences of opinion.

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

21 “(3) APPLICATION OF LEAST BURDENSOME RE-
22 QUIREMENTS.—The substantive summary required
23 under this subsection shall include a brief statement
24 regarding how the least burdensome requirements

1 were considered and applied consistent with section
2 587AA(c), as applicable.

3 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

4 “(1) REQUEST FOR SUPERVISORY REVIEW OF
5 SIGNIFICANT DECISION.—A developer may request a
6 supervisory review of the significant decision de-
7 scribed in subsection (a)(1). Such review may be
8 conducted at the next supervisory level or higher
9 above the agency official who made the significant
10 decision.

11 “(2) SUBMISSION OF REQUEST.—A developer
12 requesting a supervisory review under paragraph (1)
13 shall submit such request to the Secretary not later
14 than 30 days after the decision for which the review
15 is requested and shall indicate in the request wheth-
16 er such developer seeks an in-person meeting or a
17 teleconference review.

18 “(3) TIMEFRAME.—The Secretary shall sched-
19 ule an in-person or teleconference review, if so re-
20 quested, not later than 30 days after such request
21 is made. The Secretary shall issue a decision to the
22 developer requesting a review under this subsection
23 not later than 45 days after the request is made
24 under paragraph (1), or, in the case of a developer

1 who requests an in-person meeting or teleconference,
2 30 days after such meeting or teleconference.

3 “(c) **ADVISORY PANELS.**—The process established
4 under subsection (a) shall permit the appellant to request
5 review by an advisory committee established under section
6 587G when there is a dispute involving substantial sci-
7 entific fact. If an advisory panel meeting is held, the Sec-
8 retary shall make a determination under this subsection
9 not later than 45 days after the requested advisory com-
10 mittee meeting has concluded.

11 “(d) **LEAST BURDENSOME REVIEW.**—Any developer
12 who has submitted an application under section 587B or
13 587D may request a supervisory review of a request for
14 additional information during an evaluation of such sub-
15 mission within 60 calendar days of receipt of the addi-
16 tional information request from the Secretary.

17 “(e) **AVAILABILITY OF ALL REMEDIES.**—The proce-
18 dures set forth in this section shall be in addition to, and
19 not in lieu of, other remedies available to the developer.

20 **“SEC. 587Q. ACCREDITED PERSONS.**

21 “(a) **IN GENERAL.**—

22 “(1) **AUTHORIZATION.**—Beginning on the date
23 of enactment of the VALID Act of 2023, the Sec-
24 retary shall accredit persons for any of the following
25 purposes:

1 “(A) Reviewing applications for premarket
2 approval under section 587B and making find-
3 ings with respect to such applications.

4 “(B) Reviewing applications for technology
5 certification under section 587D and making
6 recommendations to the Secretary with respect
7 to such applications.

8 “(C) Conducting inspections as specified in
9 subsection (c) of in vitro clinical test developers
10 and other persons required to register pursuant
11 to section 587J.

12 “(2) PERSONS SUBMITTING APPLICATIONS.—A
13 person submitting an application for premarket ap-
14 proval under section 587B or an application for
15 technology certification under section 587D may
16 submit such application to the Secretary or to a per-
17 son accredited pursuant to subparagraph (A) or (B)
18 of paragraph (1).

19 “(b) ACCREDITED PERSONS APPLICATION REVIEWS,
20 FINDINGS AND RECOMMENDATIONS.—

21 “(1) REQUIREMENTS FOR PREMARKET APPLI-
22 CATION.—

23 “(A) REVIEW, FINDING, AND REC-
24 OMMENDATION REQUIREMENTS.—An accredited

1 person receiving an application for premarket
2 approval under section 587B shall either—

3 “(i) provide to the Secretary, together
4 with the application for premarket ap-
5 proval submitted by the applicant, a rec-
6 ommendation based on a finding that the
7 criteria for approval of the application
8 under section 587B(e)(2)(A) are met and
9 issue a copy of such finding to the appli-
10 cant, which finding shall plainly state—

11 “(I) the basis for the accredited
12 person’s finding that the criteria
13 under section 587B(e)(2)(A) are met;
14 and

15 “(II) any proposed restrictions,
16 mitigating measures, or conditions of
17 approval under section 587B(e)(2)(B),
18 as applicable; or

19 “(ii) provide a notification to the ap-
20 plicant that the accredited person cannot
21 find that the criteria for approval of the
22 application under section 587B(e)(2)(A)
23 are met and the reasons for such decision.

24 “(B) REQUESTING MISSING OR CLARI-
25 FYING INFORMATION.—After receipt of an ap-

1 plication from an accredited person under this
2 section, the Secretary may request missing or
3 clarifying information from the applicant con-
4 cerning the application, which the accredited
5 person shall promptly provide.

6 “(C) SECRETARY ACTION ON REC-
7 COMMENDATION THAT APPROVAL CRITERIA ARE
8 MET.—If the accredited person transmits a rec-
9 ommendation to the Secretary under subpara-
10 graph (A)(i), then prior to the date that is 45
11 calendar days after the transmittal date, the
12 Secretary shall consider such recommendation
13 and make a determination to—

14 “(i) approve the application for pre-
15 market approval under section 587B(e)(2)
16 with appropriate restrictions, mitigating
17 measures, or conditions of approval, as ap-
18 plicable; or

19 “(ii) deny approval of the application
20 by issuing a written notice that reflects ap-
21 propriate management input and concur-
22 rence to the accredited person and the ap-
23 plicant detailing the scientific basis for the
24 Secretary’s determination that the criteria

1 for issuance of an approval under section
2 587B(e)(2)(A) have not been met.

3 “(D) EFFECT OF INACTION ON REC-
4 OMMENDATION.—If the Secretary fails to take
5 an action under subparagraph (C) the Sec-
6 retary shall—

7 “(i) within 45 calendar days after the
8 transmittal date, provide written feedback
9 to the applicant that—

10 “(I) includes all outstanding
11 issues with the application preventing
12 the Secretary from taking an action
13 under subparagraph (B);

14 “(II) reflects appropriate man-
15 agement input and concurrence; and

16 “(III) includes action items for
17 the Secretary, the applicant, or both,
18 as appropriate, with an estimated date
19 of completion for the Secretary and
20 the applicant to complete their respec-
21 tive tasks, as applicable; and

22 “(ii) promptly schedule a meeting or
23 teleconference to discuss the feedback pro-
24 vided under clause (i), unless the Secretary
25 and applicant agree that the outstanding

1 issues are adequately presented through
2 written correspondence and a meeting or
3 teleconference is not necessary.

4 “(2) REQUIREMENTS FOR TECHNOLOGY CER-
5 TIFICATION.—

6 “(A) REVIEW AND RECOMMENDATION RE-
7 QUIREMENTS.—An accredited person receiving
8 an application for technology certification under
9 section 587D shall either—

10 “(i) provide to the Secretary, together
11 with the application for technology certifi-
12 cation submitted by the applicant, a rec-
13 ommendation that the criteria for issuance
14 of a technology certification order under
15 section 587D(d)(3) are met and issue a
16 copy of such recommendation to the appli-
17 cant, which recommendation shall plainly
18 state the basis for the accredited person’s
19 recommendation that the criteria under
20 section 587D(d)(3) are met; or

21 “(ii) provide a notification to the ap-
22 plicant that the accredited person cannot
23 recommend that the criteria for issuance of
24 a technology certification order under sec-

1 tion 587D(d)(3) are met and the reasons
2 for such decision.

3 “(B) REQUESTING MISSING OR CLARI-
4 FYING INFORMATION.—After receipt of an ap-
5 plication under this section, the accredited per-
6 son may request missing or clarifying informa-
7 tion from the applicant concerning the applica-
8 tion, which the applicant shall promptly pro-
9 vide.

10 “(C) SECRETARY ACTION ON REC-
11 COMMENDATION FOR ISSUANCE OF A TECH-
12 NOLOGY CERTIFICATION ORDER.—If the accred-
13 ited person transmits a recommendation to the
14 Secretary under clause (i) of subparagraph (A),
15 then prior to the date that is 60 calendar days
16 after the transmittal date the Secretary shall—

17 “(i) issue the technology certification
18 order under section 587D(d)(3), consistent
19 with such recommendation from the ac-
20 credited person; or

21 “(ii) deny approval of the application
22 by issuing a written notice to the accred-
23 ited person and the applicant detailing the
24 scientific basis for a determination by the
25 Secretary that the criteria for issuance of

1 a technology certification order under sec-
2 tion 587D(d)(3) have not been met.

3 “(c) REQUIREMENTS FOR INSPECTIONS.—

4 “(1) IN GENERAL.—When conducting inspec-
5 tion, persons accredited under subsection (a)(1)(C)
6 shall record in writing their specific observations and
7 shall present their observations to the designated
8 representative of the inspected establishment.

9 “(2) INSPECTION REPORT REQUIREMENTS.—

10 Each person accredited under subsection (a)(1)(C)
11 shall prepare and submit to the Secretary an inspec-
12 tion report in a form and manner designated by the
13 Secretary for conducting inspections. Any statement
14 or representation made by an employee or agent of
15 an establishment to a person accredited to conduct
16 inspections under subsection (a)(1)(C) shall be sub-
17 ject to section 1001 of title 18, United States Code.

18 “(3) SAVINGS CLAUSE.—Nothing in this section
19 affects the authority of the Secretary to inspect any
20 in vitro clinical test developer or other person reg-
21 istered under section 587J or recognize inspections
22 conducted by auditing organizations as described
23 under section 704(g)(15).

24 “(4) INSPECTION LIMITATIONS.—The Secretary
25 shall ensure that inspections carried out under this

1 section are not duplicative of inspections carried out
2 under section 353 of the Public Health Service Act.
3 Inspections under this section shall be limited to the
4 data and information necessary—

5 “(A) for routine surveillance activities of
6 facilities associated with an approved applica-
7 tion under section 587B or issuance of a tech-
8 nology certification order under section 587D;
9 or

10 “(B) to meet the requirements for pre-
11 market approval under section 587B or
12 issuance of a technology certification order
13 under section 587D, as applicable.

14 “(d) ACCREDITATION.—

15 “(1) ACCREDITATION PROGRAM.—The Sec-
16 retary may provide for accreditation under this sec-
17 tion through programs administered by the Food
18 and Drug Administration, by other non-Federal gov-
19 ernment agencies, or by qualified nongovernmental
20 organizations. A person may be accredited for the
21 review of applications submitted under sections
22 587B as described in subsection (a)(1)(A), for the
23 review of applications submitted under section 587D
24 as described in subsection (a)(1)(B), and to conduct

1 inspection activities under subsection (a)(1)(C), or
2 for a subset of such reviews or activities.

3 “(2) ELIGIBLE PERSONS.—

4 “(A) MINIMUM QUALIFICATIONS.—An ac-
5 credited person, at a minimum, shall—

6 “(i) not be an employee of the Federal
7 Government;

8 “(ii) not engage in the activities of a
9 developer, as defined in section 587(7);

10 “(iii) not be a person required to reg-
11 ister under section 587J, unless such per-
12 son has established sufficient processes
13 and protocols to separate activities to de-
14 velop in vitro clinical tests and the activi-
15 ties for which such person would be ac-
16 credited under subsection (a) and discloses
17 applicable information under this section;

18 “(iv) not be owned or controlled by,
19 and shall have no organizational, material,
20 or financial affiliation with, an in vitro
21 clinical test developer or other person re-
22 quired to register under section 587J;

23 “(v) be a legally constituted entity
24 permitted to conduct the activities for
25 which it seeks accreditation;

1 “(vi) ensure that the operations of
2 such person are in accordance with gen-
3 erally accepted professional and ethical
4 business practices; and

5 “(vii) include in its request for accred-
6 itation a commitment to, at the time of ac-
7 creditation and at any time it is per-
8 forming activities pursuant to this sec-
9 tion—

10 “(I) certify that the information
11 reported to the Secretary accurately
12 reflects the data or protocol reviewed,
13 and the documented inspection find-
14 ings, as applicable;

15 “(II) limit work to that for which
16 competence and capacity are available;

17 “(III) treat information received
18 or learned, records, reports, and rec-
19 ommendations as proprietary informa-
20 tion of the person submitting such in-
21 formation; and

22 “(IV) in conducting the activities
23 for which the person is accredited in
24 respect to a particular in vitro clinical
25 test, protect against the use of any

1 employee or consultant who has a fi-
2 nancial conflict of interest regarding
3 that in vitro clinical test.

4 “(B) WAIVER.—The Secretary may waive
5 any requirements in clauses (i), (ii), (iii), or (iv)
6 of subparagraph (A) upon making a determina-
7 tion that such person has implemented other
8 appropriate controls sufficient to ensure a com-
9 petent and impartial review.

10 “(3) ACCREDITATION PROCESS.—

11 “(A) ACCREDITATION PROCESS GUIDANCE
12 AND REGULATIONS.—Not later than 180 days
13 after the date of enactment of the VALID Act
14 of 2023, the Secretary shall issue draft guid-
15 ance specifying the process for submitting a re-
16 quest for accreditation and reaccreditation
17 under this section, including the form and con-
18 tent of information to be submitted, including
19 the criteria that the Secretary will consider to
20 accredit or deny accreditation and, not later
21 than 1 year after the close of the comment pe-
22 riod for the draft guidance, issue final guid-
23 ance.

24 “(B) RESPONSE TO REQUEST.—The Sec-
25 retary shall respond to a request for accredita-

1 tion or reaccreditation within 60 calendar days
2 of the receipt of the request. The Secretary's
3 response may be to accredit or reaccredit the
4 person, to deny accreditation, or to request ad-
5 ditional information in support of the request.
6 If the Secretary requests additional informa-
7 tion, the Secretary shall respond within 60 cal-
8 endar days of receipt of such additional infor-
9 mation to accredit or deny the accreditation.

10 “(C) TYPE OF ACCREDITATION.—The ac-
11 creditation or reaccreditation of a person shall
12 specify the particular activity or activities under
13 subsection (a) for which such person is accred-
14 ited, and shall include any limitation to certain
15 eligible in vitro clinical tests.

16 “(D) PUBLIC LIST.—The Secretary shall
17 publish on the website of the Food and Drug
18 Administration a list of persons who are accred-
19 ited under this section. Such list shall be up-
20 dated on at least a monthly basis. The list shall
21 specify the particular activity or activities under
22 this section for which the person is accredited.

23 “(E) AUDIT.—The Secretary may audit
24 the performance of persons accredited under
25 this section for purposes of ensuring that such

1 persons continue to meet the published criteria
2 for accreditation, and may modify the scope or
3 particular activities for which a person is ac-
4 credited if the Secretary determines that such
5 person fails to meet one or more criteria for ac-
6 creditation.

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

17 “(G) **REACCREDITATION.**—Accredited per-
18 sons may be initially accredited for up to 3
19 years. After expiration of such initial period,
20 persons may be recredited for unlimited addi-
21 tional 5-year periods, as determined by the Sec-
22 retary.

23 “(e) **COMPENSATION OF ACCREDITED PERSONS.**—
24 Compensation of an accredited person shall be determined
25 by agreement between the accredited person and the per-

1 son who engages the services of the accredited person, and
2 shall be paid by the person who engages such services.

3 “(f) INTERNATIONAL HARMONIZATION.—Notwith-
4 standing any other provision of this section, to facilitate
5 international harmonization the Secretary may recognize
6 persons accredited or recognized by governments, who
7 have also entered into information sharing agreements, in-
8 cluding confidentiality commitments, with the Commis-
9 sioner of Food and Drugs.

10 “(g) INFORMATION SHARING AGREEMENTS.—An ac-
11 credited person may enter into an agreement with a test
12 developer to provide information to the comprehensive test
13 information system under section 587T, including any re-
14 quirements under section 587J.

15 “(h) REPORTS.—Not later than 2 years after the ef-
16 fective date of the VALID Act of 2023, and annually
17 thereafter for the next 4 years, the Secretary shall post
18 on the website of the Food and Drug Administration, a
19 report describing the Secretary’s performance in imple-
20 menting this section, including the Secretary’s progress in
21 minimizing duplicative reviews of applications for which
22 an accredited person finds the criteria for approval are
23 met. Such reports shall include, for each period—

24 “(1) with regard to premarket approval applica-
25 tions—

1 “(A) the total number of findings trans-
2 mitted to the Secretary under subsection
3 (b)(1)(A)(i);

4 “(B) the total number of determinations
5 made by the Secretary under subsection
6 (b)(1)(B)(i) within 30 calendar days of the
7 transmittal date to approve an application;

8 “(C) the total number of determinations
9 made by the Secretary under subsection
10 (b)(1)(B)(ii) within 30 calendar days of the
11 transmittal date to deny approval of an applica-
12 tion; and

13 “(D) the total number of applications that
14 were approved and the total number of applica-
15 tions that were denied approval, after the Sec-
16 retary failed to make a determination within 30
17 calendar days of the transmittal date under
18 subsection (b)(1)(B); and

19 “(2) with regard to applications for technology
20 certification—

21 “(A) the total number of recommendations
22 transmitted to the Secretary under subsection
23 (b)(2)(A)(i);

24 “(B) the total number of determinations
25 made by the Secretary under subsection

1 (b)(2)(B)(i) to issue a technology certification
2 order, including determinations made within 30
3 days of the transmittal date;

4 “(C) the total number of determinations
5 made by the Secretary under subsection
6 (b)(2)(B)(ii) to deny the application for tech-
7 nology certification, including determinations
8 made within 30 calendar days of the trans-
9 mittal date; and

10 “(D) the total number of technology cer-
11 tification orders issued, and the total number of
12 applications for technology certification that
13 were denied, including applications denied after
14 the Secretary failed to make a determination
15 within 30 calendar days of the transmittal date
16 under subsection (b)(2)(B).

17 **“SEC. 587R. RECOGNIZED STANDARDS.**

18 “(a) IN GENERAL.—The Secretary may recognize all
19 or part of appropriate standards established by nationally
20 or internationally recognized standards development orga-
21 nizations for which a person may submit a declaration of
22 conformity in order to meet a requirement under this sub-
23 chapter to which that standard is applicable. Standards
24 for in vitro diagnostic devices previously recognized under
25 section 514(c) shall be considered recognized standards

1 under this section. Recognized and proposed standards
2 shall be accessible to the public at no charge. The applica-
3 tion of any such consensus standard shall only apply pro-
4 spectively. The Secretary shall issue regulations estab-
5 lishing the criteria and process, for such recognition and
6 adoption.

7 “(b) AMENDMENT PROCESS.—The procedures estab-
8 lished in this section or in regulation or guidance issued
9 under this section shall apply to amendment of an existing
10 standard.

11 **“SEC. 587S. INVESTIGATIONAL USE.**

12 “(a) IN GENERAL.—Subject to the conditions pre-
13 scribed in subsections (c), (d), (e), (f), and (g), an in vitro
14 clinical test for investigational use shall be exempt from
15 the requirements of this subchapter, other than sections
16 587A, 587P, 587T, and 587V. The Secretary may amend
17 parts 50, 54, and 56 of title 21 of the Code of Federal
18 Regulations to apply to in vitro clinical tests to permit
19 the investigational use of such tests by experts qualified
20 by scientific training and experience.

21 “(b) REGULATIONS.—

22 “(1) IN GENERAL.—Not later than 3 years
23 after the date of enactment of the VALID Act of
24 2023, the Secretary shall promulgate regulations to
25 implement this section.

1 “(2) VARIATION.—The requirements in the reg-
2 ulations promulgated under this section shall take
3 into account variations based on—

4 “(A) the scope and duration of clinical
5 testing to be conducted under investigation that
6 is the subject of such application;

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

9 “(C) the need to permit changes to be
10 made to the in vitro clinical test involved during
11 testing conducted in accordance with a plan re-
12 quired under subsection (c)(6); or

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

16 “(c) APPLICATION FOR INVESTIGATIONAL USE.—
17 The following shall apply with respect to in vitro clinical
18 tests for investigational use:

19 “(1) SIGNIFICANT RISK AND OTHER STUD-
20 IES.—In the case of an in vitro clinical test the in-
21 vestigational use of which poses a significant risk to
22 the human subject or involves an exception from in-
23 formed consent for emergency research, a sponsor of
24 an investigation of such a test seeking an investiga-
25 tional use exemption shall submit to the Secretary

1 an investigational use application with respect to the
2 in vitro clinical test in accordance with paragraphs
3 (3) and (4).

4 “(2) NON-SIGNIFICANT RISK STUDIES.—In the
5 case of an in vitro clinical test, the investigational
6 use of which is not described in paragraph (1)—

7 “(A) the sponsor of such investigation
8 shall—

9 “(i) ensure such investigation is con-
10 ducted in compliance with an investiga-
11 tional plan approved by an institutional re-
12 view committee and the labeling of the in
13 vitro clinical test involved clearly and con-
14 spicuously states, ‘For investigational use
15 only’, as specified in paragraph (4)(A)(ii);

16 “(ii) ensure each investigator obtains
17 informed consent as required under part
18 50, 54, and 56 of title 21, Code of Federal
19 Regulations (or any successor regulations),
20 subject to the exceptions set forth in para-
21 graph (6)(C);

22 “(iii) establish and maintain records
23 with respect to all requirements in this
24 subparagraph;

1 “(iv) maintain records and make re-
2 ports as required by the Secretary pursu-
3 ant to regulations issued under subsection
4 (b); and

5 “(v) ensure that investigators monitor
6 investigations, maintain records and make
7 reports as required by the Secretary pursu-
8 ant to regulations issued under subsection
9 (b); and

10 “(B) the sponsor may rely on any excep-
11 tion or exemption described in paragraph (4) or
12 as established by the Secretary in regulations
13 issued under subsection (b).

14 “(3) APPLICATION.—An investigational use ap-
15 plication shall be submitted in such time and man-
16 ner and contain such information as the Secretary
17 may require in regulation, and shall include an in-
18 vestigational plan for proposed clinical testing and
19 assurances that the sponsor submitting the applica-
20 tion will—

21 “(A) establish and maintain records rel-
22 evant to the investigation of such in vitro clin-
23 ical test; and

24 “(B) submit to the Secretary annual re-
25 ports of data obtained as a result of the inves-

1 tigational use of the in vitro clinical test during
2 the period covered by the exemption that the
3 Secretary reasonably determines will enable the
4 Secretary—

5 “(i) to ensure compliance with the
6 conditions for the exemption specified in
7 paragraph (4);

8 “(ii) to review the progress of the in-
9 vestigation involved; and

10 “(iii) to evaluate the ability to meet
11 the applicable standard.

12 “(4) CONDITIONS FOR EXEMPTION.—An appli-
13 cation for an investigational use exemption with re-
14 spect to a significant risk study shall be granted if
15 each of the following conditions is met:

16 “(A) The risks to the subjects of the in
17 vitro clinical test are outweighed by the antici-
18 pated benefits of the test to the subjects and
19 the importance of the knowledge to be gained,
20 and adequate assurance of informed consent is
21 provided in accordance with paragraphs (6)(B)
22 and (6)(C).

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

1 “(C) Such other requirements the Sec-
2 retary determines—

3 “(i) are necessary for the protection
4 of the public health and safety; and

5 “(ii) do not unduly delay investiga-
6 tion.

7 “(5) COORDINATION WITH INVESTIGATIONAL
8 NEW DRUG APPLICATIONS.—Any requirement for
9 the submission of a report to the Secretary pursuant
10 to an application for an investigational new drug ex-
11 emption involving an in vitro clinical test shall su-
12 persede the reporting requirement under paragraph
13 (3)(B), but only to the extent the requirement with
14 respect to the application for exemption with respect
15 to the drug is duplicative of the reporting require-
16 ment under such paragraph.

17 “(6) INVESTIGATIONAL PLAN, PROCEDURES,
18 AND CONDITIONS.—With respect to an investiga-
19 tional plan submitted under paragraph (3), the
20 sponsor submitting such plan shall—

21 “(A) promptly notify the Secretary of the
22 approval or the suspension or termination of
23 the approval of such plan by an institutional re-
24 view committee;

1 “(B) in the case of an in vitro clinical test
2 made available to investigators for clinical test-
3 ing, obtain agreements from each investigator
4 that any testing of the in vitro clinical test in-
5 volving human subjects will be under such in-
6 vestigator’s supervision and in accordance with
7 paragraph (C) and submit such agreements to
8 the Secretary that ensure—

9 “(i) all investigators will comply with
10 this section, regulations promulgated or re-
11 vised under this section, and applicable
12 human subjects regulations; and

13 “(ii) the investigator will ensure
14 that—

15 “(I) informed consent is obtained
16 as required under part 50 of title 21,
17 Code of Federal Regulations (or any
18 successor regulations), amended to
19 apply to in vitro clinical tests; and

20 “(II) the requirements for insti-
21 tutional review board under part 56 of
22 title 21 of the Code of Federal Regu-
23 lations (or successor regulations),
24 amended to apply to in vitro clinical
25 tests, are met; and

1 “(C) ensure that informed consent will be
2 obtained from each human subject (or the rep-
3 resentative of such subject) of proposed clinical
4 testing involving such in vitro clinical test, ex-
5 cept where, subject to such other conditions as
6 the Secretary may prescribe—

7 “(i) the proposed clinical testing poses
8 no more than minimal risk to the human
9 subject and includes appropriate safe-
10 guards to protect the rights, safety, and
11 welfare of the human subject; or

12 “(ii) the investigator conducting or
13 supervising the clinical testing determines
14 in writing that there exists a life-threat-
15 ening situation involving the human sub-
16 ject of such testing which necessitates the
17 use of such in vitro clinical test and it is
18 not feasible to obtain informed consent
19 from the subject and there is not sufficient
20 time to obtain such consent from a rep-
21 resentative of such subject.

22 “(7) CONCURRED BY LICENSED PHYSICIAN.—
23 The determination required by paragraph (6)(C)(ii)
24 shall be concurred in writing by a licensed physician
25 who is not involved in the testing of the human sub-

1 ject with respect to which such determination is
2 made unless immediate use of the in vitro clinical
3 test is required to save the life of the human subject
4 of such testing and there is not sufficient time to ob-
5 tain such concurrence.

6 “(8) SIGNIFICANT RISK.—For purposes of this
7 subsection, the term ‘significant risk’ means, with
8 respect to an in vitro clinical test, that the use of
9 such in vitro clinical test—

10 “(A) is of substantial importance in per-
11 forming an activity or activities described in
12 section 201(ss)(1) for, a serious or life-threat-
13 ening disease or condition without confirmation
14 of the diagnosis by a medically established diag-
15 nostic product or procedure;

16 “(B) requires an invasive sampling proce-
17 dure that presents a significant risk to the
18 human subject, provided that routine
19 venipuncture shall not be considered an invasive
20 sampling procedure; or

21 “(C) otherwise presents a potential for se-
22 rious risk to the health of a human subject.

23 “(d) REVIEW OF APPLICATIONS.—

24 “(1) IN GENERAL.—The Secretary may issue
25 an order approving an investigation as proposed, ap-

1 proving it with conditions or modifications, or dis-
2 approving it.

3 “(2) FAILURE TO ACT.—Unless the Secretary,
4 not later than 30 calendar days after the date of the
5 submission of an application for an investigational
6 use exemption that meets the requirements of sub-
7 section (c), issues an order under paragraph (1) and
8 notifies the sponsor submitting the application, the
9 application shall be treated as approved as of such
10 date without further action by the Secretary.

11 “(3) DENIAL.—The Secretary may deny an in-
12 vestigational use application submitted under this
13 subsection if the Secretary determines that the in-
14 vestigation with respect to which the application is
15 submitted does not conform to the requirements of
16 subsection (c). A notification of such denial sub-
17 mitted to the sponsor with respect to such a request
18 shall contain the order of disapproval and a complete
19 statement of the reasons for the Secretary’s denial
20 of the application.

21 “(e) WITHDRAWAL OF EXEMPTION.—

22 “(1) IN GENERAL.—The Secretary may, by ad-
23 ministrative order, withdraw an exemption approved
24 under this section with respect to an in vitro clinical
25 test, including an exemption treated as approved

1 based on the Secretary's failure to act pursuant to
2 subsection (d)(2), if the Secretary determines that
3 an investigation conducted under such an exemption
4 does not meet the applicable conditions under sub-
5 section (c)(3) for such exemption.

6 “(2) OPPORTUNITY TO BE HEARD.—

7 “(A) IN GENERAL.—Subject to subpara-
8 graph (B), an order withdrawing an investiga-
9 tional use exemption granted under this section
10 may be issued only after the Secretary provides
11 the sponsor of the in vitro clinical test with an
12 opportunity for an informal hearing.

13 “(B) EXCEPTION.—An order referred to in
14 subparagraph (A) with respect to an investiga-
15 tional use exemption granted under this section
16 may be issued on a preliminary basis before the
17 provision of an opportunity for an informal
18 hearing if the Secretary determines that the
19 continuation of testing under the exemption will
20 result in an unreasonable risk to the public
21 health. The Secretary will provide an oppor-
22 tunity for an informal hearing promptly fol-
23 lowing any preliminary action under this sub-
24 paragraph.

25 “(f) CHANGES.—

1 “(1) IN GENERAL.—The regulations promul-
2 gated under subsection (b) shall provide, with re-
3 spect to an in vitro clinical test for which an exemp-
4 tion under this subsection is in effect, procedures
5 and conditions under which changes are allowed
6 without the additional approval of an application for
7 an exemption or submission of a supplement to such
8 an application. Such regulations shall provide that
9 such a change may be made if—

10 “(A) the sponsor determines, on the basis
11 of credible information (as defined in regula-
12 tions) that the change meets the conditions
13 specified in paragraph (2); and

14 “(B) the sponsor submits to the Secretary,
15 not later than 5 calendar days after making the
16 change, a notice of the change.

17 “(2) CONDITIONS.—The conditions specified in
18 this paragraph are that—

19 “(A) in the case of developmental changes
20 to an in vitro clinical test, including manufac-
21 turing changes, the changes—

22 “(i) do not constitute a significant
23 change in design or in basic principles of
24 operation;

1 “(ii) do not affect the rights, safety,
2 or welfare of the human subjects involved
3 in the investigation; and

4 “(iii) are made in response to infor-
5 mation gathered during the course of an
6 investigation; and

7 “(B) in the case of changes to clinical pro-
8 tocols applicable to the test, the changes do not
9 affect—

10 “(i) the validity of data or information
11 resulting from the completion of an ap-
12 proved clinical protocol, or the relationship
13 of likely patient risk to benefit relied upon
14 to approve a product;

15 “(ii) the scientific soundness of a plan
16 submitted under subsection (c)(3); or

17 “(iii) the rights, safety, or welfare of
18 the human subjects involved in the inves-
19 tigation.

20 “(g) CLINICAL HOLD.—

21 “(1) IN GENERAL.—At any time, the Secretary
22 may impose a clinical hold with respect to an inves-
23 tigation of an in vitro clinical test if the Secretary
24 makes a written determination described in para-
25 graph (2). The Secretary shall, in imposing such

1 clinical hold, specify the basis for the clinical hold,
2 including the specific information available to the
3 Secretary which served as the basis for such clinical
4 hold, and confirm such determination in writing.
5 The applicant may immediately appeal any such de-
6 termination pursuant to section 587P.

7 “(2) DETERMINATION.—

8 “(A) IN GENERAL.—For purposes of para-
9 graph (1), a determination described in this
10 subparagraph with respect to a clinical hold is
11 a determination that, based on credible evi-
12 dence, the in vitro clinical test involved rep-
13 resents an unreasonable risk to the safety of
14 the persons who are the subjects of the clinical
15 investigation, taking into account the qualifica-
16 tions of the clinical investigators, information
17 about the in vitro clinical test, the design of the
18 clinical investigation, the condition for which
19 the in vitro clinical test is to be investigated,
20 and the health status of the subjects involved.

21 “(B) REMOVAL OF CLINICAL HOLD.—Any
22 written request to the Secretary from the spon-
23 sor of an investigation that a clinical hold be re-
24 moved shall receive a decision, in writing and
25 specifying the reasons therefor, within 30 days

1 after receipt of such request. Any such request
2 shall include sufficient information to support
3 the removal of such clinical hold.

4 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

5 “(a) ESTABLISHMENT.—Not later than 2 years after
6 the date of enactment of the VALID Act of 2023, the Sec-
7 retary shall make available a comprehensive test informa-
8 tion system for in vitro clinical tests that is designed to—

9 “(1) provide a transparent interface on the
10 website of the Food and Drug Administration for
11 stakeholders, to the extent permitted by applicable
12 law, which may include access to the—

13 “(A) regulatory pathway designation infor-
14 mation for each in vitro clinical test or tests
15 with the same indications for use;

16 “(B) registration and listing information
17 provided by developers under section 587J, in-
18 cluding the use of a link for labels;

19 “(C) adverse event reports submitted
20 under section 587M, as appropriate;

21 “(D) reports of corrections and removals
22 submitted under section 587N; and

23 “(E) other information pertaining to an in
24 vitro clinical test or tests with the same indica-

1 tions for use, as the Secretary determines ap-
2 propriate; and

3 “(2) provide a secure portal for electronic sub-
4 mission, including applications and other in vitro
5 clinical test submissions, registration and listing in-
6 formation, and adverse event reports, which provides
7 protections from unauthorized disclosure of informa-
8 tion, including of—

9 “(A) trade secret or confidential commer-
10 cial or financial information; and

11 “(B) information that could compromise
12 national security.

13 “(b) SUBMISSION FUNCTION.—The comprehensive
14 test information system shall serve as the electronic sub-
15 mission service for test developers submitting information
16 for applications under sections 587B and 587D.

17 **“SEC. 587U. PREEMPTION.**

18 “(a) IN GENERAL.—Except as provided in subsection
19 (b), no State, Tribal, or local government (or political sub-
20 division thereof) may establish or continue in effect any
21 requirement—

22 “(1) that is different from, or in addition to,
23 any requirement applicable to an in vitro clinical test
24 under this Act; or

1 “(2) with respect to the analytical validity, clin-
2 ical validity, or safety for individuals who come into
3 contact with such an in vitro clinical test.

4 “(b) EXCEPTIONS.—Subsection (a) shall not be con-
5 strued to affect the authority of a State, Tribal, or local
6 government to do any of the following:

7 “(1) To license laboratory personnel, health
8 care practitioners, or health care facilities or to reg-
9 ulate any aspect of a health care practitioner-patient
10 relationship.

11 “(2) To enforce laws of general applicability,
12 such as zoning laws, environmental laws, labor laws,
13 and general business laws.

14 “(3) To authorize laboratories to develop and
15 perform an in vitro clinical test, pursuant to a law
16 enacted by a State prior to January 1, 2022, as long
17 as such law does not impose requirements that are
18 different from any requirement applicable to an in
19 vitro clinical test under this Act. If a State has en-
20 acted such a law, the Secretary shall exempt such
21 test for laboratories in that State from compliance
22 with this subchapter.

23 “(c) CLARIFICATION.—Nothing in this section shall
24 be construed to—

1 “(1) modify any action for damages or the li-
2 ability of any person under the law of any State; or

3 “(2) shift liability to health care practitioners
4 or other users.

5 **“SEC. 587V. ADULTERATION.**

6 “An in vitro clinical test shall be deemed to be adul-
7 terated:

8 “(1) If it consists in whole or in part of any
9 filthy, putrid, or decomposed substance.

10 “(2) If it has been developed, prepared, packed,
11 or held under insanitary conditions whereby it may
12 have been contaminated with filth, or whereby it
13 may have been rendered injurious to health.

14 “(3) If its container or package is composed, in
15 whole or in part, of any poisonous or deleterious
16 substance which may render the contents injurious
17 to health.

18 “(4) If it bears or contains, for purposes of
19 coloring only, a color additive which is unsafe within
20 the meaning of section 721(a).

21 “(5) If its analytical or clinical validity, as ap-
22 plicable, or with respect to a specimen receptacle, its
23 safety, falls below that which it purports or is rep-
24 resented to possess.

1 “(6) If it is required to be, declared to be, pur-
2 ports to be, or is represented as being, in conformity
3 with any performance standard established or recog-
4 nized under section 587R and is not in conformity
5 with such standard.

6 “(7) If it is required to be in compliance with
7 mitigating measures established under section 587E
8 and is not in conformity with such mitigating meas-
9 ures.

10 “(8) If it fails to have in effect an approved
11 premarket application under section 587B, unless
12 such in vitro clinical test is in compliance with the
13 requirements for—

14 “(A) offering without an approved pre-
15 market application under section 587D(b)(1);

16 “(B) an exemption from premarket ap-
17 proval under section 587C or 587G; or

18 “(C) investigational use pursuant to sec-
19 tion 587S.

20 “(9) If it is not in conformity with any condi-
21 tion established under section 587B or 587D.

22 “(10) If it purports to be an in vitro clinical
23 test subject to an exemption under section 587C and
24 it fails to meet or maintain any criteria, condition,
25 or requirement of such exemption.

1 “(11) If it has been granted an exemption
2 under section 587S for investigational use, and the
3 person granted such exemption or any investigator
4 who uses such in vitro clinical test under such ex-
5 emption fails to comply with a requirement pre-
6 scribed by or under such section.

7 “(12) If it fails to meet the quality require-
8 ments prescribed in or established under section
9 587K (as applicable), or the methods used in, or fa-
10 cilities or controls used for, its development, pack-
11 aging, storage, or installation are not in conformity
12 with applicable requirements established under such
13 section.

14 “(13) If it has been developed, processed, pack-
15 aged, or held in any establishment, factory, or ware-
16 house and the owner, operator or agent of such es-
17 tablishment, factory, or warehouse delays, denies, or
18 limits an inspection, or refuses to permit entry or in-
19 spection.

20 “(14) If it is not in compliance with any restric-
21 tion required under section 587O.

22 **“SEC. 587W. MISBRANDING.**

23 “An in vitro clinical test shall be deemed to be mis-
24 branded:

1 “(1) If its labeling is false or misleading in any
2 particular.

3 “(2) If in a package form unless it bears a label
4 containing—

5 “(A) the name and place of business of the
6 test developer, packager, or distributor; and

7 “(B) an accurate statement of the quantity
8 of contents in terms of weight, measure, or nu-
9 merical count, unless an exemption is granted
10 by the Secretary by the issuance of guidance,
11 such as with respect to small packages.

12 “(3) If any word, statement, or other informa-
13 tion required by or under authority of this Act to
14 appear on the label or labeling, including a test re-
15 port, is not prominently placed thereon with such
16 conspicuousness (as compared with other words,
17 statements, designs, or devices, in the labeling) and
18 in such terms as to render it likely to be read and
19 understood by the ordinary individual under cus-
20 tomary conditions of purchase and use.

21 “(4) Unless its labeling bears adequate direc-
22 tions for use and such adequate warnings as are
23 necessary for the protection of users of the in vitro
24 clinical test and recipients of the results of such in
25 vitro clinical test, including patients, consumers, do-

1 nors, and related health care professionals. Required
2 labeling for in vitro clinical tests intended for use in
3 health care facilities, blood establishments, or by a
4 health care professional may be made available solely
5 by electronic means, provided that the labeling com-
6 plies with all applicable requirements of law, and
7 that the test developer, or distributor affords such
8 users the opportunity to request the labeling in
9 paper form, and after such request, promptly pro-
10 vides the requested information without additional
11 cost.

12 “(5) If there is a reasonable probability that it
13 could cause serious or adverse health consequences
14 or death, including through absence, delay, or dis-
15 continuation in diagnosis or treatment, when used in
16 the manner prescribed, recommended, or suggested
17 in the labeling thereof.

18 “(6) If it was developed, sterilized, packaged,
19 repackaged, relabeled, installed, or imported in an
20 establishment not duly registered under section
21 587J or it was not included in a listing under sec-
22 tion 587J, in accordance with timely reporting re-
23 quirements under this subchapter.

24 “(7) In the case of any in vitro clinical test sub-
25 ject to restrictions under section 587O, (1) if its ad-

1 vertising is false or misleading in any particular, (2)
2 if it is offered for clinical use, sold, distributed, or
3 used in violation of such restrictions, or (3) unless
4 the test developer or distributor includes in all ad-
5 vertisements and other descriptive printed matter
6 that such person issues or causes to be issued, a
7 brief statement of the indications for use of the in
8 vitro clinical test and relevant warnings, precautions,
9 side effects, and contraindications. This paragraph
10 shall not be applicable to any printed matter that
11 the Secretary determines to be labeling as defined in
12 section 201(m).

13 “(8) If it is subject to a mitigating measure es-
14 tablished under section 587E and does not bear such
15 labeling as may be prescribed in such mitigating
16 measure.

17 “(9) If it is subject to a standard established
18 under section 587R and it does not bear such label-
19 ing as may be prescribed in such standard.

20 “(10) Unless it bears such labeling as may be
21 required by or established under an applicable label-
22 ing requirement under this Act.

23 “(11) If there was a failure to comply with any
24 requirement prescribed in or under section 587D,
25 587J, 587K, 587L, 587M, 587N, 587X, 587Y,

1 587Z, or to provide any report, material, or other in-
2 formation required with respect to in vitro clinical
3 tests under this subchapter.

4 **“SEC. 587X. POSTMARKET SURVEILLANCE.**

5 “(a) IN GENERAL.—

6 “(1) IN GENERAL.—In addition to other appli-
7 cable requirements under this Act, the Secretary
8 may issue an order requiring a developer of a high-
9 risk or moderate-risk in vitro clinical test to conduct
10 postmarket surveillance of such in vitro clinical test,
11 if the failure of the in vitro clinical test is reasonably
12 likely to result in serious adverse health con-
13 sequences or death from use of such in vitro clinical
14 test.

15 “(2) CONSIDERATION.—In determining whether
16 to require a developer to conduct postmarket surveil-
17 lance of an in vitro clinical test, the Secretary shall
18 take into consideration the benefits and risks for the
19 patient and the least burdensome requirements
20 under section 587AA(c).

21 “(b) SURVEILLANCE APPROVAL.—

22 “(1) IN GENERAL.—Each developer required to
23 conduct surveillance of an in vitro clinical test shall
24 submit, within 30 days of receiving an order from
25 the Secretary, a plan for the required surveillance.

1 The Secretary, within 60 days of the receipt of such
2 plan, shall determine if the person designated to
3 conduct the surveillance has the appropriate quali-
4 fications and experience to undertake such surveil-
5 lance and if the plan will result in useful data that
6 can reveal unforeseen adverse events or other infor-
7 mation necessary to protect the health of patients or
8 the public.

9 “(2) **TIMELINE.**—The developer shall com-
10 mence surveillance under this section not later than
11 15 months after the day on which the Secretary or-
12 ders such postmarket surveillance, unless the Sec-
13 retary determines more time is needed to commence
14 surveillance.

15 “(3) **PROSPECTIVE SURVEILLANCE.**—The Sec-
16 retary may order a prospective surveillance period of
17 up to 3 years. Any determination by the Secretary
18 that a longer period is necessary shall be made by
19 mutual agreement between the Secretary and the de-
20 veloper or, if no agreement can be reached, upon the
21 completion of a dispute resolution process pursuant
22 to section 562.

1 **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

2 “(a) IN GENERAL.—All submissions to the Food and
3 Drug Administration with respect to an in vitro clinical
4 test, unless otherwise agreed to by the Secretary, shall—

5 “(1) be made electronically; and

6 “(2) with respect to the information required
7 under sections 587B and 587D, utilize the system
8 described in section 587T.

9 “(b) ELECTRONIC FORMAT.—Beginning on such date
10 as the Secretary specifies in final guidance issued under
11 subsection (c), submissions for in vitro clinical tests, in-
12 cluding recommendations submitted by accredited and rec-
13 ognized persons under section 587Q, and any appeals of
14 action taken by the Secretary with respect to such submis-
15 sions, shall be submitted in such electronic format as spec-
16 ified by the Secretary in such guidance.

17 “(c) GUIDANCE.—The Secretary shall issue guidance
18 implementing this section. Such guidance may—

19 “(1) provide standards for the electronic sub-
20 mission required under subsection (a) or the submis-
21 sion in electronic format required under subsection
22 (b);

23 “(2) set forth criteria for waivers of, or exemp-
24 tions from, the requirements of subsection (a) or (b);
25 and

1 “(3) provide any other information for the effi-
2 cient implementation and enforcement of this sec-
3 tion.

4 **“SEC. 587Z. POSTMARKET REMEDIES.**

5 “(a) SAFETY NOTICE.—

6 “(1) IN GENERAL.—If the Secretary determines
7 that an in vitro clinical test presents an unreason-
8 able risk of substantial harm to the public health,
9 and notification under this subsection is necessary to
10 eliminate the unreasonable risk of such harm and no
11 more practicable means is available under the provi-
12 sions of this Act (other than this section) to elimi-
13 nate the risk, the Secretary may issue such order as
14 may be necessary to ensure that adequate safety no-
15 tice is provided in an appropriate form, by the per-
16 sons and means best suited under the circumstances,
17 to all health care professionals who prescribe, order,
18 or use the in vitro clinical test and to any other per-
19 son (including developers, importers, distributors, re-
20 tailers, and users) who should properly receive such
21 notice.

22 “(2) NOTICE TO INDIVIDUALS.—An order
23 under this subsection shall require that the individ-
24 uals subject to the risk with respect to which the
25 order is to be issued be included in the persons to

1 be notified of the risk unless the Secretary deter-
2 mines that notice to such individuals would present
3 a greater danger to the health of such individuals
4 than no such notice. If the Secretary makes such a
5 determination with respect to such individuals, the
6 order shall require the health care professionals who
7 prescribed, ordered, or used the in vitro clinical test
8 provide notification to the individuals for whom the
9 health professionals prescribed, ordered, or used
10 such test, of the risk presented by such in vitro clin-
11 ical test and of any action which may be taken by
12 or on behalf of such individuals to eliminate or re-
13 duce such risk. Before issuing an order under this
14 subsection, the Secretary shall consult with the per-
15 sons required to give notice under the order.

16 “(b) REPAIR, REPLACEMENT, OR REFUND.—

17 “(1) DETERMINATION AFTER AN INFORMAL
18 HEARING.—

19 “(A) IN GENERAL.—If, after affording op-
20 portunity for an informal hearing, the Secretary
21 determines that—

22 “(i) an in vitro clinical test presents
23 an unreasonable risk of substantial harm
24 to the public health;

1 “(ii) there are reasonable grounds to
2 believe that the in vitro clinical test was
3 not properly developed or manufactured
4 considering the state of the art as it ex-
5 isted at the time of its development;

6 “(iii) there are reasonable grounds to
7 believe that the unreasonable risk was not
8 caused by failure of a person other than a
9 developer, importer, distributor, or retailer
10 of the in vitro clinical test to exercise due
11 care in the installation, maintenance, re-
12 pair, or use of the in vitro clinical test; and

13 “(iv) the notice authorized by sub-
14 section (a) would not by itself be sufficient
15 to eliminate the unreasonable risk and ac-
16 tion described in paragraph (2) of this sub-
17 section is necessary to eliminate such risk,
18 the Secretary may order the developer, im-
19 porter, or any distributor of such in vitro clin-
20 ical test, or any combination of such persons, to
21 submit to him within a reasonable time a plan
22 for taking one or more of the actions described
23 in paragraph (2). An order issued under the
24 preceding sentence which is directed to more
25 than one person shall specify which person may

1 decide which action shall be taken under such
2 plan and the person specified shall be the per-
3 son who the Secretary determines bears the
4 principal, ultimate financial responsibility for
5 action taken under the plan unless the Sec-
6 retary cannot determine who bears such respon-
7 sibility or the Secretary determines that the
8 protection of the public health requires that
9 such decision be made by a person (including a
10 health professional or user of the in vitro clin-
11 ical test) other than the person the Secretary
12 determines bears such responsibility.

13 “(B) SECRETARY APPROVAL OF PLAN.—
14 The Secretary shall approve a plan submitted
15 pursuant to an order issued under subpara-
16 graph (A) unless the Secretary determines
17 (after affording opportunity for an informal
18 hearing) that the action or actions to be taken
19 under the plan or the manner in which such ac-
20 tion or actions are to be taken under the plan
21 will not assure that the unreasonable risk with
22 respect to which such order was issued will be
23 eliminated. If the Secretary disapproves a plan,
24 the Secretary shall order a revised plan to be
25 submitted within a reasonable time. If the Sec-

1 retary determines (after affording opportunity
2 for an informal hearing) that the revised plan
3 is unsatisfactory or if no revised plan or no ini-
4 tial plan has been submitted to the Secretary
5 within the prescribed time, the Secretary
6 shall—

7 “(i) prescribe a plan to be carried out
8 by the person or persons to whom the
9 order issued under subparagraph (A) was
10 directed; or

11 “(ii) after affording an opportunity
12 for an informal hearing, by order prescribe
13 a plan to be carried out by a person who
14 is a developer, importer, distributor, or re-
15 tailer of the in vitro clinical test with re-
16 spect to which the order was issued but to
17 whom the order under subparagraph (A)
18 was not directed.

19 “(2) ACTIONS ON A PLAN.—The actions that
20 may be taken under a plan submitted under an
21 order issued under paragraph (1)(A) are as follows:

22 “(A) To repair the in vitro clinical test so
23 that it does not present the unreasonable risk
24 of substantial harm with respect to which the
25 order under paragraph (1)(A) was issued.

1 “(B) To replace the in vitro clinical test
2 with a like or equivalent test which is in con-
3 formity with all applicable requirements of this
4 Act.

5 “(C) To refund the purchase price of the
6 in vitro clinical test (less a reasonable allowance
7 for use if such in vitro clinical test has been in
8 the possession of the user for one year or more
9 at the time of notice ordered under subsection
10 (a), or at the time the user receives actual no-
11 tice of the unreasonable risk with respect to
12 which the order was issued under paragraph
13 (1)(A), whichever occurs first).

14 “(3) NO CHARGE.—No charge shall be made to
15 any person (other than a developer, importer, dis-
16 tributor, or retailer) for using a remedy described in
17 paragraph (2) and provided under an order issued
18 under paragraph (1), and the person subject to the
19 order shall reimburse each person (other than a de-
20 veloper, manufacturer, importer, distributor, or re-
21 tailer) who is entitled to such a remedy for any rea-
22 sonable and foreseeable expenses actually incurred
23 by such person in using such remedy.

24 “(c) REIMBURSEMENT.—An order issued under sub-
25 section (b)(1)(A) with respect to an in vitro clinical test

1 may require any person who is a developer, importer, dis-
2 tributor, or retailer of the in vitro clinical test to reimburse
3 any other person who is a developer, importer, distributor,
4 or retailer of such in vitro clinical test for such other per-
5 son's expenses actually incurred in connection with car-
6 rying out the order if the Secretary determines such reim-
7 bursement is required for the protection of the public
8 health. Any such requirement shall not affect any rights
9 or obligations under any contract to which the person re-
10 ceiving reimbursement or the person making such reim-
11 bursement is a party.

12 “(d) RECALL AUTHORITY.—

13 “(1) IN GENERAL.—If the Secretary finds that
14 there is a reasonable probability that an in vitro
15 clinical test approved under section 587B or offered
16 under a technology certification order under section
17 587D would cause serious, adverse health con-
18 sequences or death, including by the absence, signifi-
19 cant delay, or discontinuation of appropriate medical
20 treatment, the Secretary shall issue an order requir-
21 ing the appropriate person (including the developers,
22 importers, distributors, or retailers of the in vitro
23 clinical test)—

24 “(A) to immediately cease distribution of
25 such in vitro clinical test; and

1 “(B) to immediately notify health profes-
2 sionals and applicable in vitro clinical test user
3 facilities of the order and to instruct such pro-
4 fessionals and facilities to cease use of such in
5 vitro clinical test.

6 “(2) INFORMAL HEARING.—The order issued
7 under paragraph (1)(A), shall provide the person
8 subject to the order with an opportunity for an in-
9 formal hearing, to be held not later than 10 calendar
10 days after the date of the issuance of the order, on
11 the actions required by the order and on whether the
12 order should be amended to require a recall of such
13 in vitro clinical test. If, after providing an oppor-
14 tunity for such a hearing, the Secretary determines
15 that inadequate grounds exist to support the actions
16 required by the order, the Secretary shall vacate the
17 order.

18 “(3) AMENDED ORDER.—

19 “(A) IN GENERAL.—If, after providing an
20 opportunity for an informal hearing under
21 paragraph (2), the Secretary determines that
22 the order should be amended to include a recall
23 of the in vitro clinical test with respect to which
24 the order was issued, the Secretary shall, except
25 as provided in subparagraph (B), amend the

1 order to require a recall. The Secretary shall
2 specify a timetable in which the recall will occur
3 and shall require periodic reports describing the
4 progress of the recall.

5 “(B) REQUIREMENTS.—An amended order
6 under subparagraph (A)—

7 “(i) shall not include recall of the in
8 vitro clinical test from individuals;

9 “(ii) shall not include recall of an in
10 vitro clinical test from test user facilities if
11 the Secretary determines that the risk of
12 recalling such in vitro clinical test from the
13 facilities presents a greater health risk
14 than the health risk of not recalling the in
15 vitro clinical test from use; and

16 “(iii) shall provide for notice to indi-
17 viduals subject to the risks associated with
18 the use of such in vitro clinical test. In
19 providing the notice required by this
20 clause, the Secretary may use the assist-
21 ance of health professionals who pre-
22 scribed, ordered, or used such an in vitro
23 clinical test for individuals.

1 “(4) CLARIFICATION.—The remedy provided by
2 this subsection shall be in addition to remedies pro-
3 vided by subsections (a), (b), and (c).

4 **“SEC. 587AA. APPLICABILITY.**

5 “(a) IN GENERAL.—An in vitro clinical test shall be
6 subject to the requirements of this subchapter, except as
7 otherwise provided in this subchapter. Laboratory oper-
8 ations shall not be subject to the requirements of this sub-
9 chapter.

10 “(b) INTERSTATE COMMERCE.—Any in vitro clinical
11 test that is offered, including by making available for clin-
12 ical use in the United States is deemed to be an act that
13 constitutes introduction into interstate commerce for pur-
14 poses of enforcing the requirements of this Act.

15 “(c) LEAST BURDENSOME REQUIREMENTS.—

16 “(1) IN GENERAL.—In carrying out this sub-
17 chapter, the Secretary shall consider the least bur-
18 densome means necessary to meet the applicable
19 standard, and other regulatory requirements, as de-
20 termined by the Secretary.

21 “(2) NECESSARY DEFINED.—For purposes of
22 paragraph (1), the term ‘necessary’ means the min-
23 imum required information that would support a de-
24 termination by the Secretary that the application

1 meet the applicable standard or regulatory require-
2 ment, as determined by the Secretary.

3 “(d) SERVICE OF ORDERS.—Orders of the Secretary
4 under this section with respect to applications under sub-
5 section (a) or (b) of section 587B or supplements under
6 subsection (f) of such section shall be served—

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

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

14 “(e) LABORATORIES AND BLOOD AND TISSUE ES-
15 TABLISHMENTS.—

16 “(1) RELATION TO LABORATORY CERTIFI-
17 CATION PURSUANT TO SECTION 353 OF THE PUBLIC
18 HEALTH SERVICE ACT.—Nothing in this subchapter
19 shall be construed to modify the authority of the
20 Secretary with respect to laboratories or clinical lab-
21 oratories under section 353 of the Public Health
22 Service Act.

23 “(2) AVOIDING DUPLICATION.—In imple-
24 menting this subchapter, the Secretary shall avoid
25 issuing or enforcing regulations or guidance that are

1 duplicative of regulations or guidance under section
2 353 of the Public Health Service Act such that lab-
3 oratories would be subject to conflicting regulatory
4 obligations with respect to the same activity.

5 “(3) BLOOD AND TISSUE.—Nothing in this sub-
6 chapter shall be construed to modify the authority of
7 the Secretary with respect to laboratories, establish-
8 ments, or other facilities to the extent they are en-
9 gaged in the propagation, manufacture, or prepara-
10 tion, including filling, labeling, packaging, and stor-
11 age, of blood, blood components, human cells, tis-
12 sues, or tissue products pursuant to any require-
13 ments under this Act or section 351 or 361 of the
14 Public Health Service Act.

15 “(f) NOT COMBINATION PRODUCT.—

16 “(1) IN GENERAL.—A product constituted of a
17 device and an in vitro clinical test is not a combina-
18 tion product and may be regulated as a device or as
19 a device and in vitro clinical test, notwithstanding
20 section 201(ss)(3).

21 “(2) GUIDANCE.—Not later than October 1,
22 2026, the Secretary shall issue final guidance, after
23 an opportunity for public comment, addressing the
24 considerations for regulating a product described in
25 paragraph (1). Such guidance shall take into ac-

1 count the least burdensome requirements under sub-
2 section (c).

3 “(g) PRACTICE OF MEDICINE.—Nothing in this sub-
4 chapter shall be construed to limit or interfere with the
5 authority of a health care practitioner to prescribe or ad-
6 minister any lawfully offered in vitro clinical test for any
7 condition or disease within a legitimate health care practi-
8 tioner-patient relationship pursuant to applicable Federal
9 or State law.

10 “(h) SALE, DISTRIBUTION, LABELING.—Nothing in
11 this section shall be construed to limit the authority of
12 the Secretary to establish or enforce restrictions on the
13 sale, distribution, or labeling of an in vitro clinical test
14 under this Act.

15 “(i) PROMOTION OF UNAPPROVED USES.—Nothing
16 in this section shall be construed to alter any prohibition
17 on the promotion of unapproved uses of legally offered in
18 vitro clinical tests.

19 “(j) VOLUNTARY SUBMISSIONS.—Nothing in section
20 587C shall be construed to prevent a developer developing
21 a test described in such section, including an academic
22 medical center laboratory described in subsection (a)(7)
23 of such section, from filing an application under section
24 587B or section 587D, or from adhering to the require-
25 ments of section 587K with regard to a test protocol de-

1 scribed in section 587K or for any other test or use of
2 a test.

3 **“SEC. 587BB. JUDICIAL REVIEW.**

4 “(a) IN GENERAL.—Not later than 30 days after an
5 order issued pursuant to sections 587B or 587D, any per-
6 son adversely affected by such order may file a petition
7 with the United States Court of Appeals for the District
8 of Columbia or for the circuit wherein such person resides
9 or has a principal place of business for judicial review of
10 such order, in accordance with the procedure set forth in
11 section 517(a).

12 “(b) APPLICATION OF PROVISIONS.—Subsections (a)
13 through (e) of section 517 shall apply with respect to a
14 petition under subsection (a) of this section in the same
15 manner such subsections apply to a petition under section
16 517. Subsection (f) of section 517 shall apply to an order
17 issued under section 587B or 587D.”

18 **SEC. 303. ENFORCEMENT AND OTHER PROVISIONS.**

19 (a) PROHIBITED ACTS.—Section 301 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
21 amended by division FF of Public Law 117–328, is fur-
22 ther amended—

23 (1) in paragraphs (a), (b), (c), (g), (h), (k), (q),
24 (r), and (y), by inserting “in vitro clinical test,”
25 after “device,” each place it appears;

1 (2) in paragraph (g), by inserting after “mis-
2 branded” the following: “, and the development
3 within any Territory of any in vitro clinical test that
4 is adulterated or misbranded”;

5 (3) in paragraph (y), by inserting “or 587Q”
6 after “section 523” each place it appears;

7 (4) in paragraph (ff), by striking “or device”
8 and inserting “, device, or in vitro clinical test”; and

9 (5) by adding at the end, the following:
10 “(jjj)(1) Forging, counterfeiting, simulating, or false-
11 ly representing, or without proper authority using any
12 mark, stamp, tag, label, or other identification upon any
13 in vitro clinical test or container, packaging, or labeling
14 thereof so as to render such in vitro clinical test a counter-
15 feit in vitro clinical test.

16 “(2) Making, selling, disposing of, or keeping in pos-
17 session, control, or custody, or concealing any punch, die,
18 plate, stone, or other thing designed to print, imprint, or
19 reproduce the trademark, trade name, or other identifying
20 mark or imprint of another or any likeness of any of the
21 foregoing upon any in vitro clinical test or container, pack-
22 aging, or labeling thereof so as to render such in vitro
23 clinical test a counterfeit in vitro clinical test.

24 “(3) The doing of any act which causes an in vitro
25 clinical test to be a counterfeit in vitro clinical test, or

1 the sale or dispensing, or the holding for sale or dis-
2 pensing, of a counterfeit in vitro clinical test.

3 “(kkk)(1) The introduction or delivery for introduc-
4 tion into interstate commerce of an in vitro clinical test
5 in violation of section 587A(a).

6 “(2) The making of a false, fraudulent, or deceptive
7 statement about an in vitro clinical test that is exempt
8 from premarket review under section 587C.

9 “(3) The failure to maintain complete and accurate
10 documentation for an exemption as required under section
11 587C or the failure to provide labeling required under sec-
12 tion 587L.

13 “(4) With respect to an in vitro clinical test, the sub-
14 mission of any application, report, or listing under this
15 Act that is false or misleading in any material respect.

16 “(5) The failure to comply with a condition of ap-
17 proval, or restriction required under an approved applica-
18 tion under section 587B; the failure to perform a risk
19 analysis required by section 587B; the failure to submit
20 an annual update required under section 587J(e)(2)(B);
21 or the failure to complete postmarket surveillance as re-
22 quired under section 587X.

23 “(6) The failure to comply with applicable require-
24 ments to submit an application or report under section
25 587D(e).

1 “(7) The failure to comply with applicable mitigating
2 measures established under section 587E or to submit,
3 maintain, or make available the documentation required
4 under section 587E(b); or the failure to comply with appli-
5 cable performance standards established under section
6 587R.

7 “(8) The failure to register in accordance with section
8 587J, the failure to provide information required under
9 section 587J(b), or the failure to maintain or submit infor-
10 mation required under section 587J(c).

11 “(9) The failure to comply with requirements under
12 section 587M or 587N, the failure to comply with a re-
13 striction required under section 587O, or the failure to
14 comply with labeling and advertising requirements under
15 section 587O(b).

16 “(10) The failure to comply with the requirements
17 of section 587Q.

18 “(11) The failure to comply with any requirement of
19 section 587S; the failure to furnish any notification, infor-
20 mation, material, or report required under section 587S;
21 or the failure to comply with an order issued under section
22 587S.

23 “(12) The failure to furnish information requested by
24 the Secretary under 587G(d)(2).”.

1 (b) PENALTIES.—Section 303 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

3 (1) in subsection (b)(8), by inserting “or coun-
4 terfeit in vitro clinical test” after “counterfeit drug”;

5 (2) in subsection (c)—

6 (A) by striking “; or (5)” and inserting “;
7 (5)”; and

8 (B) by inserting before the period at the
9 end the following: “; or (6) for having violated
10 section 301(fff)(2) if such person acted in good
11 faith and had no reason to believe that use of
12 the punch, die, plate, stone, or other thing in-
13 volved would result in an in vitro clinical test
14 being a counterfeit in vitro clinical test, or for
15 having violated section 301(fff)(3) if the person
16 doing the act or causing it to be done acted in
17 good faith and had no reason to believe that the
18 in vitro clinical test was a counterfeit in vitro
19 clinical test”; and

20 (3) in subsection (f)(1)—

21 (A) in subparagraph (A)—

22 (i) by inserting “or in vitro clinical
23 tests” after “which relates to devices”;

24 (ii) by inserting “or section
25 587Q(a)(1)” after “section 704(g)”; and

1 (iii) by inserting “or in vitro clinical
2 tests, as applicable” before the period at
3 the end of the second sentence; and

4 (B) in subparagraph (B)(i), by striking “or
5 520(f)” and inserting “, 520(f), 587K, or
6 587M,”.

7 (c) SEIZURE.—Section 304 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

9 (1) in subsection (a)(2)—

10 (A) by striking “, and (E)” and inserting
11 “, (E)”; and

12 (B) by inserting before the period at the
13 end the following: “, and (F) Any in vitro clin-
14 ical test that is a counterfeit in vitro clinical
15 test, (G) Any container, packaging, or labeling
16 of a counterfeit in vitro clinical test, and (H)
17 Any punch, die, plate, stone, labeling, container,
18 or other thing used or designed for use in mak-
19 ing a counterfeit in vitro clinical test”;

20 (2) in subsection (d)(1), by inserting “in vitro
21 clinical test,” after “device,”; and

22 (3) in subsection (g)—

23 (A) in paragraph (1), by inserting “, in
24 vitro clinical test,” after “device” each place it
25 appears; and

1 (B) in paragraph (2)—

2 (i) in subparagraph (A), by inserting

3 “, in vitro clinical test,” after “device”;

4 and

5 (ii) in subparagraph (B), by inserting

6 “or in vitro clinical test” after “device”

7 each place it appears.

8 (d) DEBARMENT, TEMPORARY DENIAL OF AP-
9 PROVAL, AND SUSPENSION.—Section 306 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
11 amended by adding at the end the following:

12 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-
13 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND
14 REVIEWS.—

15 “(1) IN GENERAL.—If the Secretary finds that
16 a person has been convicted of a felony for a viola-
17 tion of section 301(gg) or 301(fff)(1), the Secretary
18 shall debar such person from being accredited under
19 section 587Q and from carrying out activities under
20 an agreement described in section 803(b).

21 “(2) DEBARMENT PERIOD.—The Secretary
22 shall debar a person under paragraph (1) for the fol-
23 lowing periods:

24 “(A) The period of debarment of a person
25 (other than an individual) shall not be less than

1 1 year or more than 10 years, but if an act
2 leading to a subsequent debarment under such
3 paragraph occurs within 10 years after such
4 person has been debarred under such para-
5 graph, the period of debarment shall be perma-
6 nent.

7 “(B) The debarment of an individual shall
8 be permanent.

9 “(3) TERMINATION OF DEBARMENT; JUDICIAL
10 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),
11 (e), (i), (j), and (l)(1) apply with respect to a person
12 (other than an individual) or an individual who is
13 debarred under paragraph (1) to the same extent
14 and in the same manner as such subsections apply
15 with respect to a person who is debarred under sub-
16 section (a)(1), or an individual who is debarred
17 under subsection (a)(2), respectively.”.

18 (e) EXPANDED ACCESS TO UNAPPROVED THERAPIES
19 AND DIAGNOSTICS.—Section 561 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-
21 ed—

22 (1) in subsections (a) through (d)—

23 (A) by striking “or investigational devices”
24 each place it appears and inserting “, investiga-

1 tional devices, or investigational in vitro clinical
2 tests”; and

3 (B) by striking “or investigational device”
4 each place it appears (other than the second
5 such place in paragraph (3)(A)) of subsection
6 (c) and inserting “, investigational device, or
7 investigational in vitro clinical test”;

8 (2) in subsection (b)(4) by striking “or 520(g)”
9 each place it appears and inserting “, 520(g), or
10 587S”;

11 (3) in subsection (c)—

12 (A) by amending the subsection heading to
13 read: “TREATMENT INVESTIGATIONAL NEW
14 DRUG APPLICATIONS, TREATMENT INVESTIGA-
15 TIONAL DEVICE EXEMPTIONS, AND TREAT-
16 MENT INVESTIGATIONAL IN VITRO CLINICAL
17 TEST EXEMPTIONS.”;

18 (B) in paragraph (3)(A), by striking “or
19 investigational device exemption in effect under
20 section 520(g)” and inserting “, investigational
21 device exemption in effect under section 520(g),
22 or investigational in vitro clinical test exemption
23 under section 587S”;

24 (C) by striking “or treatment investiga-
25 tional device exemption” each place it appears

1 and inserting “, treatment investigational device
2 exemption, or treatment investigational in vitro
3 clinical test exemption”;

4 (D) in paragraph (5), by striking “or
5 520(g)” and inserting “, 520(g), or 587S”;

6 (E) in the matter following paragraph (7)
7 by striking “or 520(g)” each place it appears
8 and inserting “, 520(g), or 587S”;

9 (4) by amending subsection (e) to read as fol-
10 lows:

11 “(e) DEFINITIONS.—In this section, the terms ‘inves-
12 tigational drug’, ‘investigational device’, ‘investigational in
13 vitro clinical test’, ‘treatment investigational new drug ap-
14 plication’, ‘treatment investigational device exemption’,
15 and ‘treatment investigational in vitro clinical test exemp-
16 tion’ shall have the meanings given the terms in regula-
17 tions prescribed by the Secretary.”.

18 (f) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section
19 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 360bbb–8a(b)) is amended—

21 (1) by striking “subsection” each place it ap-
22 pears and inserting “paragraph”; and

23 (2) by inserting “an in vitro clinical test, as de-
24 fined in paragraph (ss) of such section,” before “or
25 a biological product”.

1 (g) PATIENT PARTICIPATION IN MEDICAL PRODUCT
2 DISCUSSION.—The heading of subsection (a) of section
3 569C of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 360bbb–8c) is amended by striking “DRUGS AND
5 DEVICES” and inserting “DRUGS, DEVICES, AND IN
6 VITRO CLINICAL TESTS”.

7 (h) REGULATIONS AND HEARINGS.—Clause (ii) of
8 section 701(h)(1)(C) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 371(h)(1)(C)) is amended—

10 (1) by inserting “and in vitro clinical tests”
11 after “devices”; and

12 (2) by moving the margin of such clause 2 ems
13 to the left.

14 (i) RECORDS.—Section 703 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

16 (1) by inserting “in vitro clinical tests,” after
17 “devices,” each place such term appears; and

18 (2) by inserting “in vitro clinical test,” after
19 “device,” each place such term appears.

20 (j) FACTORY INSPECTION.—Section 704 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other
22 than subsection (g)) is amended—

23 (1) by striking “drugs or devices” each place it
24 appears and inserting “drugs, devices, or in vitro
25 clinical tests”;

1 (2) in subsection (a)(1), in the fourth sentence,
2 by striking “or chapter IX” and inserting “section
3 587S, section 587M, section 587N, or chapter IX”;

4 (3) after making the amendments in para-
5 graphs (1) and (2), by inserting “in vitro clinical
6 tests,” after “devices,” each place it appears;

7 (4) in subsection (a)(2)(B)—

8 (A) by inserting “or in vitro clinical tests”
9 after “prescribe or use devices”; and

10 (B) by inserting “or in vitro clinical tests”
11 after “process devices”;

12 (5) by inserting “in vitro clinical test,” after
13 “device,” each place it appears;

14 (6) in subsection (e), by inserting “, or section
15 587M, 587N, or 587S,” after “section 519 or
16 520(g)”;

17 (7) in subsection (f)(3)—

18 (A) in subparagraph (A), by striking “or”
19 at the end;

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

22 (C) after subparagraph (B), by inserting
23 the following:

24 “(C) is accredited under section 587Q.”;

25 and

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

2 “(i) For purposes of this section, the term ‘establish-
3 ment’ includes a laboratory performing an in vitro clinical
4 test.”.

5 (k) PUBLICITY.—Section 705(b) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended
7 by inserting “in vitro clinical tests,” after “devices,”.

8 (l) PRESUMPTION.—Section 709 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by
10 inserting “in vitro clinical test,” after “device,”.

11 (m) LISTING AND CERTIFICATION OF COLOR ADDI-
12 TIVES FOR FOODS, DRUGS, AND COSMETICS.—Section
13 721(a) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 379e(a)) is amended—

15 (1) in the matter preceding paragraph (1), by
16 inserting “or in vitro clinical tests” after “or de-
17 vices”; and

18 (2) in the flush text following paragraph (2)—

19 (A) by inserting “or an in vitro clinical
20 test” after “a device”; and

21 (B) by inserting “or in vitro clinical tests”
22 after “devices”.

23 (n) IMPORTS AND EXPORTS.—Section 801 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
25 is amended—

1 (1) in subsection (a)—

2 (A) by inserting “in vitro clinical tests,”
3 after “devices,” each place it appears; and

4 (B) by inserting “in the case of an in vitro
5 clinical test, the test does not conform to the
6 applicable requirements of section 587K, or”
7 after “requirements of section 520(f), or”;

8 (2) in subsection (d)(3)—

9 (A) in subparagraph (A)—

10 (i) in the matter preceding clause (i),
11 by inserting “and no component of an in
12 vitro clinical test or other article of in vitro
13 clinical test that requires further proc-
14 essing,” after “health-related purposes”;

15 (ii) in clause (i), by striking “drug or
16 device” and inserting “drug, device, or in
17 vitro clinical test”; and

18 (iii) in clause (i)(I), by inserting “in
19 vitro clinical test,” after “device,”; and

20 (B) in subparagraph (B), by inserting “in
21 vitro clinical test,” after “device,”;

22 (3) in subsection (e)(1), by inserting “in vitro
23 clinical test,” after “device,”; and

24 (4) in subsection (o)—

1 (A) by inserting “or in vitro clinical test”
2 after “device”; and

3 (B) by inserting “, or under section 587J
4 of each foreign establishment,” after “section
5 510(i) of each establishment”.

6 (o) OFFICE OF INTERNATIONAL RELATIONS.—Sec-
7 tion 803 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 383) is amended—

9 (1) in subsection (b)—

10 (A) in the matter preceding paragraph (1),
11 by inserting “and in vitro clinical tests” after
12 “devices”; and

13 (B) in paragraph (1), by striking “, and”
14 and inserting “and quality requirements estab-
15 lished under section 587K; and”; and

16 (2) in subsection (c)—

17 (A) in paragraph (2), by inserting “in vitro
18 clinical tests,” after “devices,”; and

19 (B) in paragraph (4), by inserting “or in
20 vitro clinical tests” after “devices”.

21 (p) RECOGNITION OF FOREIGN GOVERNMENT IN-
22 SPECTIONS.—Section 809(a)(1) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-
24 ed by inserting “, or of foreign establishments registered
25 under section 587J,” after “510(h)”.

1 (q) FOOD AND DRUG ADMINISTRATION.—Section
2 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 393(b)(2)) is amended—

4 (1) in subparagraph (D), by striking “and” at
5 the end;

6 (2) in subparagraph (E), by striking the semi-
7 colon at the end and inserting “; and”; and

8 (3) by adding at the end the following:

9 “(F) in vitro clinical tests are analytically
10 and clinically valid;”.

11 (r) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 399b(b)) is amended—

14 (1) in paragraph (1), by inserting “in vitro clin-
15 ical tests,” after “devices,”; and

16 (2) in paragraph (4), by inserting “in vitro clin-
17 ical test developers,” after “device manufacturers,”.

18 (s) COUNTERMEASURE PROVISIONS OF THE PUBLIC
19 HEALTH SERVICE ACT.—Title III of the Public Health
20 Service Act is amended—

21 (1) in section 319F–1(a)(2)(A) (42 U.S.C.
22 247d–6a(a)(2)(A))—

23 (A) in the matter preceding clause (i)—

24 (i) by striking “or device” and insert-
25 ing “device”; and

1 (ii) by inserting “or an in vitro clin-
2 ical tests (as that term is defined in sec-
3 tion 201(ss) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 321(ss)),”
5 after “Act (21 U.S.C. 321(h)),”; and

6 (B) in each of clauses (ii) and (iii), by
7 striking “or device” and inserting “device, or in
8 vitro clinical test”;

9 (2) in section 319F–2(c)(1)(B) (42 U.S.C.
10 247d–6b(c)(1)(B))—

11 (A) by striking “or device” and inserting
12 “device”; and

13 (B) by inserting “, or an in vitro clinical
14 test (as that term is defined in section 201(ss)
15 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 321(ss))” after “Act (21 U.S.C.
17 321(h)),”; and

18 (3) in section 319F–3(i)(7) (42 U.S.C. 247d–
19 6d(i)(7))—

20 (A) in the matter preceding subparagraph

21 (A)—

22 (i) by striking “or device” and insert-
23 ing “device”; and

24 (ii) by inserting “or an in vitro clin-
25 ical tests (as that term is defined in sec-

1 tion 201(ss) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 321(ss)),”
3 after “Act (21 U.S.C. 321(h))”;

4 (B) in subparagraph (A)—

5 (i) by moving the margin of clause
6 (iii) 2 ems to the left; and

7 (ii) in clause (iii), by striking “or de-
8 vice” and inserting “device, or in vitro clin-
9 ical test”; and

10 (C) in subparagraph (B)—

11 (i) in clause (i), by striking “approved
12 or cleared” and inserting “approved,
13 cleared, or offered under a technology cer-
14 tification order”; and

15 (ii) in clause (ii), by striking “or
16 520(g)” and inserting “, 520(g), or 587S”.

17 **SEC. 304. TRANSITION.**

18 (a) IMPLEMENTATION.—

19 (1) EFFECTIVE DATE.—

20 (A) IN GENERAL.—Except as otherwise
21 provided in this section, the amendments made
22 by this Act shall take effect on October 1, 2028
23 (in this section and in subchapter J of chapter
24 V of the Federal Food, Drug, and Cosmetic

1 Act, as added by this Act, referred to in this
2 section as the “effective date of this Act”).

3 (B) EXCEPTIONS.—

4 (i) IN GENERAL.—The Secretary of
5 Health and Human Services (in this sec-
6 tion referred to as the “Secretary”) may
7 take the actions described in paragraph
8 (2), and may expend such funds as the
9 Secretary determines necessary to ensure
10 an orderly transition prior to the effective
11 date of this Act.

12 (ii) IMPLEMENTATION OF CERTAIN
13 PROVISIONS.—The Secretary may imple-
14 ment sections 587J and 587U of the Fed-
15 eral Food, Drug, and Cosmetic Act (as
16 added by section 3) beginning on October
17 1, 2024, and such sections may take effect
18 not earlier than October 1, 2028, to the
19 extent and for the purposes indicated in
20 such sections. In the case of a developer
21 who, between October 1, 2024, and the ef-
22 fective date of this Act, registers under
23 such section 587J with respect to an arti-
24 cle that is an in vitro clinical test, such de-
25 veloper shall not be required to register

1 with respect to such article under section
2 510 of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360).

4 (2) ACTIONS.—The Secretary—

5 (A) shall—

6 (i) within 1 year of the date of enact-
7 ment of this Act, hold the public meetings
8 described in section 587D(i) of the Federal
9 Food, Drug, and Cosmetic Act (as added
10 by section 3); and

11 (ii) within 3 years of the date of en-
12 actment of this Act, promulgate final regu-
13 lations required under the amendments
14 made by this Act; and

15 (B) may take additional actions after the
16 date of enactment that the Secretary deter-
17 mines necessary to ensure an orderly transition,
18 including—

19 (i) establishment of mitigating meas-
20 ures for an in vitro clinical test or category
21 of in vitro clinical tests, which may not
22 take effect until after the effective date de-
23 scribed in paragraph (1)(A); and

24 (ii) establishment of the comprehen-
25 sive test information system under section

1 587T of the Federal Food, Drug, and Cos-
2 metic Act, as added by section 3.

3 (3) APPLICABILITY OF GUIDANCE AND REGULA-
4 TIONS.—Notwithstanding the date on which guid-
5 ance or regulations are issued under paragraph (2)
6 and section 587K of the Federal Food, Drug, and
7 Cosmetic Act, as added by section 3, no guidance or
8 regulations issued pursuant to the amendments
9 made by this Act shall be implemented or take effect
10 until the effective date of this Act, except as other-
11 wise specified in this Act (including the amendments
12 made by this Act).

13 (4) IMPLEMENTATION REQUIREMENTS.—In the
14 event that the Secretary fails to promulgate the reg-
15 ulations required under section 587B(a)(4),
16 587D(j), or 587S(b)(1) of the Federal Food, Drug,
17 and Cosmetic Act, as added by section 3, by the
18 deadline described in subsection (a)(2)(A)(ii), the
19 Secretary shall, within 15 days of such missed dead-
20 line—

21 (A) submit a report to the Committee on
22 Health, Education, Labor, and Pensions of the
23 Senate and the Committee on Energy and Com-
24 merce of the House of Representatives pro-

1 viding information related to the status of such
2 regulations, including—

3 (i) a rationale for missing the applica-
4 ble deadline described in such subsection;

5 (ii) a description of actions taken to
6 the date of submission of the report to pro-
7 mulgate each such regulations;

8 (iii) the expected timeline for promul-
9 gating each such regulations;

10 (iv) an assessment of the impact of
11 the delay in promulgating such regulations
12 on developers of in vitro clinical tests, in-
13 cluding an economic assessment; and

14 (v) an assessment of the impact of the
15 delay in promulgating such regulations on
16 patients; and

17 (B) open a public docket for purposes of
18 soliciting public comments on the impact of the
19 delay in promulgating such regulations.

20 (b) APPLICATION OF AUTHORITIES TO IN VITRO
21 CLINICAL TESTS UNDER REVIEW ON THE EFFECTIVE
22 DATE OF THIS ACT.—For any in vitro clinical test for
23 which a submission for approval under section 515 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e),
25 clearance under section 510(k) of such Act (21 U.S.C.

1 360(k)), authorization under section 513(f)(2) of such Act
2 (21 U.S.C. 360c(f)(2)), or licensure under section 351 of
3 the Public Health Service Act (42 U.S.C. 262) is pending
4 on the effective date of this Act, including transitional in
5 vitro clinical tests as described in subsection (c), the Sec-
6 retary may review and take action on such submission
7 after the effective date of this Act according to the statu-
8 tory provision under which such submission was sub-
9 mitted.

10 (c) APPLICATION OF AUTHORITIES TO TRANSI-
11 TIONAL IN VITRO CLINICAL TESTS.—

12 (1) DEFINITION.—For purposes of this section,
13 the term “transitional in vitro clinical test” means
14 an in vitro clinical test that—

15 (A)(i) is first offered for clinical use during
16 the period beginning on the date that is 45
17 days after the date of enactment of this Act
18 and ending on the effective date of this Act; or

19 (ii) is offered solely for investigational use
20 during the period beginning on the date of en-
21 actment of this Act and ending on the effective
22 date of this Act;

23 (B) is developed by a clinical laboratory
24 certified by the Secretary under section 353 of
25 the Public Health Service Act (42 U.S.C. 263a)

1 that meets the requirements for performing
2 high-complexity testing and performed—

3 (i) in the same clinical laboratory in
4 which the test was developed and for which
5 a certification is still in effect under such
6 section 353 that meets the requirements to
7 perform tests of high complexity;

8 (ii) by another laboratory for which a
9 certificate is in effect under such section
10 353 that meets the requirements to per-
11 form tests of high complexity, is within the
12 same corporate organization, and has com-
13 mon ownership by the same parent cor-
14 poration as the laboratory in which the
15 test was developed; or

16 (iii) in the case of a test that was de-
17 veloped by the Centers for Disease Control
18 and Prevention or another laboratory in a
19 public health laboratory network coordi-
20 nated or managed by the Centers for Dis-
21 ease Control and Prevention, by a clinical
22 laboratory for which a certificate is in ef-
23 fect under such section 353 that meets the
24 requirements to perform tests of high com-
25 plexity, and that is within a public health

1 laboratory network coordinated or man-
2 aged by the Centers for Disease Control
3 and Prevention; and

4 (C) when first offered, is not approved
5 under section 515 of the Federal Food, Drug,
6 and Cosmetic Act, cleared under section 510(k)
7 of such Act, authorized under section 513(f)(2)
8 of such Act, subject to a humanitarian device
9 exemption under section 520(m) of such Act
10 (21 U.S.C. 360j(m)), subject to an exemption
11 for investigation use under section 520(g) of
12 such Act (21 U.S.C. 360j(g)), authorized under
13 section 564 of such Act (21 U.S.C. 360bbb-3),
14 or licensed under section 351 of the Public
15 Health Service Act (42 U.S.C. 262).

16 (2) PREMARKET REVIEW OR TECHNOLOGY CER-
17 TIFICATION.—A transitional in vitro clinical test
18 that is not exempt from premarket review under sec-
19 tion 587C of the Federal Food, Drug, and Cosmetic
20 Act, as added by section 3, may continue to be of-
21 fered, sold, or distributed, as applicable, without
22 marketing authorization until completion of the Sec-
23 retary’s review of the premarket application or tech-
24 nology certification application under section 587B
25 or 587D, as applicable, if—

1 (A) such in vitro clinical test is a high-risk
2 test (as defined in section 587 of the Federal
3 Food, Drug, and Cosmetic Act, as added by
4 section 3) and the application for such test is
5 submitted not later than 90 days after the ef-
6 fective date of this Act; or

7 (B) such in vitro clinical test is a mod-
8 erate-risk test (as defined in such section 587),
9 the developer lists the test in accordance with
10 section 587J within 10 calendar days of the ef-
11 fective date of this subchapter, and the applica-
12 tion for such test is submitted not later than 1
13 year after the effective date of this Act.

14 (3) INVESTIGATIONAL USE REQUEST.—A tran-
15 sitional in vitro clinical test described in paragraph
16 (1)(A)(ii) that is used in a significant risk investiga-
17 tion may continue to be offered for investigational
18 use until completion of the Secretary's review of an
19 application under 587S, if such application is sub-
20 mitted not later than 90 days after the effective date
21 of this Act.

22 (4) TESTS APPROVED BY NEW YORK STATE.—
23 Notwithstanding paragraph (2), a transitional in
24 vitro clinical test that has been approved by the New
25 York State Department of Health may continue to

1 be offered, sold, or distributed, as applicable, after
2 the effective date if—

3 (A) starting on the effective date of this
4 Act, the in vitro clinical test complies with the
5 requirements of subchapter J of the Federal
6 Food, Drug, and Cosmetic Act, as added by
7 this Act, except for section 587B of the Federal
8 Food, Drug, and Cosmetic Act, as added by
9 section 3, and design control provisions of sec-
10 tion 587K of such Act;

11 (B) each test report for the test bears a
12 statement of adequate prominence that reads as
13 follows: “This in vitro clinical test was devel-
14 oped and first introduced prior to the effective
15 date of the VALID Act of 2023. This test was
16 approved by the New York State Department of
17 Health, but the test has not been reviewed by
18 the Food and Drug Administration.”;

19 (C) a premarket application under section
20 587B of the Federal Food, Drug, and Cosmetic
21 Act, as added by section 3, or technology cer-
22 tification application under section 587D of
23 such Act, as added by section 3, is submitted
24 no later than—

1 (i) 5 years after the effective date of
2 this Act, if the in vitro clinical test is ap-
3 proved by the New York State Department
4 of Health as a genetic testing molecular
5 test, a microbiology molecular test, an on-
6 cology molecular test, or any other type of
7 molecular test; or

8 (ii) 2 years after the effective date of
9 this Act, if the in vitro clinical test is ap-
10 proved by the New York State Department
11 of Health as a type of test not described
12 in clause (i); and

13 (D) a test in compliance with this para-
14 graph may continue to be offered, sold, or dis-
15 tributed, as applicable, until the completion of
16 the Secretary's review of the premarket applica-
17 tion or technology certification application de-
18 scribed in subparagraph (C).

19 (d) CONVERSION.—

20 (1) DEEMED PREMARKET APPROVAL.—Begin-
21 ning on the effective date of this Act—

22 (A) any in vitro clinical test with a pre-
23 market approval under section 515 of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C.
25 360e) or a licensure under section 351 of the

1 Public Health Service Act (42 U.S.C. 262) is
2 deemed to be approved pursuant to an applica-
3 tion under section 587B(a) of the Federal
4 Food, Drug, and Cosmetic Act, as added by
5 this Act; and

6 (B) any in vitro clinical test (as so defined)
7 that was cleared under section 510(k) of the
8 Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 360(k)) or authorized under section
10 513(f)(2) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 360c(f)(2)) is deemed to
12 be approved pursuant to an application under
13 section 587B(b) of the Federal Food, Drug,
14 and Cosmetic Act, as added by this Act.

15 (2) DEEMED INVESTIGATIONAL USE EXEMP-
16 TION.—Any in vitro clinical test that has an inves-
17 tigational device exemption in effect under section
18 520(g) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 360j(g)) is deemed to have an investiga-
20 tional use exemption in effect under section 587S of
21 such Act, as added by this Act, beginning on the ef-
22 fective date of this Act.

23 (3) DEEMED HUMANITARIAN DEVICE EXEMP-
24 TION.—Any in vitro clinical test that has an ap-
25 proved humanitarian device exemption under section

1 520(m) of such Act is deemed to have a humani-
2 tarian test exemption under section 587A(g) of such
3 Act, as added by this Act, beginning on the effective
4 date of this Act.

5 (4) DEEMED DESIGNATED BREAKTHROUGH.—
6 Any in vitro clinical test that has received a break-
7 through device designation under section
8 515B(e)(1)(D) of such Act (21 U.S.C. 360e-
9 3(e)(1)(D)) is deemed to have a breakthrough in
10 vitro clinical test designation under section 587C of
11 such Act, as added by this Act, beginning on the ef-
12 fective date of this Act.

13 (5) DEEMED REQUEST FOR INFORMAL FEED-
14 BACK.—With regard to any in vitro clinical test that
15 is the subject of a pre-submission request described
16 in the guidance, “Requests for Feedback and Meet-
17 ings for Medical Device Submissions: The Q-Sub-
18 mission Program”, issued by the Food and Drug
19 Administration on January 6, 2021, such request is
20 deemed to constitute a request for informal feedback
21 under section 587F of the Federal Food, Drug, and
22 Cosmetic Act, as added by section 3, beginning on
23 the effective date of this Act.

24 (e) PREVIOUSLY CLASSIFIED DEVICES.—Notwith-
25 standing section 587 of the Federal Food, Drug, and Cos-

1 metric Act, as added by section 3, for purposes of sub-
2 chapter J of chapter V of such Act, as added by section
3 3, the following apply:

4 (1) In the case of an in vitro clinical test type
5 that has been classified by the Secretary as a class
6 I device pursuant to section 513 of such Act (21
7 U.S.C. 360c), such in vitro clinical test shall be low-
8 risk, unless the in vitro clinical test is a test de-
9 scribed in the second sentence of section 510(l)(1) of
10 such Act or the test is redesignated by the Secretary
11 pursuant to section 587F of such Act.

12 (2) In the case of an in vitro clinical test type
13 that has been classified by the Secretary as a class
14 II device pursuant to section 513 of such Act (21
15 U.S.C. 360c), such in vitro clinical test shall be
16 moderate-risk, unless inaccurate results from the
17 test would be immediately life threatening or the test
18 is redesignated by the Secretary pursuant to section
19 587F of such Act.

20 (3) In the case of an in vitro clinical test type
21 that has been classified by the Secretary as a class
22 III device pursuant to section 513 of such Act (21
23 U.S.C. 360c) or an in vitro clinical test licensed pur-
24 suant to section 351 of the Public Health Service
25 Act (42 U.S.C. 262), such in vitro clinical test shall

1 be high-risk, unless redesignated by the Secretary
2 pursuant to section 587F of the Federal Food,
3 Drug, and Cosmetic Act.

4 **SEC. 305. EMERGENCY USE AUTHORIZATION.**

5 (a) IN GENERAL.—Section 564 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-
7 ed—

8 (1) by inserting “or developer” after “manufac-
9 turer”, each place such term appears;

10 (2) in subsection (a)—

11 (A) in paragraphs (1) and (4)(C), by in-
12 serting “in vitro clinical test,” before “or bio-
13 logical product” each place such term appears;

14 (B) in paragraph (2)(A), by striking “or
15 515” and inserting “515, or 587B”; and

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

17 “(F) The terms ‘develop’ and ‘developer’,
18 with respect to an in vitro clinical test, have the
19 meanings given such terms in section 587.”;

20 (3) in subsection (b), by inserting “or devel-
21 oper” after “manufacturer” each place such term
22 appears;

23 (4) in subsection (e)—

24 (A) by inserting “or developers” after
25 “manufacturers” each place such term appears;

1 (B) in paragraph (2)(B)(ii), by inserting
2 “or develop” after “not manufacture”;

3 (C) in paragraph (3)—

4 (i) in subparagraph (A), by striking
5 “or 520(f)(1)” and inserting “, 520(f)(1),
6 or 587V”;

7 (ii) in subparagraph (B), by striking
8 “and” at the end;

9 (iii) in subparagraph (C), by striking
10 the period and inserting “ or 587O; and”;
11 and

12 (iv) by adding at the end the fol-
13 lowing:

14 “(D) quality requirements (with respect to
15 in vitro clinical tests) under section 587K.”;
16 and

17 (D) in paragraph (4)—

18 (i) in subparagraph (A), by striking “;
19 or” and inserting a semicolon;

20 (ii) in subparagraph (B), by striking
21 the period and inserting “; or”; and

22 (iii) by adding at the end the fol-
23 lowing:

1 “(C) with respect to in vitro clinical tests,
2 requirements applicable to restricted in vitro
3 clinical tests pursuant to section 587O.”;

4 (5) in subsection (k), by striking “or 520(g)”
5 and inserting “520(g), or 587S”; and

6 (6) in subsection (m)—

7 (A) in the subsection heading, by striking
8 “LABORATORY TESTS ASSOCIATED WITH DE-
9 VICES” inserting “IN VITRO CLINICAL TESTS”
10 after “DEVICES”; and

11 (B) in paragraph (1)—

12 (i) by striking “to a device” and in-
13 serting “to an in vitro clinical test”; and

14 (ii) by striking “such device” and in-
15 serting “such in vitro clinical test”.

16 (b) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-
17 tion 564A of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360bbb–3a) is amended—

19 (1) in subsection (a)—

20 (A) in paragraph (2), by inserting “in vitro
21 clinical test,” after “device,”; and

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

23 “(3) DEVELOPER.—The term ‘developer’, with
24 respect to an in vitro clinical test, has the meaning
25 given such term in section 587.”;

1 (2) by inserting “or developer” after “manufac-
2 turer” each place it appears; and

3 (3) in subsection (c)(1)—

4 (A) by inserting “or quality requirements”
5 after “good manufacturing practice require-
6 ments”; and

7 (B) by striking “or 520(f)(1)” and insert-
8 ing “, 520(f)(1), or 587K”.

9 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
10 tion 564B(2) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360bbb–3b(2)) is amended—

12 (1) in subparagraph (A), by striking “or 515”
13 and inserting “515, or 587B”; and

14 (2) in subparagraph (B), by striking “or 520”
15 and inserting 520, or 587S.

16 **SEC. 306. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

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

19 (1) in subsection (a)(1)(C)—

20 (A) by striking “clear under section
21 510(k), classify under section 513(f)(2), or ap-
22 prove under section 515” and inserting “ap-
23 prove under section 587B, exempt from pre-
24 market review under section 587C, or grant a

1 technology certification order under section
2 587D”; and

3 (B) by striking “testing devices” and in-
4 serting “in vitro clinical tests”;

5 (2) in subsection (c)(5)—

6 (A) by striking “drug or device” and in-
7 serting “drug, device, or in vitro clinical test”;

8 and

9 (B) by striking “the drug or the device”
10 and inserting “the drug, device, or in vitro clin-
11 ical test”;

12 (3) in subsection (e)—

13 (A) in the heading, by striking “TESTING
14 DEVICES” and inserting “IN VITRO CLINICAL
15 TESTS”;

16 (B) in paragraph (1)—

17 (i) by striking “510, 513, and 515,”
18 and inserting “587B, and 587D”;

19 (ii) by striking “antimicrobial suscep-
20 tibility testing device” and inserting “anti-
21 microbial susceptibility in vitro clinical
22 test”; and

23 (iii) by striking “such device” and in-
24 serting “such in vitro clinical test”; and

25 (C) in paragraph (2)—

1 (i) in the heading, by striking “TEST-
2 ING DEVICES” and inserting “IN VITRO
3 CLINICAL TESTS”;

4 (ii) in subparagraphs (A) and (B)
5 (other than clause (iii) of such subpara-
6 graph (B)), by striking “device” each place
7 it appears and inserting “in vitro clinical
8 test”;

9 (iii) in subparagraph (B)(iii), by strik-
10 ing “a device” and inserting “an in vitro
11 clinical test”; and

12 (iv) by amending subparagraph (C) to
13 read as follows:

14 “(C) The antimicrobial susceptibility in
15 vitro clinical test meets all other requirements
16 to be approved under section 587B, to be ex-
17 empted from premarket review under section
18 587C, or to be offered under a technology cer-
19 tification order under section 587D.”;

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

22 “(1) The term ‘antimicrobial susceptibility in
23 vitro clinical test’ means an in vitro clinical test that
24 utilizes susceptibility test interpretive criteria to de-

1 termine and report the in vitro susceptibility of cer-
2 tain microorganisms to a drug (or drugs).”; and

3 (5) in subsection (g)(2)—

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

6 “(2) with respect to approving an application
7 under section 587B or granting a technology certifi-
8 cation order under section 587D—”; and

9 (B) in subparagraph (A)—

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

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

16 **SEC. 307. COMBINATION PRODUCTS.**

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

20 (1) in paragraph (1)—

21 (A) in subparagraph (A), by striking “or
22 biological product” and inserting “in vitro clin-
23 ical test (except for a product constituted of a
24 device and an in vitro clinical test), or biological
25 product”;

1 (B) in subparagraph (B), by adding at the
2 end the following: “For purposes of this Act, a
3 product that constitutes a combination of a de-
4 vice and an in vitro clinical test is not a com-
5 bination product within the meaning of this
6 subsection and an in vitro clinical test that is
7 offered as a separate product intended to in-
8 form the use of a drug, biological product, or
9 device is not a combination product within the
10 meaning of this subsection.”; and

11 (C) in subparagraph (D)(ii)—

12 (i) by inserting “or in vitro clinical
13 test” after “device”; and

14 (ii) by inserting “and in vitro clinical
15 tests” before “shall”;

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

21 (3) in paragraph (4)—

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

1 mitted in accordance with paragraph (5)),
2 587B, or 587D”; and

3 (B) in subparagraph (C), by striking “or
4 515” and inserting “515, or 587B, or that is
5 under an order under section 587D”;

6 (4) in paragraph (5)(A), by striking “or
7 510(k)” and inserting “, 510(k), 587B, or 587D”;

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

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

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

16 (7) in paragraph (9)—

17 (A) in subparagraph (C)(i), by striking “or
18 520(g)” and inserting “520(g), 587B, or
19 587D”; and

20 (B) in subparagraph (D), by striking “or
21 520” and inserting “520, 587B, or 587D”.

22 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 360bbb–2) is amended by adding at the end the following:

1 “(d) EXEMPTION.—This section shall not apply to a
2 product constituted of only a device and an in vitro clinical
3 test.”.

4 **SEC. 308. RESOURCES.**

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

12 (b) ESTABLISHMENT OF USER FEE PROGRAM.—

13 (1) DEVELOPMENT OF USER FEES FOR IN
14 VITRO CLINICAL TESTS.—

15 (A) IN GENERAL.—Beginning not later
16 than October 1, 2025, the Secretary of Health
17 and Human Services (in this section referred to
18 as the “Secretary”) shall initiate the develop-
19 ment of recommendations in accordance with
20 this section to present to Congress with respect
21 to the goals, and plans for meeting the goals,
22 for the process for the review of in vitro clinical
23 test submissions and applications under sub-
24 chapter J of chapter V of the Federal Food,
25 Drug, and Cosmetic Act, as added by this Act,

1 for the first 4 fiscal years after fiscal year 2028
2 and for the authorization of the In Vitro Clin-
3 ical Test User Fee Program for such fiscal
4 years. In developing such recommendations, the
5 Secretary shall consult with—

6 (i) the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate;

8 (ii) the Committee on Energy and
9 Commerce of the House of Representa-
10 tives;

11 (iii) scientific and academic experts;

12 (iv) health care professionals;

13 (v) representatives of patient and con-
14 sumer advocacy groups; and

15 (vi) the regulated industry.

16 (B) PRIOR PUBLIC INPUT.—Prior to begin-
17 ning negotiations with the regulated industry
18 on the authorization of the In Vitro Clinical
19 Test User Fee Program, as described in this
20 section, the Secretary shall—

21 (i) publish a notice in the Federal
22 Register requesting public input on the au-
23 thorization of user fees;

24 (ii) hold a public meeting at which the
25 public may present its views on the author-

1 ization, including specific suggestions for
2 the recommendations submitted under sub-
3 paragraph (E);

4 (iii) provide a period of 30 days after
5 the public meeting to obtain written com-
6 ments from the public suggesting changes
7 to the In Vitro Clinical Test User Fee Pro-
8 gram; and

9 (iv) publish any comments received
10 under clause (iii) on the website of the
11 Food and Drug Administration.

12 (C) PERIODIC CONSULTATION.—Not less
13 frequently than once every month during nego-
14 tiations with the regulated industry, the Sec-
15 retary shall hold discussions with representa-
16 tives of patient and consumer advocacy groups
17 to continue discussions of the authorization of
18 the In Vitro Clinical Test User Fee Program
19 and to solicit suggestions to be included in the
20 recommendations transmitted to Congress
21 under subparagraph (F).

22 (D) UPDATES TO CONGRESS.—The Sec-
23 retary, in consultation with regulated industry,
24 shall provide regular updates on negotiations on
25 the reauthorization of the In Vitro Clinical Test

1 User Fee Program to the Committee on Health,
2 Education, Labor, and Pensions of the Senate
3 and the Committee on Energy and Commerce
4 of the House of Representatives.

5 (E) PUBLIC REVIEW OF RECOMMENDA-
6 TIONS.—After negotiations with the regulated
7 industry, the Secretary shall—

8 (i) present the recommendations de-
9 veloped under subparagraph (A) to the
10 Committee on Health, Education, Labor,
11 and Pensions of the Senate and the Com-
12 mittee on Energy and Commerce of the
13 House of Representatives;

14 (ii) publish such recommendations in
15 the Federal Register;

16 (iii) provide for a period of 30 days
17 for the public to provide written comments
18 on such recommendations;

19 (iv) hold a meeting at which the pub-
20 lic may present its views on such rec-
21 ommendations; and

22 (v) after consideration of such public
23 views and comments, revise such rec-
24 ommendations as necessary.

1 (F) TRANSMITTAL OF RECOMMENDA-
2 TIONS.—

3 (i) IN GENERAL.—Not later than Jan-
4 uary 15, 2027, the Secretary shall trans-
5 mit to Congress the revised recommenda-
6 tions under subparagraph (A), a summary
7 of the views and comments received under
8 such subparagraph, and any changes made
9 to the recommendations in response to
10 such views and comments.

11 (ii) RECOMMENDATION REQUIRE-
12 MENTS.—The recommendations trans-
13 mitted under this subparagraph shall—

14 (I) include the number of full-
15 time equivalent employees per fiscal
16 year that are agreed to be hired to
17 carry out the goals included in such
18 recommendations for each year of the
19 5-year period;

20 (II) provide that the amount of
21 operating reserve balance in the user
22 fee program established under this
23 section is not more than the equiva-
24 lent of 10 weeks of operating reserve;

1 (III) require the development of
2 a strategic plan for any surplus within
3 the operating reserve account above
4 the 10-week operating reserve within
5 2 years of the establishment of the
6 program;

7 (IV) include an operating reserve
8 adjustment such that, if the Secretary
9 has an operating reserve balance in
10 excess of 10 weeks of such operating
11 reserves, the Secretary shall decrease
12 such fee revenue and fees to provide
13 for not more than 10 weeks of such
14 operating reserves;

15 (V) if an adjustment is made as
16 described in subclause (IV), provide
17 the rationale for the amount of the
18 decrease in fee revenue and fees shall
19 be contained in the Federal Register;
20 and

21 (VI) provide that the fees as-
22 sessed and collected for the full-time
23 equivalent employees at the Center for
24 Devices and Radiological Health, with
25 respect to which the majority of time

1 reporting data indicates are dedicated
2 to the process for the review of in
3 vitro clinical test submissions and ap-
4 plications under paragraph (5), are
5 not supported by the funds authorized
6 to be collected and assessed under sec-
7 tion 738 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 379j).

9 (G) PUBLICATION OF RECOMMENDA-
10 TIONS.—The Secretary shall publish on the
11 website of the Food and Drug Administration
12 the revised recommendations under subpara-
13 graph (F), a summary of the recommendations,
14 views, and comments received under subpara-
15 graphs (B), (C), and (E), and any changes
16 made to the recommendations originally pro-
17 posed by the Secretary in response to such rec-
18 ommendations, views, and comments.

19 (H) MINUTES OF NEGOTIATION MEET-
20 INGS.—

21 (i) PUBLIC AVAILABILITY.—The Sec-
22 retary shall make publicly available, on the
23 website of the Food and Drug Administra-
24 tion, minutes of all negotiation meetings
25 conducted under this subsection between

1 the Food and Drug Administration and the
2 regulated industry not later than 30 days
3 after such meeting.

4 (ii) CONTENT.—The minutes de-
5 scribed under clause (i) shall summarize
6 any substantive proposal made by any
7 party to the negotiations, any significant
8 controversies or differences of opinion dur-
9 ing the negotiations, and the resolution of
10 any such controversy or difference of opin-
11 ion.

12 (2) ESTABLISHMENT OF USER FEE PRO-
13 GRAM.—Effective on October 1, 2028, provided that
14 the Secretary transmits the recommendations under
15 paragraph (1)(F), the Secretary is authorized to col-
16 lect user fees relating to the review of in vitro clin-
17 ical test submissions and applications submitted
18 under subchapter J of chapter V of the Federal
19 Food, Drug, and Cosmetic Act, as added by this
20 Act, and any other activities or goals included in rec-
21 ommendations transmitted to Congress pursuant to
22 this subsection. Fees under such program shall be
23 assessed and collected only if the requirements under
24 paragraph (4) are met.

25 (3) AUDIT.—

1 (A) IN GENERAL.—Beginning 2 years after
2 first receiving a user fee applicable to submis-
3 sion of an in vitro clinical test application sub-
4 mitted under subchapter J of chapter V of the
5 Federal Food, Drug, and Cosmetic Act, as
6 added by this Act, the Secretary shall, on a bi-
7 ennial basis, perform an audit of the costs of
8 reviewing such applications and any other ac-
9 tivities under such subchapter J included in
10 recommendations transmitted to Congress pur-
11 suant to this subsection. Such an audit shall
12 compare the costs of reviewing such applica-
13 tions and other activities under such subchapter
14 J to the amount of the user fee applicable to
15 such applications and make any necessary ad-
16 justments as described in subparagraph (B).

17 (B) ALTERATION OF USER FEE.—The fol-
18 lowing adjustments shall apply with respect to
19 audits performed under subparagraph (A):

20 (i) If the audit performed 2 years
21 after first receiving a user fee applicable to
22 submission of an in vitro clinical test appli-
23 cation described under subparagraph (A)
24 indicates that the user fees collected for
25 purposes of such subchapter J exceed 33

1 percent of the costs of reviewing such ap-
2 plications and carrying out activities in-
3 cluded in recommendations transmitted to
4 Congress pursuant to this subsection, the
5 Secretary shall alter the user fees applica-
6 ble to applications submitted under such
7 subchapter J such that the user fees do
8 not exceed such percentage.

9 (ii) If the audit performed 6 years
10 after first receiving a user fee applicable to
11 submission of an in vitro clinical test appli-
12 cation described under subparagraph (A)
13 indicates that the user fees collected for
14 purposes of such subchapter J exceed 40
15 percent of the costs of reviewing such ap-
16 plications, and carrying out activities in-
17 cluded in recommendations transmitted to
18 Congress pursuant to this subsection, the
19 Secretary shall alter the user fees applica-
20 ble to applications submitted under such
21 subchapter J such that the user fees do
22 not exceed such percentage.

23 (iii) If the audit performed 12 years
24 after first receiving a user fee applicable to
25 submission of an in vitro clinical test appli-

1 cation described under subparagraph (A),
2 and any audit performed after such date,
3 indicates that the user fees collected for
4 purposes of such subchapter J exceed 49
5 percent of the costs of reviewing such ap-
6 plications, and carrying out activities in-
7 cluded in recommendations transmitted to
8 Congress pursuant to this subsection, the
9 Secretary shall alter the user fees applica-
10 ble to applications submitted under such
11 subchapter J such that the user fees do
12 not exceed such percentage.

13 (C) ACCOUNTING STANDARDS.—The Sec-
14 retary shall perform an audit under subpara-
15 graph (A) in conformance with the accounting
16 principles, standards, and requirements pre-
17 scribed by the Comptroller General of the
18 United States under section 3511 of title 31,
19 United States Code, to ensure the validity of
20 any potential variability.

21 (D) IMPLEMENTATION REQUIREMENTS.—
22 In the event that the Secretary fails to promul-
23 gate the regulations described in sections
24 587B(a)(4), 587D(j), or 587S(b)(1) of the Fed-
25 eral Food, Drug, and Cosmetic Act, as added

1 by section 3, by the applicable deadline for each
2 such regulations as described in section
3 5(a)(2)(A)(ii), the Secretary shall provide that
4 the user fees applicable to applications sub-
5 mitted under subchapter J of chapter V of the
6 Federal Food, Drug, and Cosmetic Act, as
7 added by section 3, do not exceed 30 percent of
8 the costs of reviewing such applications.

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

21 (5) USER FEE PROGRAM DEFINITIONS AND RE-
22 SOURCE REQUIREMENTS.—

23 (A) IN GENERAL.—The term “process for
24 the review of in vitro clinical test submissions
25 and applications” means the following activities

1 of the Secretary with respect to the review of in
2 vitro clinical test premarket and technology cer-
3 tification applications including supplements for
4 such applications:

5 (i) The activities necessary for the re-
6 view of premarket applications, premarket
7 reports, technology certification applica-
8 tions, and supplements to such applica-
9 tions.

10 (ii) Actions related to submissions in
11 connection with in vitro clinical test devel-
12 opment, the issuance of action letters that
13 allow the marketing of in vitro clinical
14 tests or which set forth in detail the spe-
15 cific deficiencies in such applications, re-
16 ports, supplements, or submissions and,
17 where appropriate, the actions necessary to
18 support the development of in vitro clinical
19 tests.

20 (iii) The inspection of manufacturing
21 establishments and other facilities under-
22 taken as part of the Secretary's review of
23 pending premarket applications, technology
24 certifications, and supplements.

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

4 (v) Review of in vitro clinical test ap-
5 plications subject to section 351 of the
6 Public Health Service Act (42 U.S.C. 262)
7 and activities conducted in anticipation of
8 the submission of such applications for in-
9 vestigational use under section 587S of the
10 Federal Food, Drug, and Cosmetic Act (as
11 added by section 3).

12 (vi) The development of guidance, pol-
13 icy documents, or regulations to improve
14 the process for the review of premarket ap-
15 plications, technology certification applica-
16 tions, and supplements.

17 (vii) The development of voluntary
18 test methods, consensus standards, or
19 mandatory performance standards in con-
20 nection with the review of such applica-
21 tions, supplements, or submissions and re-
22 lated activities.

23 (viii) The provision of technical assist-
24 ance to in vitro clinical test developers in
25 connection with the submission of such ap-

1 plications, reports, supplements, or submis-
2 sions.

3 (ix) Any activity undertaken in con-
4 nection with the initial classification or re-
5 classification of an in vitro clinical test in
6 connection with any requirement for ap-
7 proval or eligibility for an exemption from
8 premarket review of an in vitro clinical
9 test.

10 (x) Any activity undertaken in connec-
11 tion with making a pathway determination
12 of an in vitro clinical test, including the
13 identification, establishment, and imple-
14 mentation of mitigation measures.

15 (xi) Evaluation of postmarket studies
16 required as a condition of an approval of
17 a premarket application of an in vitro clin-
18 ical test and ensuring such studies are con-
19 ducted as required.

20 (xii) Any activity undertaken in con-
21 nection with ensuring in vitro clinical tests
22 offered under an exemption from pre-
23 market review pursuant to section 587C or
24 587G meet the criteria for such exemption
25 and the applicable standard.

1 (xiii) Compiling, developing, and re-
2 viewing information on in vitro clinical
3 tests necessary to identify issues with the
4 ability of in vitro clinical tests to meet the
5 applicable standard, as applicable.

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

11 (i) be subject to the limitation under
12 section 738(g)(3) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C.
14 379j(g)(3)), in the same manner that fees
15 collected and assessed under section
16 737(9)(C) of such Act (21 U.S.C.
17 379i(9)(C)) are subject to such limitation;

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

24 (iii) not be allocated to purposes de-
25 scribed under section 722(a) of the Con-

1 solidated Appropriations Act, 2018 (Public
2 Law 115–141).

3 (c) REPORTS.—

4 (1) PERFORMANCE REPORT.—

5 (A) IN GENERAL.—

6 (i) GENERAL REQUIREMENTS.—Be-
7 ginning with fiscal year 2028, for each fis-
8 cal year for which fees are collected under
9 this section, the Secretary shall prepare
10 and submit to the Committee on Health,
11 Education, Labor, and Pensions of the
12 Senate and the Committee on Energy and
13 Commerce of the House of Representatives
14 annual reports concerning the progress of
15 the Food and Drug Administration in
16 achieving the goals identified in the rec-
17 ommendations transmitted to Congress by
18 the Secretary pursuant to subsection
19 (b)(1)(F) during such fiscal year and the
20 future plans of the Food and Drug Admin-
21 istration for meeting the goals.

22 (ii) ADDITIONAL INFORMATION.—Be-
23 ginning with fiscal year 2028, the annual
24 report under this subparagraph shall in-
25 clude the progress of the Food and Drug

1 Administration in achieving the goals, and
2 future plans for meeting the goals, includ-
3 ing—

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

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

15 (III) the number of breakthrough
16 designations under section 587I of the
17 Federal Food, Drug, and Cosmetic
18 Act during the applicable fiscal year;
19 and

20 (IV) the number of information
21 requests requested by the Secretary
22 pursuant to section 587G(d) of such
23 Act.

24 (iii) REAL-TIME REPORTING.—

1 (I) IN GENERAL.—Not later than
2 30 calendar days after the end of the
3 second quarter of fiscal year 2028,
4 and not later than 30 calendar days
5 after the end of each quarter of each
6 fiscal year thereafter, the Secretary
7 shall post the data described in sub-
8 clause (II) on the website of the Food
9 and Drug Administration for such
10 quarter and on a cumulative basis for
11 such fiscal year, and may remove du-
12 plicative data from the annual report
13 under this subparagraph.

14 (II) DATA.—The Secretary shall
15 post the following data in accordance
16 with subclause (I):

17 (aa) The number and titles
18 of draft and final regulations on
19 topics related to the process for
20 the review of in vitro clinical test
21 submissions and applications,
22 and whether such regulations
23 were required by statute or pur-
24 suant to the recommendations
25 transmitted to Congress by the

1 Secretary pursuant to subsection
2 (b)(1)(F).

3 (bb) The number and titles
4 of draft and final guidance on
5 topics related to the process for
6 the review of in vitro clinical test
7 submissions and applications,
8 and whether such guidances were
9 issued as required by statute or
10 pursuant to the recommendations
11 transmitted to Congress by the
12 Secretary pursuant to subsection
13 (b)(1)(F).

14 (cc) The number and titles
15 of public meetings held on topics
16 related to the process for the re-
17 view of in vitro clinical tests, and
18 if such meetings were required by
19 statute or pursuant to the rec-
20 ommendations transmitted to
21 Congress by the Secretary pursu-
22 ant to subsection (b)(1)(F).

23 (iv) RATIONALE FOR IVCT USER FEE
24 PROGRAM CHANGES.—Beginning with fis-
25 cal year 2028, the Secretary shall include

1 in the annual performance report under
2 paragraph (1)—

3 (I) data, analysis, and discussion
4 of the changes in the number of indi-
5 viduals hired as agreed upon in the
6 recommendations transmitted to Con-
7 gress by the Secretary pursuant to
8 subsection (b)(1)(F) and the number
9 of remaining vacancies, the number of
10 full-time equivalents funded by fees
11 collected pursuant to this section, and
12 the number of full-time equivalents
13 funded by budget authority at the
14 Food and Drug Administration by
15 each division within the Center for
16 Devices and Radiological Health, the
17 Center for Biologics Evaluation and
18 Research, the Office of Regulatory Af-
19 fairs, and the Office of the Commis-
20 sioner;

21 (II) data, analysis, and discus-
22 sion of the changes in the fee revenue
23 amounts and costs for the process for
24 the review of in vitro clinical test sub-

1 missions and applications, including
2 identifying—

3 (aa) drivers of such changes;

4 and

5 (bb) changes in the average
6 total cost per full-time equivalent
7 in the in vitro clinical test review
8 program;

9 (III) for each of the Center for
10 Devices and Radiological Health, the
11 Center for Biologics Evaluation and
12 Research, the Office of Regulatory Af-
13 fairs, and the Office of the Commis-
14 sioner, the number of employees for
15 whom time reporting is required and
16 the number of employees for whom
17 time reporting is not required; and

18 (IV) data, analysis, and discus-
19 sion of the changes in the average
20 full-time equivalent hours required to
21 complete review of each type of in
22 vitro clinical test application.

23 (v) ANALYSIS.—For each fiscal year,
24 the Secretary shall include in the report

1 under clause (i) an analysis of the fol-
2 lowing:

3 (I) The difference between the
4 aggregate number of premarket appli-
5 cations filed under section 587B or
6 section 587D of the Federal Food,
7 Drug, and Cosmetic Act and the ag-
8 gregate number of major deficiency
9 letters, not approvable letters, and de-
10 nials for such applications issued by
11 the agency, accounting for—

12 (aa) the number of applica-
13 tions filed under each of sections
14 587B and 587D of the Federal
15 Food, Drug, and Cosmetic Act
16 during one fiscal year for which a
17 decision is not scheduled to be
18 made until the following fiscal
19 year; and

20 (bb) the aggregate number
21 of applications under each of sec-
22 tions 587B and 587D of the
23 Federal Food, Drug, and Cos-
24 metic Act for each fiscal year
25 that did not meet the goals as

1 identified by the recommenda-
2 tions transmitted to Congress by
3 the Secretary pursuant to sub-
4 section (b)(1)(F).

5 (II) Relevant data to determine
6 whether the Center for Devices and
7 Radiological Health has met perform-
8 ance enhancement goals identified by
9 the recommendations transmitted to
10 Congress by the Secretary pursuant to
11 subsection (b)(1)(F).

12 (III) The most common causes
13 and trends for external or other cir-
14 cumstances affecting the ability of the
15 Food and Drug Administration to
16 meet review time and performance en-
17 hancement goals identified by the rec-
18 ommendations transmitted to Con-
19 gress by the Secretary pursuant to
20 subsection (b)(1)(F).

21 (B) PUBLICATION.—With regard to infor-
22 mation to be reported by the Food and Drug
23 Administration to industry on a quarterly and
24 annual basis pursuant to recommendations
25 transmitted to Congress by the Secretary pur-

1 suant to subsection (b)(1)(F), the Secretary
2 shall make such information publicly available
3 on the website of the Food and Drug Adminis-
4 tration not later than 60 days after the end of
5 each quarter or 120 days after the end of each
6 fiscal year, respectively, to which such informa-
7 tion applies.

8 (C) UPDATES.—The Secretary shall in-
9 clude in each report under subparagraph (A)
10 information on all previous cohorts for which
11 the Secretary has not given a complete response
12 on all in vitro clinical test premarket applica-
13 tions and technology certification orders and
14 supplements, premarket, and technology certifi-
15 cation notifications in the cohort.

16 (2) CORRECTIVE ACTION REPORT.—Beginning
17 with fiscal year 2029, for each fiscal year for which
18 fees are collected under this section, the Secretary
19 shall prepare and submit a corrective action report
20 to the Committee on Health, Education, Labor, and
21 Pensions and the Committee on Appropriations of
22 the Senate and the Committee on Energy and Com-
23 merce and the Committee on Appropriations of the
24 House of Representatives. The report shall include
25 the following information, as applicable:

1 (A) GOALS MET.—For each fiscal year, if
2 the Secretary determines, based on the analysis
3 under paragraph (1)(A)(v), that each of the
4 goals identified by the recommendations trans-
5 mitted to Congress by the Secretary pursuant
6 to subsection (b)(1)(F) for the applicable fiscal
7 year have been met, the corrective action report
8 shall include recommendations on ways in which
9 the Secretary can improve and streamline the in
10 vitro clinical test premarket application and
11 technology certification review process.

12 (B) GOALS MISSED.—For each of the goals
13 identified by the letters described in rec-
14 ommendations transmitted to Congress by the
15 Secretary pursuant to subsection (b)(1)(F) for
16 the applicable fiscal year that the Secretary de-
17 termines to not have been met, the corrective
18 action report shall include—

19 (i) a justification for such determina-
20 tion;

21 (ii) a description of the types of cir-
22 cumstances, in the aggregate, under which
23 applications or reports submitted under
24 sections 587B and 587D of the Federal
25 Food, Drug, and Cosmetic Act missed the

1 review goal times but were approved dur-
2 ing the first cycle review, as applicable;

3 (iii) a summary and any trends with
4 regard to the circumstances for which a re-
5 view goal was missed; and

6 (iv) the performance enhancement
7 goals that were not achieved during the
8 previous fiscal year and a description of ef-
9 forts the Food and Drug Administration
10 has put in place for the fiscal year in
11 which the report is submitted to improve
12 the ability of such agency to meet each
13 such goal for the such fiscal year.

14 (3) FISCAL REPORT.—

15 (A) IN GENERAL.—For fiscal years 2029
16 and annually thereafter, not later than 120
17 days after the end of each fiscal year during
18 which fees are collected under this section, the
19 Secretary shall prepare and submit to the Com-
20 mittee on Health, Education, Labor, and Pen-
21 sions of the Senate and the Committee on En-
22 ergy and Commerce of the House of Represent-
23 atives, a report on the implementation of the
24 authority for such fees during such fiscal year
25 and the use, by the Food and Drug Administra-

1 tion, of the fees collected during such fiscal
2 year for which the report is made.

3 (B) CONTENTS.—Such report shall include
4 expenditures delineated by budget authority and
5 user fee dollars related to administrative ex-
6 penses and information technology infrastruc-
7 ture contracts and expenditures.

8 (C) OPERATING RESERVE.—Such report
9 shall provide the amount of operating reserves
10 of carryover user fees available each year, and
11 any planned allocations or obligations of such
12 balance of operating reserves for the program.

13 (4) PUBLIC AVAILABILITY.—The Secretary
14 shall make the reports required under paragraphs
15 (1) through (3) available to the public on the website
16 of the Food and Drug Administration.

17 (5) ENHANCED COMMUNICATION.—

18 (A) COMMUNICATIONS WITH CONGRESS.—
19 Each fiscal year, as applicable and requested,
20 representatives from the Centers with expertise
21 in the review of in vitro clinical tests shall meet
22 with representatives from the Committee on
23 Health, Education, Labor, and Pensions of the
24 Senate and the Committee on Energy and Com-
25 merce of the House of Representatives to report

1 on the contents described in the reports under
2 this section.

3 (B) PARTICIPATION IN CONGRESSIONAL
4 HEARING.—Each fiscal year, as applicable and
5 requested, representatives from the Food and
6 Drug Administration shall participate in a pub-
7 lic hearing before the Committee on Health,
8 Education, Labor, and Pensions of the Senate
9 and the Committee on Energy and Commerce
10 of the House of Representatives, to report on
11 the contents described in the reports under this
12 section. Such hearing shall occur not later than
13 120 days after the end of each fiscal year for
14 which fees are collected under this section.

15 **SEC. 309. AUTHORIZATION OF APPROPRIATIONS.**

16 For purposes of funding implementation of this Act
17 (including the amendments made by this Act), including
18 undertaking activities for the development of regulations
19 and guidances, hiring of necessary staff, and the develop-
20 ment of technology systems to implement this Act (includ-
21 ing the amendments made by this Act) in a timely, effec-
22 tive, and efficient manner, there is authorized to be appro-
23 priated \$480,000,000, to remain available through the end
24 of fiscal year 2028.

1 **SEC. 310. GUIDANCE ON DIAGNOSTIC INNOVATION.**

2 Not later than January 1, 2025, the Secretary shall
3 issue guidance to assist developers of in vitro clinical tests
4 intended to identify or diagnose rare diseases and in vitro
5 clinical tests intended to address an unmet medical need.
6 Such guidance shall include considerations for addressing
7 barriers to developing sufficient data to demonstrate clin-
8 ical validity for such tests, such as challenges associated
9 with data collection and obstacles to the timely generation
10 of evidence.

11 **SEC. 311. GAO REPORT ON UNIQUE CONSIDERATIONS.**

12 Not later than 3 years after the date of enactment
13 of this Act, the Comptroller General of the United States
14 shall submit to the Committee on Health, Education,
15 Labor, and Pensions of the Senate and the Committee on
16 Energy and Commerce of the House of Representatives
17 a report—

18 (1) evaluating the unique considerations for
19 hospital-based laboratories, laboratories serving aca-
20 demic medical centers, and other health care practi-
21 tioners, as appropriate, in implementing this Act, in-
22 cluding the amendments made by this Act; and

23 (2) including recommendations based on the
24 findings of the report.

1 **SEC. 312. ASSESSMENTS.**

2 Section 1834A(g) of the Social Security Act (42
3 U.S.C. 1395m–1(g)) is amended by adding at the end the
4 following new paragraph:

5 “(3) DETERMINATIONS WITH RESPECT TO IN
6 VITRO CLINICAL TESTS.—On or after the date that
7 is 45 days after the date of enactment of the
8 VALID Act of 2023, for purposes of determining
9 whether an in vitro clinical test (as defined in sec-
10 tion 201(ss) of the Federal Food, Drug, and Cos-
11 metic Act) is reasonable and necessary for the diag-
12 nosis or treatment of illness or injury (under section
13 1862(a)(1)(A)), any assessment of the analytical va-
14 lidity or clinical validity of such test shall apply the
15 definitions given such terms in subchapter J of
16 chapter V of the Federal Food, Drug, and Cosmetic
17 Act.”.

18 **SEC. 313. SEVERABILITY.**

19 If any provision of this Act is declared unconstitu-
20 tional, or the applicability of this Act to any person or
21 circumstance is held invalid, the constitutionality of the
22 remainder of this Act and the applicability thereof to other
23 persons and circumstances shall not be affected.

