I

116TH CONGRESS
2D SESSION

H. R. 6102

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2020

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Verifying Accurate Leading-edge IVCT Development Act of 2020'' or the ''VALID Act of 2020''.

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

SEC. 2. DEFINITIONS.

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

(1) by adding at the end the following:

''(ss)(1) The term 'in vitro clinical test'—

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

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

"(i) identifying or diagnosing a disease or condition;

"(ii) providing information for diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing, or monitoring a disease or condition, including by making a determination of an individual's state of health; or

"(iii) selecting, monitoring, or informing therapy or treatment for a disease or condition; and

"(B) may include—

"(i) a test protocol or laboratory test protocol;

"(ii) an instrument (as defined in section 587(11));

"(iii) an article for taking, deriving, holding, or transporting specimens from the human body (as defined in section 587(16));

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

"(v) subject to subparagraph (2), a component or part of a test, a test protocol, an instrument, an article, or software described in any of clauses (A) through (D) of such subparagraph, whether alone or in combination, including reagents, calibrators, and controls.

"(2) Notwithstanding subparagraph (1)(v), an article intended to be used as a component or part of an in vitro clinical test described in subparagraph (1) is excluded from the definition in subparagraph (1) if the article consists of any of the following:

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

"(B) An article used for invasive sampling, a needle, or a lancet, except to the extent such article, needle, or lancet is an integral component of an article for holding, storing, or transporting a specimen.

"(C) General purpose laboratory equipment, including certain pre-analytical equipment, as determined by the Secretary.

''(D) An article used solely for personal protection during the administering, conducting, or otherwise performing of test activities.'';

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

''(3) The term 'drug' does not include an in vitro clinical test.''; and

(3) in section 201(h), by striking ''section 520(o)'' and inserting ''section 520(o) or an in vitro clinical test''.

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

(1) by striking ''(1) The term 'biological product' means'' and inserting ''(1)(A) The term 'biological product' means''; and

(2) by adding at the end the following:

''(B) The term 'biological product' does not include an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act.''.

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

SEC. 3. REGULATION OF IN VITRO CLINICAL TESTS.

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

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

(2) by adding at the end of chapter V the following:

''Subchapter J—In Vitro Clinical Tests

''SEC. 587. DEFINITIONS.

''In this subchapter:

''(1) ANALYTICAL VALIDITY.—

''(A) The term 'analytical validity' means, with respect to an in vitro clinical test, the ability of the in vitro clinical test, to—

''(i) sufficiently identify, measure, detect, calculate, or analyze one or more analytes, biomarkers, substances, or other targets intended to be identified, measured, detected, calculated, or analyzed by the test; or

''(ii) as applicable, assist in such identification, measurement, detection, calculation, or analysis.

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

section 201(ss)(1)(B)(iii), the term 'analytical validity' means that such article performs as intended and will support the analytical validity of an in vitro clinical test with which it is used.

''(2) APPLICABLE STANDARD.—The term 'applicable standard', with respect to an in vitro clinical test, means a reasonable assurance of analytical and clinical validity, except that such term—

''(A) with respect to test instruments, means a reasonable assurance of analytical validity; and

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

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

''(4) CLINICAL VALIDITY.—The term 'clinical validity' means the ability of an in vitro clinical test

to achieve the purpose for which it is intended as described in section 201(ss)(1)(A).

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

''(6) DEVELOP.—The term 'develop', with respect to an in vitro clinical test, means—

''(A) designing, validating, producing, manufacturing, remanufacturing, propagating, or assembling an in vitro clinical test;

''(B) importing an in vitro clinical test;

''(C) modifying an in vitro clinical test initially developed by a different person in a manner that—

''(i) changes any of the listing elements that define indications for use specified in paragraph (10), performance claims, or, as applicable, the safety of such in vitro clinical test; or

''(ii) affects the analytical or clinical validity of the in vitro clinical test as intended by the developer; or

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

"(7) DEVELOPER.—The term 'developer' means a person who engages in an activity described in paragraph (6) for clinical use.

"(8) FIRST OF A KIND.—The term 'first-of-a-kind' means, with respect to an in vitro clinical test, a test that has an intended use and a combination of the elements specified in paragraph (10) that differ from the intended use and such elements of other in vitro clinical tests that already are legally available in the United States.

"(9) HIGH-RISK.—

"(A) IN GENERAL.—Subject to subparagraph (B), the term 'high-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means that an undetected inaccurate result from such test or category—

"(i) presents potential unreasonable risk for serious or irreversible harm or death to a patient or patients, or would otherwise cause serious harm to the public health; or

"(ii) is potentially likely to result in the absence, delay, or discontinuation of life-supporting or life-sustaining medical treatment.

"(B) EXCEPTION.—The term 'high-risk' does not include an in vitro clinical test described in subparagraph (A) if mitigating measures are established and applied to sufficiently mitigate the risk of inaccurate results as described in subparagraph (A), including—

"(i) the degree to which the technology for the intended use of the in vitro clinical test is well-characterized, and the criteria for performance of the test are well-established to be sufficient for the intended use; and

"(ii) the clinical circumstances under which the in vitro clinical test is used, and the availability of other tests (such as confirmatory or adjunctive tests) or relevant material standards.

"(10) INDICATIONS FOR USE.—The term 'indications for use' means one or more in vitro clinical tests that have all of the following notification elements in common:

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

"(B) Test method.

"(C) Test purpose or purposes, as described in section 201(ss)(1)(A).

"(D) Diseases or conditions for which the in vitro clinical test is intended for use, including intended patient populations.

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

"(11) INSTRUMENT.—The term 'instrument' means an in vitro clinical test that is hardware intended by the hardware's developer to be used with one or more in vitro clinical tests to generate a clinical test result, including software used to effectuate the hardware's functionality.

"(12) INSTRUMENT FAMILY.—The term 'instrument family' means more than one instrument for which the developer demonstrates and documents, with respect to all such instruments, that all—

''(A) have the same basic architecture, design, and performance characteristics, such as tolerance limits and signal range;

''(B) have the same intended use or uses and function;

''(C) share the same measurement principles, detection methods, and reaction conditions; and

''(D) produce the same or similar analytical results from samples of the same specimen type or types.

''(13) LABORATORY OPERATIONS.—The term 'laboratory operations'—

''(A) means the conduct of a laboratory examination or other laboratory procedure on materials derived from the human body, including the conduct of an in vitro clinical test and associated activities within or under the oversight of a laboratory and not related to the design of an in vitro clinical test; and

''(B) includes—

''(i) performing pre-analytical and post-analytical processes for an in vitro clinical test;

"(ii) conducting standard operating procedures; and

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

"(14) LOW-RISK.—The term 'low-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means that—

"(A) an undetected inaccurate result from such in vitro clinical test, or such category of in vitro clinical tests, when used as intended—

"(i) would cause minimal or no harm, or minimal or no disability, or immediately reversible harm, or would lead to only a remote risk of adverse patient impact or adverse public health impact; or

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

"(B) mitigating measures are sufficient to ensure the test meets the requirements of subparagraph (A)

"(15) MITIGATING MEASURES.—The term 'mitigating measures'—

''(A) means requirements that the Secretary determines, based on available evidence, are necessary—

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

''(ii) to mitigate the risk of harm ensuing from an inaccurate result or misinterpretation of any result; and

''(B) includes, as appropriate, applicable requirements regarding labeling, performance standards, performance testing, submission of clinical data, advertising, website posting of information, clinical studies, postmarket surveillance, user comprehension studies, training, and conformance to standards.

''(16) SPECIMEN RECEPTACLE.—The term 'specimen receptacle' means an in vitro clinical test specifically intended for the holding, storing, or transporting of specimens derived from the human body or for in vitro examination for purposes described in clause (i) or (ii) of section 201(ss)(1)(A).

''(17) TECHNOLOGY.—The term 'technology'—

''(A) means a developer's grouping of in vitro clinical tests that do not significantly dif-

fer in control mechanisms, energy sources, or operating principals and for which design, development, and manufacturing, including analytical and clinical validation as applicable, of the tests would be addressed in a similar manner or through similar procedures; and

"(B) may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spectrometry or chromatography (such as HPLC), microbial culture, next generation sequencing (also known as 'NGS'), nephlometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, single-based technology, spectroscopy, and any other technology, as the Secretary determines appropriate.

"(18) TEST.—The term 'test', unless otherwise provided, means an in vitro clinical test.

"(19) VALID SCIENTIFIC EVIDENCE.—The term 'valid scientific evidence'—

"(A) means, with respect to an in vitro clinical test, evidence—

"(i) that has been generated and evaluated by persons qualified by training or experience to do so, using procedures generally accepted by other persons so qualified; and

"(ii) from which it can be fairly and responsibly concluded by qualified experts whether the applicable standard has been met by the in vitro clinical test for its intended use; and

"(B) may include evidence described in subparagraph (A) consisting of—

"(i) peer-reviewed literature;

"(ii) clinical guidelines;

"(iii) reports of significant human experience with an in vitro clinical test;

"(iv) bench studies;

"(v) case studies or histories;

"(vi) clinical data;

"(vii) consensus standards;

"(viii) reference standards;

"(ix) data registries;

"(x) postmarket data;

"(xi) real world data;

"(xii) clinical trials; and

''(xiii) data collected in countries other than the United States if such data are demonstrated to be adequate for the purpose of making a regulatory determination under the applicable standard in the United States.

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

''(A) Peer-reviewed literature.

''(B) Practice guidelines.

''(C) Consensus standards.

''(D) Recognized standards of care.

''(E) Technology in use for many years.

''(F) Scientific publication by multiple sites.

''(G) Adoption by the scientific or clinical community.

''(H) Real world data.

''SEC. 587A. APPLICABILITY.

''(a) IN GENERAL.—

''(1) APPLICABILITY OF THIS SUBCHAPTER.—

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

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

"(C) NON-APPLICABLE REQUIREMENT.—Subject to any exemption or exclusion in this section, an in vitro clinical test shall not be subject to any provision or requirement of this Act other than this subchapter unless such other provision or requirement—

"(i) applies expressly to in vitro clinical tests; or

"(ii) describes the authority of the Secretary when regulating such in vitro clinical tests or subset of in vitro clinical tests, with respect to—

"(I) all articles regulated by the Secretary pursuant to this Act; or

"(II) a subset of such articles that includes in vitro clinical tests.

''(2) LABORATORIES AND BLOOD AND TISSUE ESTABLISHMENTS.—

''(A) RELATION TO LABORATORY CERTIFICATION PURSUANT TO SECTION 353 OF THE PHSA.—Nothing in this subchapter shall be construed to modify the authority of the Secretary with respect to laboratories or clinical laboratories under section 353 of the Public Health Service Act.

''(B) AVOIDING DUPLICATION.—In implementing this subchapter, the Secretary shall avoid issuing or enforcing regulations that are duplicative of regulations under section 353.

''(C) BLOOD AND TISSUE.—Nothing in this subchapter shall be construed to modify the authority of the Secretary with respect to laboratories, establishments, or other facilities to the extent they are engaged in the propagation, manufacture, or preparation, including filling, testing, labeling, packaging, and storage, of blood, blood components, human cells, tissues, or tissue products under this Act or section 351 or 361 of the Public Health Service Act.

''(3) PRACTICE OF MEDICINE.—

''(A) IN GENERAL.—Nothing in this subchapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed in vitro clinical test for any condition or disease within a health care practitioner-patient relationship pursuant to applicable Federal or State law.

''(B) RULES OF CONSTRUCTION.—

''(i) SALE, DISTRIBUTION, LABELING.—Nothing in this paragraph shall be construed to limit the authority of the Secretary to establish or enforce restrictions on the sale, distribution, or labeling of an in vitro clinical test under this Act.

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

''(4) SPECIAL RULE.—

''(A) PREMARKET REVIEW APPLICABLE.—Notwithstanding the exemptions from premarket review under section 587B set forth in subsections (b), (c), (d), (e), (f), (g), (h), (j),

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

"(i)(I) there is insufficient valid scientific evidence to support the analytical validity or the clinical validity of such in vitro clinical test; and

"(II) such in vitro clinical test is being offered by its developer with materially deceptive or fraudulent analytical or clinical claims;

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

"(iii) in the case of specimen receptacles, there is sufficient valid scientific evidence indicating that a specimen receptacle did not perform as intended, will not support the analytical validity of tests with which it is used, or as applicable, is not safe for use.

"(B) PROCESS.—

"(i) REQUEST FOR INFORMATION.—If the Secretary has valid scientific evidence indicating that the criteria listed in subparagraph (A) apply to an in vitro clinical test, the Secretary may request that the developer of the test submit information—

"(I) pertaining to such criteria; and

"(II) establishing the basis for any claimed exemption from premarket review.

"(ii) DEADLINE FOR SUBMITTING INFORMATION.—Upon receiving a request for information under clause (i), the developer of an in vitro clinical test shall submit the information within 30 days of such receipt.

"(iii) REVIEW DEADLINE.—Upon receiving a submission under clause (ii), the Secretary shall—

"(I) review the submitted information within 60 calendar days of such receipt; and

"(II) determine whether the criteria listed in subparagraph (A) apply to the in vitro clinical test.

"(iv) PREMARKET REVIEW REQUIRED.—

"(I) IN GENERAL.—If the Secretary finds that the criteria listed in subparagraph (A) apply to the in vitro clinical test, the developer shall—

"(aa) promptly, and not later than 90 days after the date of receipt of such information, submit an application for premarket review of the test under section 587B; or

"(bb) cease to market the test.

"(II) EXTENSION.—The Secretary may grant an extension to a developer of the 90-day time period under subclause (I)(aa), as appropriate.

"(v) CONTINUED MARKETING.—During the period beginning on the date of a request for information under clause (ii) and ending on the date of the disposition of an application for premarket review of the in vitro clinical test under section

587B, the developer of the test may continue to market the test for clinical use, unless the Secretary issues an order to the developer under clause (vi) to immediately cease distribution of the test.

"(vi) ORDER TO CEASE DISTRIBUTION.—

"(I) IN GENERAL.—If the developer of an in vitro clinical test fails to submit an application for premarket review of the test by the deadline applicable under clause (iv), or the Secretary finds that the criteria listed in subparagraph (A) apply to an in vitro clinical test and that it is in the best interest of the public health, the Secretary may issue an order, within 10 calendar days of the applicable deadline or finding by the Secretary, requiring the developer of such in vitro clinical test, and any other appropriate person (including a distributor or retailer of the in vitro clinical test) to immediately—

"(aa) cease distribution of the test pending approval of an application for premarket review of the test under section 587B; and

"(bb) notify health professionals and other user facilities of the order to cease distribution and advise health care professionals to cease use of such in vitro clinical test.

"(II) HEARING AND REVIEW.—An order under subclause (I) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such in vitro clinical test. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required

by the order, the Secretary shall terminate the order within 30 days of the hearing. Upon terminating an order, the Secretary shall provide written notice of such termination to the developer.

''(vii) AMENDMENT TO REQUIRE RECALL.—If the Secretary determines that an order issued under clause (vi) should be amended to include a recall of the in vitro clinical test with respect to which the order was issued, the Secretary shall amend the order to require a recall. In such amended order, the Secretary shall specify a timetable in which the in vitro clinical test recall will occur and shall require periodic reports to the Secretary describing the progress of the recall. Upon termination of the recall, the Secretary shall provide written notice of such termination to the developer.

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

granted approval under section 587B, provided that the in vitro clinical test is developed and offered for clinical use in accordance with such approval.

"(5) EMERGENCY USE.—

"(A) IN GENERAL.—In the case of a public health emergency under section 319 of the Public Health Service Act, an in vitro clinical test is exempt from the requirements of this subchapter and may be lawfully marketed in accordance with subparagraph (B).

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

"(i) is authorized for an emergency use under section 564(b); or

"(ii) is developed and used in laboratories for which a certificate is in effect under section 353 of the Public Health Service Act to conduct high-complexity testing and the developer—

"(I) is pursuing an emergency use authorization under section 564 and provides updates to the Secretary

on efforts to pursue such authorization;

"(II) validates such in vitro clinical test prior to use;

"(III) notifies the Secretary of the assay validation; and

"(IV) includes a statement together with the results of the test that reads: 'This IVCT was developed for use as a part of a response to a public health emergency. This test has not been reviewed by the Food and Drug Administration.'.

"(C) DISPOSITION OF PRODUCT.—With respect to a previously unapproved in vitro clinical test or an in vitro clinical tests with an unapproved use, for which an emergency use authorization under section 564(b) ceases to be effective, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

"(D) STREAMLINING OF APPLICATION REVIEW.—A developer may include any data or information already submitted to the Secretary within the emergency use authorization as a

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

"(b) COMPONENTS AND PARTS.—

"(1) EXEMPTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), a component, part, or raw material described in section 201(ss)(1)(F) is exempt from the requirements of this subchapter if it is—

"(i) intended for further development as described in paragraph (2); or

"(ii) is otherwise to be regulated based on its risk when used as intended by the developer, notwithstanding its subsequent use by a developer as a component, part, or raw material of another in vitro clinical test.

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

unless the test is otherwise exempted under this section.

''(2) FURTHER DEVELOPMENT.—A component, part, or raw material (as described in paragraph (1)(A)) is intended for further development (for purposes of such paragraph) if—

''(A) it is intended solely for use in the development of another in vitro clinical test; and

''(B) in the case of such a test that is introduced or delivered for introduction into interstate commerce after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the labeling of such test bears the following statement: 'This product is intended solely for further development of an in vitro clinical test and is exempt from FDA regulation. This product must be evaluated by the in vitro clinical test developer if it is used with or in the development of an in vitro clinical test.'.

''(c) GRANDFATHERED TESTS.—

''(1) EXEMPTION.—An in vitro clinical test that meets the criteria set forth in paragraph (2) is exempt from the requirements of this subchapter, except as provided under section 587A(a)(4), the reg-

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

"(A) each test report template for the test bears a statement of adequate prominence that reads as follows: 'This in vitro clinical test was developed and first introduced prior to the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020 and has not been reviewed by the Food and Drug Administration.'; and

"(B) the developer of the test—

"(i) maintains documentation demonstrating that the test meets and continues to meet the criteria set forth in paragraph (2); and

"(ii) makes such documentation available to the Secretary upon request.

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

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

the Verifying Accurate Leading-edge IVCT Development Act of 2020;

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

"(iii) is performed—

"(I) in the same clinical laboratory in which it was developed;

"(II) by another clinical laboratory for which a certificate is in effect under section 353 within the same corporate organization and having common ownership by the same parent corporation; or

"(III) by a laboratory within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention;

"(B) does not have in effect an approval under section 515, a clearance under section 510(k), an authorization under section 513(f)(2), or an approval under section 520(m); and

"(C) is not modified on or after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020 by its initial developer (or another person) in a manner such that the test is a new in vitro clinical test under subsection (l).

"(3) MODIFICATIONS.—In the case of a modification to an vitro clinical test that is exempt as specified in paragraph (1) or determines that such modification is otherwise not subject to premarket review pursuant to section 587A(l), the test continues to qualify for such exemption if the person modifying such test—

"(A) documents each such modification and maintains a summary of the basis for such determination; and

"(B) provides such documentation and summary to the Secretary upon request or inspection.

"(d) TESTS EXEMPT FROM SECTION 510(k).—

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

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

"(ii) immediately prior to such date of enactment was exempt pursuant to subsection (l) or (m)(2) of section 510 from the requirements for submission of a report under section 510(k); or

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

"(ii) is not a test platform; and

"(iii) falls within a category of tests that was exempt from the requirements for submission of a report under section 510(k) as of such date of enactment (including class II devices and excluding class I devices described in section 510(l)).

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

Act of 2020 shall be deemed a mitigating measure applicable under section 587E to an in vitro clinical test within the successor category, except to the extent such mitigating measure is withdrawn or changed in accordance with section 587E.

''(3) NEAR-PATIENT TESTING.—Not later than 1 year after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall issue draft guidance indicating categories of tests that shall be exempt from premarket review under section 587B when offered for near-patient testing (point of care), which were not exempt from submission of a report under section 510(k) pursuant to subsection (l) or (m)(2) of section 510 and regulations imposing limitations on exemption for in vitro devices intended for near-patient testing (point of care).

''(e) LOW-RISK TESTS.—

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

''(2) LIST OF LOW-RISK TESTS.—

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

''(B) INCLUSION.—The list under subparagraph (A) shall consist of—

''(i) all in vitro clinical tests and categories of in vitro clinical tests that are exempt from premarket review pursuant to subsection (d)(1) or (d)(3); and

''(ii) all in vitro clinical tests and categories of in vitro clinical tests that are designated by the Secretary pursuant to subparagraph (C) as low-risk for purposes of this subsection.

''(C) DESIGNATION OF TESTS AND CATEGORIES.—Without regard to subchapter II of chapter 5 of title 5, United States Code, the Secretary may designate, in addition to the tests and categories described in subparagraph (B)(i), additional in vitro clinical tests, and categories of in vitro clinical tests, as low-risk in

vitro clinical tests for purposes of the exemption under this subsection. The Secretary may make such a designation on the Secretary's own initiative or in response to a request by any person. In making such a designation for a test or category of tests, the Secretary shall consider—

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

"(ii) such other factors as the Secretary determines to be relevant to the protection of the public health.

"(f) MANUAL TESTS.—

"(1) EXEMPTION.—An in vitro clinical test is exempt from all requirements of this subchapter if the output of such in vitro clinical test is the result of direct, manual observation, without the use of automated instrumentation or software for intermediate or final interpretation, by a qualified laboratory professional, and such in vitro clinical test—

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

quirements under section 353 for performing high-complexity testing;

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

"(C) is not intended for testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products.

"(2) HIGH-RISK TEST LIMITATION OR CONDITION.—A high-risk test may be exempt under paragraph (1) from the requirements of this subchapter only if—

"(A) no component or part of such test, including any reagent, is introduced into interstate commerce under the exemption under subsection (b)(1) (relating to components or parts intended for further development), and any article for taking or deriving specimens from the human body used in conjunction with the test remains subject to the requirements of this subchapter; or

"(B) the test has been developed in accordance with the applicable test design and quality requirements under section 587J.

"(g) HUMANITARIAN TEST EXEMPTION.—

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

"(A) such in vitro clinical test—

"(i) is intended for use for a disease or condition for which no more than 10,000 (or such other number determined by the Secretary) individuals would be subject to negative or positive diagnosis by such test in the United States per year; and

"(ii) is not intended to diagnose a contagious disease or condition that is highly likely to result in fatal or irreversibly debilitating outcome and for which prompt and accurate diagnosis offers the opportunity to mitigate a public health impact of the condition; and

"(B) the developer of the test—

''(i) maintains documentation (which may include literature citations in specialized medical journals, textbooks, specialized medical society proceedings, governmental statistics publications, or, if no such studies or literature citations exist, credible conclusions from appropriate research or surveys) demonstrating that such test meets and continues to meet the criteria described in this paragraph; and

''(ii) makes such documentation available to the Secretary upon request.

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

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

''(1) such in vitro clinical test—

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

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

''(B) is a custom test developed or modified to diagnose a unique pathology or physical condition of a specific patient for which no other in vitro clinical test is commercially available in the United States, and is—

''(i) not intended for use with respect to other patients; and

''(ii) after the development of the custom test, not included in any test menu, template test report, or other promotional materials, and not otherwise advertised; and

''(2) the developer of the test—

''(A) maintains documentation demonstrating that such test meets and continues to meet the applicable criteria described in paragraph (1);

''(B) makes such documentation, such as a prescription order requesting the custom test

for an individual patient, available to the Secretary upon request; and

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

''(i) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

''(1) IN GENERAL.—The provisions of this subchapter shall not apply to a test intended by the developer to be used solely for public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

''(2) LIMITATION.—Such activities—

''(A) are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, risk factors, patterns in diseases, or increases in injuries from using consumer products); and

''(B) include those associated with providing timely situational awareness and priority

setting during the course of a threat to the public health (including natural or man-made disasters and deliberate attacks on the United States).

''(3) EXCLUSION.—An in vitro clinical test is not excluded from the provisions of this subchapter if such test is intended for use in making clinical decisions for individual patients.

''(j) LAW ENFORCEMENT OR EMPLOYER TESTING.—An in vitro clinical test that is intended solely for use in forensic analysis, law enforcement activity, or employment purposes is exempt from the requirements of this Act. An in vitro clinical test that is intended for use in making clinical decisions for individual patients, or whose individually identifiable results may be reported back to an individual patient or the patient's health care provider, even if also intended for law enforcement or employment testing purposes, is not intended solely for use in law enforcement or employment testing for purposes of this subsection.

''(k) IN VITRO CLINICAL TESTS UNDER A TECHNOLOGY CERTIFICATION ORDER.—An in vitro clinical test that is within the scope of a technology certification order, as described in section 587D(a)(2), is exempt from premarket review under section 587B.

''(l) MODIFIED TESTS.—

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

''(A) affects the analytical or clinical validity of such test;

''(B) causes the test to no longer comply with applicable mitigating measures under section 587E or restrictions under section 587N; or

''(C) as applicable, affects the safety of an article for taking or deriving specimens from the human body for a purpose described in section 201(ss)(1).

''(2) EXEMPTIONS.—Notwithstanding paragraph (1), an in vitro clinical test that is modified by the initial developer of the test or a different person is not a new in vitro clinical test if the modification—

''(A) is a software update that does not have an adverse effect on the analytical or clinical validity or result in an increased risk to patients and consumers;

"(B) is made pursuant to methods or criteria included in the change protocol premarket submission, amendment, or supplement approved by the Secretary for the in vitro clinical test being modified;

"(C) is a labeling change that is appropriate to address patient or user harm; or

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

"(3) DOCUMENTATION.—When a person modifies an in vitro clinical test that was developed by another person, such modified test is exempt from the requirements of this subchapter provided that such person—

"(A) documents the modification that was made and the basis for determining that the modification, considering the changes individually and collectively, was not a type of modification described in paragraph (1); and

"(B) provides such documentation to the Secretary upon request or inspection.

''(m) INVESTIGATIONAL USE.—An in vitro clinical test for investigational use is exempt from the requirements of this Act, except as provided in section 587R.

''(n) TRANSFER OR SALE OF IN VITRO CLINICAL TESTS.—

''(1) TRANSFER AND ASSUMPTION OF REGULATORY OBLIGATIONS.—If ownership of an in vitro clinical test is sold or transferred in such manner that the developer transfers the regulatory submissions and obligations applicable under this subchapter with respect to the test, the transferee or purchaser becomes the developer of the test and shall have all regulatory obligations applicable to such a test under this subchapter. The transferee or purchaser shall update the registration and listing information under section 587I for the in vitro clinical test.

''(2) TRANSFER OR SALE OF PREMARKET APPROVAL.—

''(A) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells the approval of the in vitro clinical test, the transferor or seller shall—

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

istration and listing information under section 587I for the in vitro clinical test; and

''(ii) submit a supplemental application if required under section 587B(h).

''(B) EFFECTIVE DATE OF APPROVAL TRANSFER.—A transfer or sale described in subparagraph (A) shall become effective upon completion of a transfer or sale described in paragraph (1) or the approval of a supplemental application under section 587B(h) if required, whichever is later. The transferee or purchaser shall update the registration and listing information under section 587I for the in vitro clinical test within 15 calendar days of the effective date of the transfer or sale.

''(3) TRANSFER OR SALE OF TECHNOLOGY CERTIFICATION.—

''(A) REQUIREMENTS FOR TRANSFER OR SALE OF TECHNOLOGY CERTIFICATION.—An unexpired technology certification can be transferred or sold if the transferee or purchaser—

''(i) is an eligible person under section 587D(b)(1); and

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

quirements, processes and procedures under the scope of technology certification, and scope of the technology certification identified in the applicable technology certification order.

"(B) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells a technology certification order that has not expired, the transferor or seller shall submit a notice of the transfer or sale to the Secretary and shall update the registration and listing information under section 587I for all in vitro clinical tests covered by the technology certification.

"(C) EFFECTIVE DATE OF TECHNOLOGY CERTIFICATION TRANSFER.—The transfer of a technology certification shall become effective upon completion of a transfer or sale described in subparagraph (A). The transferee or purchaser shall update the registration and listing information under section 587I for the in vitro clinical test within 30 calendar days of the effective date of the technology certification transfer.

''(D) NEW TECHNOLOGY CERTIFICATION REQUIRED.—If the requirements of subclause (A)(ii) are not met, then the technology certification order cannot be transferred and the transferee or purchaser of an in vitro clinical test must submit an application for technology certification and obtain a technology certification order prior to offering the test for clinical use.

''(o) GENERAL LABORATORY EQUIPMENT.—Any instrument that does not produce an analytical result, and that functions as a component of pre-analytical procedures related to in vitro clinical tests, is not subject to the requirements of this subchapter, provided that—

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

''(2) the instrument can be serviced by the manufacturer of such instrument or, if that manufacturer is no longer in business, a third party with the ability to service such instrument.

''(p) INSTRUMENT FAMILIES.—In the case of an instrument family, premarket approval under section 587B(d) of one version of the in vitro clinical test is required, and previous and updated versions of the same test

within such instrument family shall be deemed to be subject to the approval pursuant to that section, unless the Secretary determines otherwise, as set forth in guidance.

''(q) GENERAL EXEMPTION AUTHORITY.—The Secretary may, by order published in the Federal Register following notice and an opportunity for comment, exempt a class of persons from any section under this subchapter upon a finding that such exemption is appropriate for the protection of the public health and other relevant considerations.

''(r) REGULATIONS.—The Secretary may issue regulations to implement this subchapter.

''SEC. 587B. PREMARKET REVIEW.

''(a) IN GENERAL.—No person shall introduce or deliver for introduction into interstate commerce any in vitro clinical test, unless—

''(1) an approval of an application filed pursuant to subsection (c) or (d) is effective with respect to test; or

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

''(b) TRANSPARENCY AND PREDICTABILITY.—

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

(c) or (d), any person may request a meeting or written correspondence with the Secretary to discuss the eligibility of an in vitro clinical test for premarket review or other information related to the filing of an application. The Secretary shall respond to such request within 45 calendar days.

''(2) STREAMLINING OF APPLICATIONS.—

''(A) PREMARKET APPLICATION AND TECHNOLOGY CERTIFICATION.—If a person files a premarket application under this section and provides any additional documentation required under section 587D, the in vitro clinical test that is the subject of the application may be utilized as the representative test reviewed by the Secretary to provide an approval for both a premarket application under this section and a technology certification order under section 587D.

''(B) REPRESENTATIVE ASSAYS FOR PREMARKET APPROVAL.—With respect to a technology certification application filed under section 587D, the representative test, as described in subparagraph (A), used to issue a technology certification order under section 587D shall be

deemed a test with premarket approval under this section.

''(c) APPLICATION.—

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

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

''(A) General information regarding the in vitro clinical test, including—

''(i) the name and address of the applicant;

''(ii) the table of contents for the application and the identification of the information the applicant claims as trade secret or confidential commercial or financial information;

''(iii) a description of the test's intended use;

''(iv) an explanation regarding test function and any significant performance characteristics; and

''(v) an explanation of how the development and validation activities support the test meeting the applicable standard.

''(B) A summary of the data and information in the application for the in vitro clinical test, including—

''(i) a brief description of any existing alternative practices or procedures for diagnosing the disease or condition for which the in vitro clinical test is intended, as applicable;

''(ii) a brief description of the foreign and domestic marketing history of the test, if any, including a list of all countries in which the test has been marketed and a list of all countries in which the test has been withdrawn from marketing for any reason related to the applicable standard of the in vitro clinical test, if known by the applicant;

''(iii) a summary of the any studies submitted for such test, including a description of the objective of the study, a description of the experimental design of the study, a brief description of how the

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

"(iv) a risk assessment of the test; and

"(v) conclusions drawn from any studies described in clause (iii), including a discussion demonstrating that the data and information in the application constitute valid scientific evidence and meet the applicable standard under section 587(10), an explanation of how the development and validation activities, as applicable, support that the test meets the applicable standard under section 587(10), and a discussion of any adverse effects of the test on health and proposals to mitigate those risks, if any.

"(C) The signature of the person filing the premarket application or an authorized representative.

"(D) A bibliography of all published reports reasonably known to the applicant related to such test and a discussion of data and infor-

mation relevant to the evaluation of the applicable standard that may be met by such test.

"(E) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the application.

"(F) Except as provided under subsection (d), applicable information regarding the methods used in, or the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality requirements under section 587J.

"(G) Information demonstrating compliance with any relevant—

"(i) mitigating measures under section 587E; and

"(ii) standards established or recognized under section 514 prior to the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, or, after applicable standards are established or recognized under section 587Q, with such standards.

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

"(i) summary information for all supporting validation studies performed; and

"(ii) raw data, such as tabulations of data and results as required under section 814.20(b)(6)(ii) of title 21, Code of Federal Regulations (or any successor regulations);

"(iii) for nonclinical laboratory studies involving the test, a statement that studies were conducted in compliance with applicable good laboratory practices; and

"(iv) for investigations involving human subjects, statements that any clinical investigation involving human subjects was conducted in compliance with applicable—

"(I) institutional review board regulations;

"(II) informed consent regulations; and

"(III) investigational use requirements in section 587R.

"(I) To the extent the application seeks authorization to make modifications to the test within the scope of the approval, a change protocol that includes validation procedures and acceptance criteria for anticipated modifications that could be made to the test within the scope of the approval.

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

"(K) Such other data or information as the Secretary may require in accordance with the least burdensome requirements of subsection (j).

"(3) GUIDANCE FOR PREMARKET AND SPECIAL PREMARKET APPLICATIONS.—In accordance with section 5 of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall issue draft guidance detailing the information to be provided in a premarket application and special premarket application under this section. The Secretary shall issue final guidance not later than 90 calendar days after the close of the comment period for such guidance.

"(4) REFUSE TO FILE A PREMARKET OR SPECIAL PREMARKET APPLICATION.—If, after receipt of

an application under this section, the Secretary refuses to file such application, the Secretary shall provide to the developer, within 60 calendar days of receipt of such application, a description of the reason for such refusal, and identify the information required, if any, to allow for the filing of the application.

''(5) SUBSTANTIVE REVIEW FOR DEFICIENT APPLICATION.—If, after receipt of an application under this section, the Secretary determines that any portion of such application is deficient, the Secretary shall provide to the applicant, within 75 calendar days of receipt of such application, a description of such deficiencies and identify the information required to correct such deficiencies.

''(d) SPECIAL PREMARKET REVIEW.—

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

''(A) an instrument;

''(B) a specimen receptacle;

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

"(D) a first-of-a-kind test, unless it is a high-risk test, a direct-to-consumer test, or cross-referenced test that does not have mitigating measures.

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

"(A) the information required for applications submitted under subsection (c)(2), except that applications under paragraph (1) need not include—

"(i) quality requirement information; or

"(ii) raw data unless explicitly requested by the Secretary;

"(B) in the case of a specimen receptacle, safety information; and

"(C) data, as applicable, to support software validation, electromagnetic compatibility, and electrical safety, and information demonstrating compliance with maintaining quality systems documentation.

"(3) INSPECTIONS.—With respect to an application under paragraph (1), preapproval inspections authorized by an employee of the Food and Drug Administration or a person accredited under section

587P need not occur unless requested by the Secretary.

''(e) INSTRUMENT FAMILY.—When an in vitro clinical test has been approved, or is otherwise legally marketed, for use on a specific approved or legally marketed instrument within an instrument family, a submission under this section shall not be required for that in vitro clinical test in order for it to be used on a new instrument within that instrument's family.

''(f) AMENDMENTS TO AN APPLICATION.—

''(1) IN GENERAL.—An applicant may amend an original or supplemental application under subsection (c) or (d).

''(2) REQUIRED AMENDMENT OR SUPPLEMENT.—An applicant shall amend or supplement an application submitted under subsection (c) or (d) if the applicant becomes aware of information that—

''(A) could reasonably affect an evaluation of whether the applicable standard has been met; or

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

''(3) REQUEST FOR AMENDMENT OR SUPPLEMENT.—The Secretary may request that an appli-

cant amend or supplement an application under subsection (c) or (d) with any information necessary for review under this section.

"(g) ACTION ON AN APPLICATION FOR PREMARKET APPROVAL.—

"(1) REVIEW.—

"(A) DISPOSITION.—As promptly as possible, but not later than 90 calendar days after an application under subsection (c) is accepted for submission (unless the Secretary determines that an extension is necessary to review one or more major amendments to the application), or not later than 60 calendar days after an application under subsection (d) is accepted for submission, the Secretary, after considering any applicable report and recommendations pursuant to advisory committees under section 587G, or prior to the establishment of such advisory committees, any recommendations by a classification panel under section 513, shall issue an order approving the application, unless the Secretary finds that the grounds for approval in paragraph (2) are not met.

"(B) RELIANCE ON PROPOSED LABELING.—In determining whether to approve or

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

''(2) APPROVAL OF AN APPLICATION.—

''(A) IN GENERAL.—The Secretary shall approve an application submitted under subsection (c) with respect to an in vitro clinical test if the Secretary finds that there is a reasonable assurance that the applicable standard is met, and—

''(i) except as provided under subsection (d), the applicant is in compliance with applicable quality requirements in section 587J or as otherwise specified in a condition of approval, or maintains the documentation required to be in compliance with such requirements if the applicant is not required to submit such documentation as a part of the application under this section;

''(ii) the application does not contain a false statement of material fact;

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

"(iv) except as provided under subsection (d), the applicant permits, if requested, authorized employees of the Food and Drug Administration and persons accredited under section 587P an opportunity—

"(I) to inspect at a reasonable time and in a reasonable manner the facilities and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, including all things (including records, files, papers, and controls) bearing on whether an in vitro clinical test is adulterated, misbranded, or otherwise in violation of this Act; and

"(II) to view and to copy and verify all records pertinent to the application and the in vitro clinical test;

"(v) the test conforms with any applicable performance standards under section

587Q and any applicable mitigating measures under section 587E; and

''(vi) all nonclinical laboratory studies and clinical investigations involving human subjects that are described in the application were conducted in a manner that meets the requirements of this section.

''(B) CONDITIONS OF APPROVAL.—An order approving an application pursuant to this paragraph may require conditions of approval for the in vitro clinical test, including conformance with performance standards under section 587Q and restrictions under section 587N.

''(C) FIRST-OF-A-KIND TEST.—For a first-of-a-kind in vitro clinical test, an order approving an application pursuant to this paragraph—

''(i) may impose requirements for tests with the same indications for use, including conformance with performance standards under section 587Q and mitigating measures under section 587E, and comply with restrictions under section 587N; and

''(ii) shall indicate whether subsequent in vitro clinical tests with the same in-

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

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

''(i) contains commercially confidential or trade secret information; or

''(ii) relates to national security or countermeasures is restricted from disclosure pursuant to statutory provisions other than this section.

''(3) REVIEW OF DENIALS.—An applicant whose application submitted under subsection (c) or (d) has been denied approval may, by petition filed not more than 60 calendar days after the date on which the applicant receives notice of such denial, obtain review of the denial in accordance with section 587O.

''(h) SUPPLEMENTS TO AN APPLICATION.—

''(1) RISK ANALYSIS.—Prior to implementing any modification to an in vitro clinical test, the holder of the application approved under subsection (c) or (d) for such test shall perform risk analyses in accordance with section 587J, unless such modification is included in the change protocol submitted by the applicant and approved under this section or exempt under section 587A(l).

''(2) SUPPLEMENT REQUIREMENT.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), or otherwise specified by the Secretary, the holder of the application approved under subsection (g) for an in vitro clinical test shall submit to the Secretary and receive approval of a supplement before implementing a modification to the test, unless such modification is exempt under section 587A(l).

''(B) ADJUSTMENTS TO CHANGE PROTOCOL.—A person may submit under this paragraph a supplemental application adjusting the change protocol of the test at any time after the initial filing of an application under subsection (c) or (d).

''(C) EXCEPTIONS.—Subject to subparagraphs (D) and (E), and so long as the holder

of an approved application submitted under subsection (c) or (d) for an in vitro clinical test does not add a manufacturing site, or change activities at an existing manufacturing site, with respect to the test, the holder may, without prior approval of a supplement, implement the following modifications to the test:

''(i) Modifications included in and implemented in accordance with an approved change protocol under subsection (c)(2)(I).

''(ii) Modifications that do not change—

''(I) the analytical or clinical validity of the test;

''(II) the intended use of the test unless provided under an approved change protocol under subsection (c)(2)(I); or

''(III) the safety of the specimen receptacles.

''(iii) Labeling changes to address a safety concern.

''(iv) Modifications that are exempt under section 587A(l).

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

"(i) report any modification to the test described in clause (i) or (ii) of subparagraph (B) in the next annual report for the test under subsection (k) following the date on which the test, with such modification, is introduced into interstate commerce; and

"(ii) include in such report—

"(I) a description of the modification; and

"(II) as applicable, a summary of the analytical validity and clinical validity of the test, as modified, and any changes to acceptance criteria.

"(E) REPORTING FOR OTHER CATEGORY OF EXCEPTIONS.—The holder of the application approved under subsection (c) or (d) for an in vitro clinical test shall—

"(i) report to the Secretary any modification to the test described in clause (iii)

of subparagraph (C) not more than 60 days after the date on which the test, with the modification, is introduced into interstate commerce; and

"(ii) include in the report—

"(I) a summary of the relevant change or changes;

"(II) the rationale for implementing such change or changes; and

"(III) a description of how the change or changes were evaluated.

"(F) REQUEST FOR SUPPLEMENT.—Upon review of the information received under subparagraph (D) and a finding that the relevant modification is inconsistent with the standard specified under subparagraph (C), the Secretary may require a supplement under subparagraph (A). If the Secretary determines that a supplement under subparagraph (A) is required, the Secretary shall notify the applicant of such determination. Such notification shall include a justification for the submission of a supplement. Prior to the submission of a supplement under this subparagraph, the applicant may request a meeting or written correspondence to gain agen-

cy feedback as to the necessity of such supplemental filing. The Secretary shall respond to such meeting request within 30 calendar days of receipt.

''(3) CONTENTS OF SUPPLEMENT.—Unless otherwise specified by the Secretary, a supplement under this subsection shall include—

''(A) for modifications other than manufacturing site changes—

''(i) a description of the modification;

''(ii) data to demonstrate that the applicable standard is met;

''(iii) acceptance criteria; and

''(iv) any revised labeling; and

''(B) for manufacturing site changes—

''(i) the matter listed in subparagraph (A); and

''(ii) information regarding the methods used in, or the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality requirements under section 587J.

''(4) ADDITIONAL DATA.—The Secretary may require, when necessary, data to evaluate a modification to an in vitro clinical test that is in addition to

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

''(5) CONDITIONS OF APPROVAL.—In an order approving a supplement under this subsection, the Secretary may require conditions of approval for the in vitro clinical test, including compliance with restrictions under section 587N and conformance to performance standards under section 587Q.

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

''(A) the data demonstrate that the modified in vitro clinical test meets the applicable standard; and

''(B) the holder of the application approved under subsection (g) for the test has demonstrated compliance with applicable quality and inspection requirements, as applicable and appropriate.

''(7) PUBLICATION.—The Secretary shall publish on the public website of the Food and Drug Administration notice of any order approving a supplement under this subsection, except that such publication shall exclude—

''(A) commercial confidential or trade secret information; and

''(B) any other information that the Secretary determines to relate to national security or countermeasures or to be restricted from disclosure pursuant to another provision of law.

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

''(i) WITHDRAWAL AND TEMPORARY SUSPENSION OF APPROVAL.—

''(1) ORDER WITHDRAWING APPROVAL.—

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

''(i) the grounds for approval in subsection (g) are no longer met; or

"(ii) there is a reasonable likelihood that the test would cause death or serious adverse health consequences, including by causing the absence, delay, or discontinuation of life-saving or life sustaining medical treatment.

"(B) CONTENT.—An order under subparagraph (A) withdrawing approval of an application shall state each ground for withdrawal and shall notify the holder of such application 60 calendar days prior to issuing such order.

"(C) PUBLICATION.—The Secretary shall publish any order under subparagraph (A) on the public website of the Food and Drug Administration, except that such publication shall exclude—

"(i) commercial confidential or trade secret information; and

"(ii) any other information that the Secretary determines to relate to national security or countermeasures or to be restricted from disclosure pursuant to another provision of law.

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

informal hearing to the holder of an approved application for an in vitro clinical test under this section, the Secretary determines there is a reasonable likelihood that the in vitro clinical test would cause death or serious adverse health consequences, including by causing the absence, delay, or discontinuation of life-saving or life-sustaining medical treatment, the Secretary shall by order temporarily suspend the approval of the application. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw approval of such application.

''(j) LEAST BURDENSOME REQUIREMENTS.—

''(1) IN GENERAL.—In carrying out this subchapter, the Secretary shall consider the least burdensome means necessary to provide a reasonable assurance of analytical and clinical validity, or applicable standard, and other regulatory requirements, as determined by the Secretary.

''(2) NECESSARY DEFINED.—For purposes of paragraph (1) and paragraph (3), the term 'necessary' means the minimum required information that would support a determination by the Secretary that the application provides a reasonable assurance of analytical and clinical validity, or other applicable

standard or regulatory requirement, as determined by the Secretary.

''(3) CONSIDERATION OF ROLE OF POSTMARKET INFORMATION.—For purposes of this subsection, the Secretary shall consider the role of postmarket information in determining the least burdensome appropriate means necessary to demonstrate that the applicable standard and other regulatory requirements have been met.

''(k) ANNUAL REPORT.—

''(1) IN GENERAL.—Unless the Secretary specifies otherwise, the holder of an approved application under this section shall submit an annual report each year at a time designated by the Secretary in the approval order. Such report shall—

''(A) identify all modifications required to be reported that an approved application holder has made to any test that is covered by the approval order, including any modification that requires a supplement under subsection (h)(2); and

''(B) include any other information required by the Secretary.

''(2) EXCEPTION.—The annual reporting requirement in paragraph (1) shall not apply to in

vitro clinical tests that are deemed to have a premarket approval based on a prior approval under section 515(c), clearance under section 510(k), or authorization under section 513(f).

''(l) SERVICE OF ORDERS.—Orders of the Secretary under this section with respect to applications under subsection (c) or (d) or supplements under subsection (h) shall be served—

''(1) in person by any officer or employee of the Department of Health and Human Services designated by the Secretary; or

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

''SEC. 587C. BREAKTHROUGH IN VITRO CLINICAL TESTS.

''(a) IN GENERAL.—The purpose of this section is to encourage the Secretary and provide the Secretary with sufficient authority to apply efficient and flexible approaches to expedite the development of, and prioritize the review of, in vitro clinical tests that represent breakthrough technologies.

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

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

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

''(1) provides or enables more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions compared to existing approved or precertified alternatives; and

''(2) is a test—

''(A) that represents a breakthrough technology;

''(B) for which no approved or precertified alternative exists;

''(C) that offers a clinically meaningful advantage over existing approved or precertified alternatives, including the potential, compared to existing approved or precertified alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

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

''(d) DESIGNATION.—

''(1) REQUEST.—To receive breakthrough approval under this section, an applicant may request that the Secretary designate the in vitro clinical test for expedited development and priority review. Any such request for designation may be made at any time prior to the submission of an application under section 587B, and shall include information demonstrating that the test is eligible for designation under subsection (c).

''(2) DETERMINATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether the in vitro clinical test that is the subject of the request meets the criteria described in subsection (c). If the Secretary determines that the test meets the criteria, the Secretary shall designate the test for expedited development and priority review.

''(3) REVIEW.—Review of a request under paragraph (1) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

''(4) WITHDRAWAL.—

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

deemed to be withdrawn, and such in vitro clinical test shall no longer be eligible for designation under this section, if an application for approval under section 587B is denied. Such test would be eligible for designation upon a new request for such designation.

''(B) EXCEPTION.—The Secretary may not withdraw a designation granted under this subsection based on the subsequent approval or technology certification of another test that—

''(i) is designated under this section; or

''(ii) was given priority review under section 515B.

''(e) ACTIONS.—For purposes of expediting the development and review of in vitro clinical tests under this section, the Secretary may take the actions and additional actions set forth in section 515B(e) when reviewing such tests. Any reference or authorization in section 515B(e) with respect to a device shall be deemed a reference or authorization with respect to an in vitro clinical test for purposes of this section.

''(f) GUIDANCE.—

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

rate Leading-edge IVCT Development Act of 2020, the Secretary shall issue draft guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (d);

"(B) provide a template for request under subsection (d);

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

"(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review in vitro clinical tests designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on the draft guidance. The Secretary shall issue final guidance one year after the close of the comment period for the draft guidance.

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

apply to in vitro clinical tests designated under this section.

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

''(1) in person by any officer or employee of the Department of Health and Human Services designated by the Secretary; or

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

''SEC. 587D. TECHNOLOGY CERTIFICATION.

''(a) IN GENERAL.—

''(1) ELIGIBILITY.—Any eligible person may seek a technology certification in accordance with this section.

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

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

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

''(b) ELIGIBILITY.—

''(1) ELIGIBLE PERSON.—In this section, the term 'eligible person' means an in vitro clinical test developer unless, at the time such person seeks or would seek technology certification order, the person—

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

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

''(ii) such violation has been resolved; or

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

''(B) such person fails to maintain required certifications under section 353 of the Public Health Service Act;

''(C) has been found to have submitted information that—

''(i) makes false or misleading statements about a technology certification order previously issued or an application approved under section 587B; or

''(ii) violates any requirement of this subchapter related to technology certification under this section or approval under section 587B, where such violation exposes persons to serious risk of illness, injury, or death.

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

''(A) such test is—

''(i) a component or part of an in vitro clinical test as described under section 201(ss)(1)(B)(v);

''(ii) an instrument under section 201(ss)(1)(B)(ii);

''(iii) a specimen receptacle under section 201(ss)(1)(B)(iii); or

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

cipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products; or

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

"(i) a first-of-a-kind in vitro clinical test;

"(ii) a test system for home use;

"(iii) a high-risk in vitro clinical test;

"(iv) a cross-referenced in vitro clinical test; or

"(v) a direct-to-consumer in vitro clinical test.

"(e) PUBLIC MEETING AND INPUT.—

"(1) PUBLIC DOCKET.—Not later than 30 days after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall establish a public docket to receive comments concerning recommendations for implementation of this section, including criteria and procedures for subsections (e) through (j). The public docket shall remain open for the duration of time that this section remains in effect.

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

Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall convene a public meeting to which stakeholders from organizations representing patients and consumers, academia, and the in vitro clinical test industry are invited in order to discuss components of the technology certification process including application requirements, inspections, alignment with third-party accreditors, and the definition of 'technology' under section 587(17). The public meeting shall be assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.

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

ance shall be updated as appropriate, and not less frequently than each time the Secretary identifies a unique technology.

"(e) APPLICATION FOR TECHNOLOGY CERTIFICATION.—

"(1) IN GENERAL.—A person seeking a technology certification order shall submit an application under this subsection, which shall contain the information specified under paragraph (2).

"(2) CONTENT OF APPLICATION.—An application for technology certification shall contain—

"(A) a statement identifying the scope of the proposed technology certification, which shall be no broader than a single technology intended to be offered under the application;

"(B) information showing that the person seeking a technology certification order is an eligible person under subsection (b)(1);

"(C) information showing that the methods used in, and the facilities and controls used for, the development of eligible in vitro clinical tests covered by the scope of the technology certification conform to the applicable quality requirements of section 587J;

"(D) procedures for analytical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a reasonable assurance of analytical validity of all eligible in vitro clinical tests within the proposed scope of technology certification order;

"(E) information showing that the person has an established clinical program, including procedures for clinical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a reasonable assurance of clinical validity of all eligible in vitro clinical tests within the proposed scope of technology certification order;

"(F) a notification under section 587I for each applicable in vitro clinical test that the developer plans to offer initially upon receiving a technology certification order and that would be introduced or delivered for introduction into interstate commerce upon the issuance of the technology certification order;

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

''(i) one of the tests within the scope of the technology certification application with the greatest analytical complexity at the time of the filing of the application under this section that would be introduced or delivered for introduction into interstate commerce upon the issuance of the technology certification order to serve as the representative test and validate and run within the developer's stated scope, and a rationale for such selection;

''(ii) the information specified in subsection (c) or (d) of section 587B for the representative in vitro clinical test or tests, except that raw data shall be provided for any such in vitro clinical test unless the Secretary determines otherwise;

''(iii) an explanation of the choice of the representative in vitro clinical test or tests for the technology certification application and how such test adequately demonstrates the range of procedures that the

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

''(iv) a brief explanation of the ways in which the procedures included in the application under subparagraphs (C), (D), (E), and (F) have been applied to the representative in vitro clinical test or tests;

''(H) such other information relevant to the subject matter of the application as the Secretary may require; and

''(I) a statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted.

''(f) ACTION ON AN APPLICATION FOR TECHNOLOGY CERTIFICATION.—

''(1) SECRETARY RESPONSE.—

''(A) IN GENERAL.—As promptly as practicable, and no later than 90 days after receipt of an application under subsection (c), the Secretary shall—

''(i) issue a technology certification order granting the application, which shall specify the scope of the technology certifi-

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

''(ii) deny the application if the Secretary finds (and sets forth the basis of such finding as part of or accompanying such denial) that one or more grounds for granting the application specified in paragraph (3) are not met.

''(B) EXTENSION.—The timeline described in subparagraph (A) may be extended by mutual agreement between the Secretary and the applicant.

''(2) DEFICIENT APPLICATIONS.—If, after receipt of an application under this section, the Secretary determines that any portion of such application is deficient, the Secretary, not later than 90 days after receipt of such application, shall provide to the applicant a description of such deficiencies and identify the information required to correct such deficiencies.

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

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

"(A) in accordance with subsection (e)(2)(D), there is a showing of reasonable assurance of analytical validity for all eligible in vitro clinical tests within the proposed scope of the technology certification, as evidenced by the procedures for analytical validation;

"(B) in accordance with subsection (e)(2)(E), there is a showing of reasonable assurance of clinical validity for all eligible in vitro clinical tests within the proposed scope of the technology certification, as evidenced by the clinical program, including procedures for clinical validation;

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

"(D) based on a fair evaluation of all material facts, the applicant's proposed labeling and advertising is not false or misleading in any particular;

"(E) the application does not contain a false statement of material fact;

"(F) there is a showing that the representative in vitro clinical test or tests—

"(i) meets the applicable standard for approval; and

"(ii) reasonably represent the range of procedures for analytical validation and clinical validation included in the application, as applicable; and

"(G) the applicant permits authorized employees of the Food and Drug Administration or persons accredited under this Act an opportunity to inspect at a reasonable time and in a reasonable manner the facilities and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, including all things (including records, files, papers, and controls) bearing on whether an in vitro clinical test is adulterated, misbranded, or otherwise in violation of this Act, and permits such authorized employees or persons accredited under this Act to view and to copy and verify all records pertinent to the application and the in vitro clinical test.

''(4) REVIEW OF DENIALS.—An applicant whose application has been denied may, by petition filed on or before the date that is 30 calendar days after the date upon which such applicant receives notice of such denial, obtain review thereof in accordance with section 587O.

''(g) DURATION; SUBSEQUENT SUBMISSIONS.—

''(1) ORDER DURATION.—A technology certification order shall remain in effect until the earlier of—

''(A) the expiration of such technology certification order under paragraph (2); or

''(B) the withdrawal of such technology certification order under subsection (j).

''(2) EXPIRATION.—An initial technology certification order issued under subsection (f)(3) shall expire on such date specified by the Secretary that is not later than 4 years after the date that such order is issued, except that if an application for renewal under paragraph (3) has been received not later than 30 days prior to the expiration of such order under this paragraph, such order shall expire on the date on which the Secretary has granted or denied the application for renewal. Any such subsequent renewal of a technology certification shall ex-

pire on such date specified by the Secretary that is not later than 4 years after the date that such technology certification order is issued.

''(3) RENEWAL.—

''(A) IN GENERAL.—Any person with a technology certification order in effect with respect to development of in vitro clinical tests may seek renewal of such order provided that—

''(i) such person is an eligible person under subsection (b)(1); and

''(ii) none of the information specified in subsection (e)(2) has substantially changed, except as described in supplements approved under paragraph (4).

''(B) CONTENT.—An application for renewal under this paragraph shall include information concerning one or more representative in vitro clinical tests in accordance with subsection (e)(2)(G), except that such representative test or tests shall be different from the representative test or tests relied upon as the representative assay in any prior technology certification that has not yet been reviewed, if applicable.

''(C) PROCESS.—The Secretary's action on an application for renewal of technology certification under this paragraph shall be conducted, to the extent practicable, in coordination with inspections conducted under section 353 of the Public Health Service Act, and any order resulting from such renewal application shall be treated as a technology certification order for purposes of this subchapter.

''(4) SUPPLEMENTS AND REPORTS.—

''(A) SUPPLEMENTS.—Except as provided in subparagraph (B), any person with a technology certification order in effect may seek a supplement to such order upon a change or changes to the information provided in the application for technology certification under subparagraphs (C), (D), and (E) of subsection (e)(2), provided that—

''(i) such person is an eligible person under subsection (b)(1); and

''(ii) that such change does not expand the scope of the technology certification unless the Secretary deems appropriate.

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

''(B) REPORTS.—

''(i) IN GENERAL.—If a change described in subparagraph (A) is made in order to address a potential risk to public health by adding a new specification or test method, the person may immediately implement such change or changes and shall report such changes or changes to the Secretary within 30 days.

''(ii) CONTENT.—Any report to the Secretary under this subparagraph shall include—

''(I) a summary of the relevant change or changes;

''(II) the rationale for implementing such change or changes; and

''(III) a description of how the change or changes were evaluated.

''(iii) SUPPLEMENTAL REPORTS.—Upon review of such report and a finding that the relevant change or changes are inconsistent with the standard specified under this subparagraph, the Secretary may require a supplement under subparagraph (A).

''(h) MAINTENANCE REQUIREMENTS.—For the duration of a technology certification order, a holder of a technology certification order shall—

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

''(2) ensure compliance with any applicable mitigating measures;

''(3) maintain, and provide to the Secretary upon request, records related to any in vitro clinical test offered without premarket review under the technology certification order, where those records are necessary to demonstrate compliance with applicable provisions of this subchapter; and

''(4) comply with the notification requirements under section 587I for each in vitro clinical test offered without premarket review under the technology certification order.

''(i) TEMPORARY HOLD.—

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

''(2) NOTIFICATION TO THE DEVELOPER.—The Secretary shall not place a temporary hold under this subsection unless the Secretary has promptly notified the developer of such hold and provided 30 calendar days for the developer to come into compliance with or resolve the findings under paragraph (4).

''(3) WRITTEN REQUESTS.—Any written request to the Secretary from the holder of a technology certification order that a temporary hold under paragraph (1) be removed shall receive a decision, in writing and specifying the reasons therefore, within 90 days after receipt of such request. Any

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

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

''(A) is not in compliance with any maintenance requirements under subsection (h);

''(B) labels or advertises one or more in vitro clinical tests with false or misleading claims; or

''(C) is no longer an eligible person under subsection (b)(1).

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

''(1) the application, supplement, or report under subsection (e) or (g) contains false or misleading information or fails to reveal a material fact;

''(2) such holder fails to correct false or misleading labeling or advertising upon the request of the Secretary;

''(3) in connection with a technology certification, the holder provides false or misleading information to the Secretary; or

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

''(k) REPORTS TO CONGRESS.—

''(1) IN GENERAL.—Not later than one year after the effective date, and annually for 4 years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and make publicly available, including through posting on the internet website of the Food and Drug Administration, a report containing the information required under paragraph (2).

''(2) CONTENT.—

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

''(i) the total number and type of applications for technology certifications filed, granted, withdrawn or denied;

''(ii) the total number of technology certification orders put on temporary hold under subsection (i) and the number of technology certification orders withdrawn under subsection (j);

''(iii) the types of technologies for which technology certification orders were granted; and

''(iv) the total number of laboratories and developers with technology certification orders in effect.

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

''(C) PERFORMANCE REPORTS.—The reports required under this section may be issued as a component of performance reports as required under section 9 of the Verifying Accurate Leading-edge IVCT Development Act of 2020.

''SEC. 587E. MITIGATING MEASURES.

''(a) ESTABLISHMENT OF MITIGATING MEASURES.—

''(1) ESTABLISHING, CHANGING, OR WITHDRAWING.—

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

''(B) PROCESS.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may—

''(i) establish, change, or withdraw mitigating measures by—

''(I) publishing a proposed administrative order in the Federal Register;

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

''(III) after consideration of any comments submitted, publishing a final administrative order in the Federal Register; and

''(ii) may establish mitigating measures with respect to a category in a pre-

market approval order or technology certification order.

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

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

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

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

"(B) CHANGES.—The Secretary may establish, change, or withdraw mitigating meas-

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

''(b) DOCUMENTATION.—

''(1) TESTS SUBJECT TO PREMARKET REVIEW.—The developer of an in vitro clinical test subject to premarket review under section 587B and to which mitigating measures apply shall—

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

''(B) if such application is approved, maintain documentation demonstrating that such mitigating measures continue to be met following a test modification by the developer; and

''(C) after responding to any informal communications from the Secretary, make such documentation available to the Secretary upon request or inspection.

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

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

"(A) maintain documentation in accordance with the applicable quality requirements under section 587J demonstrating that such mitigating measures continue to be met following a test modification by the developer;

"(B) after responding to any informal communications from the Secretary, make such documentation available to the Secretary upon request or inspection; and

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

"(c) MITIGATING MEASURES FOR CROSS-REFERENCED TESTS.—Not later than 1 year after the implementation of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall issue mitigating measures for cross-referenced tests.

"SEC. 587F. REGULATORY PATHWAY REDESIGNATION.

"(a) TECHNOLOGY CERTIFICATION AND EXEMPTION DETERMINATIONS.—

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

evidence respecting tests with the same indications for use pursuant to section 587(10), the Secretary may, upon the initiative of the Secretary or upon petition of an interested person—

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

"(B) determine that such indications for use are eligible for technology certification in accordance with section 587D(b)(2), or are otherwise exempt from premarket review under section 587B.

"(2) PROCESS.—Any action under paragraph (1) shall be made by publication of a notice of such proposed action on the internet website of the Food and Drug Administration, the consideration of comments to a public docket on such proposal, and publication of a final action on such internet website within 60 calendar days of the close of the comment period posted to such public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

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

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

''(2) PROCESS.—Any action under this subsection shall be made by publication of a notice of such proposed action in the Federal Register, consideration of comments to a public docket on such proposal, and publication of a final notice in the Federal Register, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

''SEC. 587G. ADVISORY COMMITTEES.

''(a) IN GENERAL.—The Secretary may establish advisory committees or use advisory committee panels of experts established before the date of enactment of this section for the purposes of providing expert scientific advice and making recommendations related to—

''(1) the approval of an application for an in vitro clinical test submitted under this subchapter, including for evaluating, as applicable, the analytical validity, clinical validity, and safety of in vitro clinical tests;

''(2) the potential effectiveness of mitigating measures for a determination on the applicable regulatory pathway under section 587F or risk evaluation for an in vitro clinical test or tests;

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

''(4) such other purposes as the Secretary determines appropriate.

''(b) APPOINTMENTS.—

''(1) VOTING MEMBERS.—The Secretary shall appoint to each committee established under subsection (a), as voting members, individuals who are qualified by training and experience to evaluate in vitro clinical tests referred to the committee for the purposes specified in subsection (a), including individuals with, to the extent feasible, scientific expertise in the development, manufacture, or utilization of such in vitro clinical tests, laboratory operations, and the use of in vitro clinical tests. The Secretary shall designate one member of each committee to serve as chair.

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

Secretary shall appoint to each committee established under subsection (a), as nonvoting members—

''(A) a representative of consumer interests; and

''(B) a representative of interests of in vitro clinical test developers not directly affected by the matter to be brought before the committee.

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

''(4) EDUCATION AND TRAINING.—The Secretary shall, as appropriate, provide education and training to each new committee member before such member participates in a committee's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to committee meetings.

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

to the committee not more than 60 calendar days after the matter is ready for such review. Meetings of the committee may be held using electronic communication to convene the meetings.

''(6) COMPENSATION.—Members of an advisory committee established under subsection (a), while attending meetings or conferences or otherwise engaged in the business of the advisory committee—

''(A) shall be entitled to receive compensation at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above level GS–15 of the General Schedule; and

''(B) may be allowed travel expenses as authorized by section 5703 of title 5, United States Code, for employees serving intermittently in the Government service.

''(c) GUIDANCE.—The Secretary may issue guidance on the policies and procedures governing advisory committees established under subsection (a).

''SEC. 587H. REQUEST FOR INFORMAL FEEDBACK.

''Before submitting a premarket application or technology certification application for an in vitro clinical test—

''(1) the developer of the test may submit to the Secretary a written request for a meeting or conference to discuss and provide information relating to the regulation of such in vitro clinical test which may include—

''(A) the submission process and the type and amount of evidence expected to demonstrate the applicable standard;

''(B) which regulatory pathway is appropriate for an in vitro clinical test; and

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

''(2) upon receipt of such a request, the Secretary shall—

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

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

"SEC. 587I. REGISTRATION AND LISTING.

"(a) REGISTRATION OF ESTABLISHMENTS FOR IN VITRO CLINICAL TESTS.—

"(1) IN GENERAL.—Each person described in subsection (b)(1), or an accredited person under section 587P, acting on behalf of such a person, shall—

"(A) during the period beginning on October 1 and ending on December 31 of each year, register with the Secretary the name of such person, places of business of such person, all establishments engaged in the activities specified under this paragraph, the establishment registration number of each such establishment, and a point of contact for each such establishment, including an electronic point of contact; and

"(B) submit an initial registration containing the information required under subparagraph (A) not later than—

"(i) the date of implementation of this section if such establishment is engaged in any activity described in subsection (b)(1) on the date of enactment of this section, unless the Secretary establishes by guidance a date later than such implementation

date for all or a category of such establishments; or

''(ii) 30 days prior to engaging in any activity described in subsection (b)(1) after enactment of this section, if such establishment is not engaged in any activity described in this paragraph on the date of enactment of this section.

''(2) REGISTRATION NUMBERS.—The Secretary may assign a registration number to any person or an establishment registration number to any establishment registered in accordance with this section. Registration information shall be made publicly available by publication on the internet website maintained by the Food and Drug Administration, in accordance with subsection (d).

''(3) INSPECTION.—Every person or establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

''(b) LISTING INFORMATION FOR IN VITRO CLINICAL TESTS.—

''(1) IN GENERAL.—Each person who—

''(A) is a developer, a contract manufacturer (including contract packaging), contract

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

''(B) introduces or proposes to begin the introduction or delivery for introduction into interstate commerce through an exemption under section 587A(f)(2)(b) or 587A(g) or through the filing of an application under section 587B or 587D,

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

''(2) SUBMISSIONS.—Each developer submitting a listing under paragraph (1) shall electronically submit to the comprehensive test information system under section 587T the following information for each in vitro clinical test for which such person is a developer in the form and manner prescribed by the Secretary:

''(A) Name of the establishment and its facility registration number.

"(B) Contact information for the official correspondent for the listing.

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

"(D) CLIA certificate number for any laboratory certified by the Secretary under section 263a of title 42 that meets the requirements for performing high-complexity testing that is the developer of the in vitro clinical test, and CLIA certificate number for any laboratory under common ownership that is performing the test developed by such test developer.

"(E) Whether the in vitro clinical test is, as applicable, offered as a test approved under section 587B, offered under a technology certification order issued under section 587D, or offered as an in vitro clinical test under section 587A.

"(F) Indications for use information under section 587(10).

"(G) Brief narrative description of the in vitro clinical test.

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

"(I) A brief description of conformance with any applicable mitigating measures, restrictions, and standards.

"(J) Representative labeling for the in vitro clinical test, as appropriate.

"(K) A statement that the information submitted is truthful and accurate.

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

"(4) ABBREVIATED LISTING.—A person who is not a developer but is otherwise required to register pursuant to subsection (a) shall submit an abbreviated listing to the Secretary containing the information described in subparagraphs (A) through (C) of paragraph (2), and the name of the developer. The information shall be submitted in accordance with the applicable schedule described under sub-

section (c). Such abbreviated listing shall be prepared in such form and manner as the Secretary may specify in guidance. Listing information shall be submitted to the comprehensive test information system in accordance with section 587T, as appropriate.

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

''(6) LOW-RISK TESTS.—A developer of a low risk in vitro clinical test shall notify and submit listing information to the Secretary within one year of offering such test for clinical use.

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

''(c) TIMELINES FOR SUBMISSION.—

''(1) IN GENERAL.—The timelines for submission of registration and listing under subsections (a) and (b) are as follows:

"(A) For an in vitro clinical test that was listed as a device under section 510(j) prior to the date of enactment of this section, a person shall maintain a device listing under section 510 until such time as the system for submitting the notification information required under subsection (b) becomes available and thereafter shall submit the notification information no later than 1 year after the system for submitting the notification under this section becomes available.

"(B) For an in vitro clinical test that is subject to the grandfathering provisions of section 587A(c), a person shall submit the listing information required under subsection (b)(5) no later than 1 year after the system for submitting the notification under this section becomes available.

"(C) For an in vitro clinical test that is not subject to subparagraph (A) or (B), a person shall submit the required notification information prior to offering, introducing, or marketing the in vitro clinical test as follows:

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

under section 587B, a person shall submit the required listing information no later than 30 business days after the date of approval of the premarket approval application.

''(ii) For a developer who has received a technology certification order under section 587D, a person shall submit the required listing information at least 30 business days after receiving such technology certification order.

''(2) UPDATES.—

''(A) UPDATES AFTER CHANGES.—Each developer required to submit listing information under this section shall update such information within 10 business days of any change that causes any previously notified information to be inaccurate or incomplete.

''(B) ANNUAL UPDATES.—Each developer required to submit listing information under this section shall update its information annually during the period beginning on October 1 and ending on December 31 of each year as a component of the annual report submitted under sections 587B and 587D.

"(d) PUBLIC AVAILABILITY OF NOTIFICATION INFORMATION.—

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

"(2) CONFIDENTIALITY.—Notification information for an in vitro clinical test that is subject to premarket approval or technical certification shall remain confidential until such date as the in vitro clinical test receives the applicable premarket approval or the developer receives a technology certification order.

"(3) EXCEPTIONS FROM PUBLIC AVAILABILITY REQUIREMENTS.—The registration and listing information requirements described in subsections (a) and (b) shall not apply to the extent the Secretary determines that such information relates to—

"(A) trade secret or commercial confidential information; or

"(B) national security or countermeasures or is restricted from disclosure pursuant to another provision of law.

''(e) SUBMISSION OF INFORMATION BY ACCREDITED PERSONS.—If agreed upon by the developer, the information required under this section may be submitted by an accredited person under section 587P.

"SEC. 587J. TEST DESIGN AND QUALITY REQUIREMENTS.

''(a) APPLICABILITY.—

''(1) IN GENERAL.—Each developer and each other person required to register under section 587I(b)(1) shall establish and maintain quality requirements in accordance with the applicable requirements set forth in subsection (b), except as provided in section 587A.

''(2) CERTIFIED LABORATORY REQUIREMENTS.—A developer that operates a clinical laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

''(A) meets the requirements for performing high-complexity testing;

''(B)(i) develops an vitro clinical test or indications for use; or

''(ii) modifies another developer's in vitro clinical test in that certified laboratory in a manner described in section 587(6); and

''(C) develops an in vitro clinical test or indications for use that are for use only within

that certified laboratory or within another certified laboratory with common ownership,

shall establish and maintain quality requirements that comply with the requirements set forth in subsection (b)(2).

''(3) APPLICABILITY FOR CERTAIN IN VITRO CLINICAL TESTS.—The applicable requirements set forth in subsection (b)(1) shall apply to any instrument, specimen receptacle, or component or part that is developed for use by a clinical laboratory to which paragraph (2) applies.

''(4) REGULATIONS.—The Secretary may promulgate regulations to implement this section. In so promulgating regulations, the Secretary shall consider whether and to what extent international harmonization is appropriate.

''(b) QUALITY REQUIREMENTS.—

''(1) QUALITY REQUIREMENTS FOR LABORATORIES WITHOUT CLIA CERTIFICATION TO CONDUCT HIGH-COMPLEXITY TESTS.—The quality requirements applicable under this section shall—

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

''(B) apply only to the development, validation, production, preparation, propagation, or

assembly related to the design and associated manufacture and distribution of an in vitro clinical test offered under this subchapter;

"(C) not apply with respect to laboratory operations; and

"(D) shall include the following, subject to paragraphs (2) and (3)—

"(i) management responsibility;

"(ii) quality audits;

"(iii) personnel;

"(iv) design controls;

"(v) document controls;

"(vi) purchasing controls;

"(vii) identification and traceability;

"(viii) production and process controls;

"(ix) acceptance activities;

"(x) nonconforming product;

"(xi) corrective and preventive action;

"(xii) labeling and packaging controls;

"(xiii) handling, storage, distribution, and installation;

"(xiv) records;

"(xv) servicing; and

"(xvi) statistical techniques.

''(2) QUALITY REQUIREMENTS FOR LABORATORIES CERTIFIED TO CONDUCT HIGH-COMPLEXITY TESTS.—Quality requirements applicable to the in vitro clinical tests and developers described in subsection (a)(2) shall—

''(A) avoid duplication of regulations under section 353 of the Public Health Service Act; and

''(B) consist of, as directed related to the design and development—

''(i) design controls;

''(ii) purchasing controls;

''(iii) acceptance activities;

''(iv) corrective and preventative action; and

''(v) records.

''(3) QUALITY REQUIREMENTS FOR CERTAIN LABORATORIES DISTRIBUTING IN VITRO CLINICAL TESTS OR TEST PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC HEALTH NETWORKS.—

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

"(i) The requirements in paragraph (2).

"(ii) The labeling requirements in paragraph (1)(C)(xii).

"(iii) The requirement to maintain records of the laboratories to which the in vitro clinical test or test protocol is distributed.

"(B) DISTRIBUTING LABORATORY.—Subparagraph (A) shall apply to developers that meet the following conditions:

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

"(ii) The laboratory develops its own in vitro clinical test or modifies another developer's in vitro clinical test in a manner described in section 587(6).

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

"(I) is certified by the Secretary under section 353 of the Public

Health Service Act and meets the requirements for performing high-complexity testing;

''(II) is within the same corporate organization and having common ownership by the same parent corporation; or as applicable, is a laboratory within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention; and

''(III) implements the test protocol without further modification.

''(c) REGULATIONS.—In implementing quality requirements for test developers under this section, the Secretary shall—

''(1) for purposes of facilitating international harmonization, consider whether the developer participates in an audit program in which the United States participates or the United States recognizes or conforms with standards recognized by the Secretary; and

''(2) ensure a least burdensome approach described in section 587B(j) by leveraging, to the extent applicable, the quality assurance requirements

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

"SEC. 587K. LABELING REQUIREMENTS.

"(a) IN GENERAL.—An in vitro clinical test shall bear or be accompanied by labeling, and a label as applicable, that meet the requirements set forth in subsections (b) and (c), unless such test is exempt as specified in subsection (d) or (e).

"(b) LABELS.—

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

"(A) consists solely of a test protocol; or

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

"(2) REGULATIONS.—The label of an in vitro clinical test shall state the name and place of business of its developer and meet the requirements set forth in regulations promulgated under this section.

"(c) LABELING.—

''(1) IN GENERAL.—Labeling accompanying an in vitro clinical test, including labeling in the form of a package insert, standalone laboratory reference document, or other similar document except the labeling specified in paragraph (2), shall include adequate directions for use and shall meet the requirements set forth in regulations promulgated under this section, except as provided in subsection (d) or (e). Labeling in the form of a package insert shall also include the information in subparagraph (A) or (B) of paragraph (2).

''(2) CONTENT.—

''(A) IN GENERAL.—Labeling accompanying an in vitro clinical test that is in the form of a test report template or ordering information shall include—

''(i) the test listing number that was provided to the developer at the time of listing;

''(ii) instructions for how and where to report an adverse event under section 587L;

''(iii) instructions for how and where to access the performance summary data

displayed in the listing database for the test;

"(iv) the intended use of the in vitro clinical test; and

"(v) any warnings, contraindications, or limitations.

"(B) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make all of the information described in subparagraph (A) with respect to each in vitro clinical test available to the public, as applicable, in accordance with section 587T, except to the extent that the Secretary determines that such information is—

"(i) trade secret or commercial confidential information; or

"(ii) national security or countermeasures or is restricted from disclosure pursuant to another provision of law.

"(3) ADDITIONAL REQUIREMENTS.—Labeling for an in vitro clinical test used for immunohematology testing shall meet the following applicable requirements set forth in part 660 of the Code of Federal Regulations (or any successor regulation), related to the labeling of blood grouping reagents, reagent red blood cells, and anti-human globulin.

"(d) EXEMPTIONS AND ALTERNATIVE REQUIREMENTS.—

"(1) IN GENERAL.—

"(A) IN GENERAL.—With respect to an in vitro clinical test that meets the criteria of subparagraph (B), the 'state in one place' regulations under section 809.10(b) of title 21 of the Code of Federal Regulations (or any successor regulations) may be satisfied by the laboratory posting such information on its website or in multiple documents, if such documents are maintained and accessible in one place.

"(B) APPLICABLE TESTS.—An in vitro clinical test meets the criteria of this subparagraph if such test is—

"(i) designed and manufactured by a laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements for performing high-complexity testing; and

"(ii) performed in the same laboratory in which it was developed or by another such laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements

for performing high complexity testing and is under common ownership with the laboratory that designed and manufactured the test.

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

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

''(4) LAB RESEARCH OR INVESTIGATIONAL USE.—A shipment or other delivery of an in vitro clinical test for research or investigational use pursuant to section 587A(m) shall be exempt from the labeling requirements of subsections (b) and (c)(1) and from any standard promulgated through regulations, except as required under section 353 of the

Public Health Service Act or section 587R of this Act.

''(5) GENERAL PURPOSE LABORATORY REAGENTS.—The labeling of general purpose laboratory reagents (such as hydrochloric acid) whose uses are generally known by persons trained in their use need not bear the directions for use required by subsection (b) and subsection (c)(1).

''(6) ANALYTE SPECIFIC REAGENTS.—The labeling for analyte specific reagents shall bear the following statement: 'This product is intended solely for further development of an in vitro clinical test and is exempt from most FDA regulation. This product must be evaluated by the in vitro clinical test developer in accordance with applicable requirements.'. If the labeling of an analyte specific reagent bears the information set forth in this paragraph, it need not bear the information required by subsection (c)(1).

''(7) OVER-THE-COUNTER TEST SAMPLE COLLECTION SYSTEMS LABELING.—The labeling for over-the-counter test sample collection systems for drugs of abuse testing shall bear the name and place of business of the developer included in the registration listing under section 587I, in language appro-

priate for the intended users. If the labeling of such over-the-counter test sample collection system bears the information set forth in this paragraph (4)(G), it need not bear the information required by subsection (c)(1).

''(e) TESTS IN THE STRATEGIC NATIONAL STOCKPILE.—

''(1) IN GENERAL.—The Secretary may grant an exception or alternative to any provision listed in this section, unless explicitly required by a statutory provision outside this section, for specified lots, batches, or other units of an in vitro clinical test, if the Secretary determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such products that are or will be included in the Strategic National Stockpile.

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

''(f) GUIDANCE.—The Secretary may, in collaboration with developers, issue guidance on standardized, general content and format for in vitro clinical test labeling

to help ensure compliance with applicable requirements in this subsection.

"SEC. 587L. ADVERSE EVENT REPORTING.

"(a) APPLICABILITY.—

"(1) IN GENERAL.—Each in vitro clinical test developer shall establish and maintain a system for reporting adverse events in accordance with subsection (b), except as provided in section 587A.

"(2) REGULATIONS.—The Secretary shall promulgate regulations to implement this section, including information necessary to be reported to ensure the analytical and clinical validity of in vitro clinical tests, and the safety of articles for taking or deriving specimens from the human body.

"(b) ADVERSE EVENT REPORTING REQUIREMENTS.—Each developer shall report to the Secretary whenever information that reasonably suggests that one of the developer's in vitro clinical tests is associated with an adverse event becomes known to the developer.

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

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

"(A) 5 calendar days after an in vitro clinical test developer receives or otherwise becomes

aware of information that reasonably suggests the adverse event involves a patient death; or

''(B) 5 calendar days after an in vitro clinical test developer receives or otherwise becomes aware of information that reasonably suggests the event presents an imminent threat to public health.

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

''(d) DEFINITIONS.—In this section—

''(1) the term 'adverse event'—

''(A) means—

''(i) death of, or serious injury to, a specific patient or user for which it is reasonably believed that an in vitro clinical test error contributed to such death or serious injury; or

''(ii) an in vitro clinical test error that may have reasonable likelihood to cause serious injury or death; and

''(B) excludes laboratory errors that are subject to the requirements of section 353 of

the Public Health Service Act and corrective or preventive actions to prevent such errors;

"(2) the term 'in vitro clinical test error'—

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

"(B) includes an inaccurate false result that reaches a health care provider, patient, or consumer, except that such term excludes any such event or error related to laboratory operations pursuant to section 353 of the Public Health Service Act; and

"(3) the term 'serious injury' means—

"(A) a significant delay in a critical diagnosis or causing the absence, delay, or discontinuation of critical medical treatment or that irreversibly or seriously and negatively alters the course of the disease or condition; or

"(B) an injury that—

"(i) is life threatening;

"(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

''(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

''SEC. 587M. CORRECTIONS AND REMOVALS.

''(a) IN GENERAL.—The Secretary shall promulgate regulations to implement this section, including information necessary to be reported to ensure the analytical and clinical validity of in vitro clinical tests, and the safety of specimen receptacles.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) IN GENERAL.—Each in vitro clinical test developer or importer shall report to the Secretary any correction or removal of an in vitro clinical test undertaken by such developer or importer if the removal or correction was undertaken—

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

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

''(2) EXCEPTION.—No report of the correction or removal of an in vitro clinical test is required under paragraph (1) if a report of the correction or

removal is required under, and has been submitted under, section 587L.

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

''(d) RECORDKEEPING.—A developer or importer of an in vitro clinical test who undertakes a correction or removal of an in vitro clinical test which is not required to be reported under this subsection shall keep a record of such correction or removal.

''(e) RECALL COMMUNICATIONS.—Upon the voluntary reporting of a correction or removal by the developer—

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

''(2) not later than 45 calendar days after the developer or other responsible party notifies the Secretary that it has completed a recall action, the Secretary shall provide the developer or other responsible party with a written statement closing the recall action or stating the reasons the Secretary cannot close the recall at that time.

''(f) LIMITATION.—The developer is not required to report a correction or removal of an in vitro clinical test based solely on an adverse event report under section 587L that captures an error within the approved performance standards for such test.

''(g) DEFINITIONS.—For purposes of this section—

''(1) the term 'correction' means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of an in vitro clinical test without its physical removal from its point of use to another location, and does not include routine servicing; and

''(2) the term 'removal' means the physical removal of an in vitro clinical test from its point of use to another location for repair, modification, adjustment, relabeling, destruction, or inspection, and does not include routine servicing.

"SEC. 587N. RESTRICTED IN VITRO CLINICAL TESTS.

''(a) APPLICABILITY.—

''(1) IN GENERAL.—The Secretary, in issuing an approval of an in vitro clinical test under section 587B of a category described in paragraph (3) may require that such test be restricted to sale, distribution, or use upon such conditions as the Secretary may prescribe under paragraph (2).

"(2) CONDITIONS PRESCRIBED BY THE SECRETARY.—The conditions prescribed by the Secretary under this paragraph, with respect to an in vitro clinical test described in paragraph (3), are those conditions which the Secretary determines due to the potentiality for harmful effect of such test (including any resulting absence, delay, or discontinuation of appropriate medical treatment), are necessary to assure the analytical or clinical validity of the test, or the safety of a specimen receptacle.

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

"(b) LABELING AND ADVERTISING OF A RESTRICTED IN VITRO CLINICAL TEST.—The label, labeling, and advertising of an in vitro clinical test to which restrictions apply under subsection (a) shall bear such appropriate statements of the restrictions as the Secretary may prescribe in the approval, provisional approval, technology certification, or regulation, as applicable.

"(c) REQUIREMENTS PRIOR TO ENACTMENT.—An in vitro clinical test that was offered, sold, or distributed as

a restricted device prior to the enactment date of this subchapter shall continue to comply with the applicable restrictions imposed under section 515 or section 520(e) until the effective date of restrictions issued under subsection (a).

"SEC. 587O. APPEALS.

"(a) SIGNIFICANT DECISION.—

"(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission of an application for, or a review of, an in vitro clinical test under section 587B or section 587D or regarding an exemption under section 587A, including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

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

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement

regarding how the least burdensome requirements were considered and applied consistent with section 587B(j), as applicable.

''(b) REVIEW OF SIGNIFICANT DECISIONS.—

''(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the agency official who made the significant decision.

''(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after the decision for which the review is requested and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

''(3) TIMEFRAME.—The Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who re-

quests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

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

"SEC. 587P. ACCREDITED PERSONS.

''(a) IN GENERAL.—

''(1) REVIEW OF APPLICATIONS.—

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

''(i) Reviewing applications for pre-market approval under section 587B and applications for technology certification under section 587D.

''(ii) Making recommendations to the Secretary with respect to an approval of an

application under section 587B or issuance of a technology certification order under section 587D.

''(B) REQUIREMENT REGARDING REVIEW RECOMMENDATIONS.—

''(i) IN GENERAL.—In making a recommendation to the Secretary under this section, an accredited person shall notify the Secretary in writing of the reasons for the recommendation concerning the application.

''(ii) TIME PERIOD FOR REVIEW.—Not later than 30 calendar days after the date on which the Secretary is notified of a recommendation under this section with respect to an application for premarket approval or technology certification, the Secretary shall make a determination with respect to the application.

''(C) LACK OF APPLICATIONS WITHIN 2-YEAR TIMEFRAME.—If the Secretary does not receive applications from persons that meet the criteria under subsection (c) within such period, the Secretary—

''(i) may accredit persons under this paragraph after the 2-year period described in subparagraph (A); and

''(ii) shall issue a public notice on the internet website of the Food and Drug Administration calling for applications for such accreditation.

''(2) INSPECTIONS.—

''(A) ACCREDITATION FOR INSPECTIONS.—Subject to subparagraph (B), during the period beginning on the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020 and ending 2 years after the date of enactment of such Act, the Secretary shall accredit persons for the purpose of conducting inspections of in vitro clinical test developers and other persons required to register pursuant to section 587I.

''(B) LACK OF APPLICATIONS WITHIN 2-YEAR TIMEFRAME.—If no persons who meet the criteria for such accreditation apply during the 2-year period described in subparagraph (A), the Secretary—

''(i) may accredit persons under this subparagraph after such period; and

''(ii) shall issue a public notice on the internet website of the Food and Drug Administration calling for applications for such accreditation.

''(C) EFFECT OF ACCREDITATION.—

''(i) IN GENERAL.—Persons accredited under subparagraph (A) to conduct inspections, when conducting such inspections, shall record in writing their specific observations and shall present their observations to the designated representative of the inspected establishment.

''(ii) INSPECTION REPORT REQUIREMENTS.—Each person accredited under this paragraph shall prepare and submit to the Secretary an inspection report in a form and manner designated by the Secretary for conducting inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary. Any statement or representation made by an employee or agent of an establishment to a person accredited to conduct

inspections shall be subject to section 1001 of title 18, United States Code.

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

''(E) INSPECTION LIMITATIONS.—The Secretary shall ensure that inspections carried out under this section are not duplicative of inspections carried out under section 353 of the Public Health Service Act. Inspections under this section shall be limited to the data and information necessary—

''(i) for routine surveillance activities associated with applications under sections 587B and 587D; or

''(ii) to meet the requirements to receive premarket approval under section 587B or a technology certification order under section 587D, as applicable.

''(b) ACCREDITATION.—

''(1) ACCREDITATION PROGRAM.—

''(A) IN GENERAL.—The Secretary may provide for accreditation under this section through programs administered by the Food

and Drug Administration, by other non-Federal government agencies, or by qualified nongovernmental organizations. A person may be accredited for the review of both applications submitted under sections 587B and 587D as described in subsection (a)(1)(A) and to conduct inspection activities under subsection (a)(2)(A), or for a subset of such review or activities.

''(B) ELIGIBLE PERSONS.—Not later than 180 days after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall issue draft guidance on the criteria that the Secretary will use to accredit or deny accreditation to a person who requests such accreditation under subsection (a), and not later than one year after the close of the comment period for the draft guidance issued in this section, issue final guidance.

''(C) REQUIREMENTS.—

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

''(ii) SCOPE OF ACCREDITATION.—The accreditation of a person under this section shall specify the particular activities under subsection (a) for which such person is accredited.

''(D) PUBLIC LIST.—The Secretary shall publish on the internet website of the Food and Drug Administration a list of persons who are accredited under this section. Such list shall be updated on at least a monthly basis. The list shall specify the particular activity or activities under this section for which the person is accredited.

''(2) ACCREDITATION PROCESS.—

''(A) ACCREDITATION PROCESS GUIDANCE.—The Secretary shall—

''(i) not later than 180 days after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, issue draft guidance specifying the process for submitting a request for each type of accreditation and reaccreditation under this section, including the form and content of information to be submitted in such a request; and

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

"(B) RESPONSE TO REQUEST.—The Secretary shall respond to a request for accreditation or reaccreditation within 60 calendar days of the receipt of the request. The Secretary's response may be to accredit or reaccredit the person, to deny accreditation, or to request additional information in support of the request. If the Secretary requests additional information, the Secretary shall respond within 60 calendar days of receipt of such additional information to accredit or deny the accreditation.

"(C) TYPE OF ACCREDITATION.—The accreditation or reaccreditation of a person shall specify the particular activity or activities under subsection (a) for which such person is accredited, and shall include any limitation to certain eligible in vitro clinical tests.

"(D) AUDIT.—The Secretary may audit the performance of persons accredited under this section for purposes of ensuring that such persons continue to meet the published criteria for accreditation, and may modify the scope or

particular activities for which a person is accredited if the Secretary determines that such person fails to meet one or more criteria for accreditation.

''(E) SUSPENSION OR WITHDRAWAL.—The Secretary may suspend or withdraw accreditation of any person accredited under this section, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or the published criteria for accreditation, or poses a threat to public health, or fails to act in a manner that is consistent with the purposes of this section.

''(F) REACCREDITATION.—Accredited persons may be initially accredited for up to 4 years. After expiration of such initial period, persons may be reaccredited for unlimited additional 4-year periods, as determined by the Secretary.

''(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

''(1) ELIGIBILITY.—An accredited person, at a minimum, shall—

''(A) not be an employee of the Federal Government;

"(B) not engage in the activities of a developer, as defined in section 587(7);

"(C) not be a person required to register under section 587I, unless such person has established sufficient processes and protocols to separate activities to develop in vitro clinical tests and the activities for which such person would be accredited under subsection (a) and discloses applicable information under this section;

"(D) not be owned or controlled by, and shall have no organizational, material or financial affiliation with, an in vitro clinical test developer or other person required to register under section 587I;

"(E) be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

"(F) ensure that the operations of such person are in accordance with generally accepted professional and ethical business practices; and

"(G) include in its request for accreditation a commitment to, at the time of accredita-

tion and at any time it is performing activities pursuant to this section—

"(i) certify that the information reported to the Secretary accurately reflects the data or protocol reviewed, and the documented inspection findings, as applicable;

"(ii) limit work to that for which competence and capacity are available;

"(iii) treat information received or learned, records, reports, and recommendations as proprietary information of the person submitting such information; and

"(iv) in conducting the activities for which the person is accredited in respect to a particular in vitro clinical test, protect against the use of any employee or consultant who has a financial conflict of interest regarding that in vitro clinical test.

"(2) WAIVER.—The Secretary may waive any requirements in subparagraph (A), (B), (C), or (D) of paragraph (1) upon making a determination that such person has implemented other appropriate controls sufficient to ensure a competent and impartial review.

"(d) COMPENSATION OF ACCREDITED PERSONS.—

''(1) IN GENERAL.—Compensation of an accredited person who reviews an application for premarket approval submitted under section 587B or an application for technical certification submitted under section 587D shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

''(2) INSPECTION ACCREDITATION.—Compensation of an accredited person who is conducting an inspection under section 704 shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

''(e) COOPERATIVE AGREEMENTS.—The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether in vitro clinical tests intended for use in the United States by a person whose facility is located outside the United States shall be refused admission on any of the grounds set forth in section 801(a).

''(f) INFORMATION SHARING AGREEMENTS.—An accredited person may enter into an agreement with a test developer to provide information to the comprehensive test information system under section 587T, including any requirements under section 587I.

''SEC. 587Q. RECOGNIZED STANDARDS.

''(a) IN GENERAL.—The Secretary may by order establish performance standards for an in vitro clinical test or tests with the same indication for use to provide reasonable assurance of the analytical validity, clinical validity, or as applicable safety, of that in vitro clinical test or tests with the same indications for use.

''(b) OTHER STANDARDS.—The Secretary may recognize all or part of appropriate standards established by nationally or internationally recognized standard development organizations for which a person may submit a declaration of conformity in order to meet a requirement under this subchapter to which that standard is applicable. In recognizing a standard, any person requesting recognition of a standard or seeking to use a recognized standard, the Secretary shall follow the processes and requirements, in accordance with section 514(c). Standards for in vitro diagnostic devices previously recognized under section 514(c) shall be considered recognized standards under this section. The application of any such consensus standard

shall only apply prospectively. The Secretary shall issue guidance establishing the criteria and process for such recognition and adoption.

''(c) ORDER PROCESS.—In establishing a standard under subsection (a), the Secretary shall issue a draft order proposing to establish a standard and shall provide for a comment period of not less than 60 calendar days. The Secretary may choose to seek the recommendation of an advisory committee under section 587G concerning a proposed standard either prior to or after issuance of a proposed order. After considering the comments and within 90 days of the close of the comment period, the Secretary shall issue a final order adopting the proposed standard, adopting a modification of the proposed standard or terminating the proceeding.

''(d) AMENDMENT PROCESS.—The procedures established in this section or in guidance issued under this section shall apply to amendment of an existing standard.

''SEC. 587R. INVESTIGATIONAL USE.

''(a) IN GENERAL.—Except as provided in subsection (c), an in vitro clinical test for investigational use shall be exempt from the requirements of this subchapter other than sections 587A, 587O, and 587U.

''(b) REGULATIONS.—Not later than 2 years after the date of enactment of the Verifying Accurate Leading-

edge IVCT Development Act of 2020, the Secretary shall promulgate regulations to implement this section.

''(c) APPLICATION FOR INVESTIGATIONAL USE.—

''(1) IN GENERAL.—The following shall apply with respect to in vitro clinical tests for investigational use:

''(A) STREAMLINING APPLICATIONS SUBMITTED UNDER THIS SECTION.—Requirements with respect to such tests shall be completed in accordance with current investigational use requirements for institutional review boards and current processes for any analytical or clinical validation.

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

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

''(ii) the number of human subjects that are to be involved in such testing;

''(iii) the need to permit changes to be made in the in vitro clinical test involved during testing conducted in accordance

with a plan required under paragraph (3)(B); or

''(iv) whether the clinical testing of such in vitro clinical test is for the purpose of developing data to obtain approval to offer such test.

''(C) SIGNIFICANT RISK STUDIES.—In the case of an in vitro clinical test the investigational use of which poses a significant risk, a sponsor of an investigation of such a test seeking an investigational use exemption shall submit to the Secretary an investigational use application with respect to the test in accordance with paragraphs (2) and (3). For purposes of this subparagraph, the term 'significant risk' means, with respect to an in vitro clinical test that is a high-risk test, and that the use of the test—

''(i) is a use of substantial importance in performing an activity or activities described in subsection (ss)(1)(A) for, a serious or life-threatening disease or condition without confirmation of the diagnosis by a medically established means;

"(ii) requires an invasive sampling procedure that presents a significant risk to the human subject; or

"(iii) otherwise presents a reasonably foreseeable serious risk to the health of a human subject.

"(D) NON-SIGNIFICANT RISK TESTS.—In the case of an in vitro clinical test, the investigational use of which does not pose a significant risk—

"(i) the sponsor of such investigation shall—

"(I) conduct such investigation in compliance with an investigational plan specified in paragraph (5) and labeling specified in paragraph (3)(A)(ii);

"(II) ensure each investigator obtains informed consent under part 50 of title 21, Code of Federal Regulations (or any successor regulations), subject to the exceptions set forth in paragraphs (5)(A)(iii) and (5)(B);

"(III) submit a listing to the Secretary of such investigation; and

''(IV) maintain records with respect to all requirements in this subparagraph; and

''(ii) the sponsor may rely on any exception or exemption identified in paragraph (5)(B) or as established by the Secretary in regulations issued under subsection (b).

''(2) APPLICATION CONTENT.—An investigational use application shall be submitted in such time and manner and contain such information as the Secretary may require in regulation, and shall include an investigational plan for proposed clinical testing and assurances that the sponsor submitting the application will—

''(A) establish and maintain records relevant to the investigation of such in vitro clinical test; and

''(B) submit to the Secretary annual reports of data obtained as a result of the investigational use of the in vitro clinical test during the period covered by the exemption that the Secretary reasonably determines will enable the Secretary—

"(i) to ensure compliance with the conditions for approval specified in paragraph (3);

"(ii) to review the progress of the investigation involved; and

"(iii) to evaluate the analytical validity and clinical validity of such test.

"(3) CONDITIONS OF APPROVAL.—

"(A) IN GENERAL.—An investigational use application with respect to significant risk tests shall only be approved if each of the following conditions is met:

"(i) The risks to the subjects of the in vitro clinical test are outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, and adequate assurance of informed consent is provided in accordance with paragraph (5)(A)(iii).

"(ii) The proposed labeling for the in vitro clinical test involved clearly and conspicuously states 'For investigational use'.

"(iii) Such other requirements the Secretary determines to be necessary for the protection of the public health and

safety as long as the requirements do not unduly delay investigation after finding that the results of such investigation establish sufficient data to support clinical or analytical validity.

''(B) CERTAIN SIGNIFICANT RISK IN VITRO CLINICAL TESTS FOR AN UNMET NEED.—As a condition of approval under this paragraph, the Secretary shall not impose a limit on the sample size for a significant risk in vitro clinical test that meets the requirements of section 587C, as long as such test is developed within a laboratory that is certified to conduct high-complexity testing under section 353 of the Public Health Service Act.

''(4) COORDINATION WITH INVESTIGATIONAL NEW DRUG APPLICATIONS.—Any requirement for the submission of a report to the Secretary pursuant to an investigational new drug application involving an in vitro clinical test shall supersede the reporting requirement in paragraph (2)(B), but only to the extent the requirement with respect to the investigational new drug application is duplicative of the reporting requirement under such paragraph.

''(5) INVESTIGATION PLAN REQUIREMENTS.—

"(A) IN GENERAL.—With respect to an investigational plan submitted under paragraph (2)(A), the sponsor submitting such plan shall—

"(i) in the case of such a plan submitted to an institutional review committee, promptly notify the Secretary of the approval or the suspension or termination of the approval of such plan by an institutional review committee;

"(ii) in the case of an in vitro clinical test made available to investigators for clinical testing, assurance that all investigators will comply with this section, regulations promulgated or revised under this section, and applicable human subjects regulations; and

"(iii) submit an assurance to the Secretary that informed consent will be obtained from each human subject (or the representative of such subject) of proposed clinical testing involving such in vitro clinical test, except in the case that—

"(I) there is a life-threatening situation involving the human subject

of such testing which necessitates the use of such in vitro clinical test;

''(II) it is not feasible to obtain informed consent from the subject; and

''(III) there is not sufficient time to obtain such consent from a representative of such subject.

''(B) EXCEPTION.—The informed consent of human subjects shall not be required with respect to clinical testing conducted as part of an investigation, if—

''(i) the clinical testing uses remnants of specimens collected for routine clinical care or analysis that would have been discarded, leftover specimens that were previously collected for other research purposes, or specimens obtained from specimen repositories;

''(ii) the identity of the subject of the specimen is not known to, and may not readily be ascertained by, the investigator or any other individual associated with the investigation, including the sponsor;

"(iii) any clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor;

"(iv) the individuals caring for the human subjects as patients are different from, and do not share information about the patient with, the individuals conducting the investigation; and

"(v) the specimens are provided to the investigators without personally identifiable information and the supplier of the specimens has established policies and procedures to prevent the release of personally identifiable information.

"(d) REVIEW OF APPLICATIONS.—

"(1) IN GENERAL.—The Secretary may issue an order approving an investigation as proposed, approving it with conditions or modifications, or disapproving it.

"(2) FAILURE TO ACT.—Unless the Secretary, not later than the date that is 30 calendar days after the date of the submission of an investigational

use application that meets the requirements of subsection (c)(2), issues an order under subsection (d)(1) and notifies the sponsor submitting the application, the application shall be treated as approved as of such date without further action by the Secretary.

''(3) DISAPPROVAL.—The Secretary may disapprove an investigational use application submitted under this subsection if the Secretary determines that the investigation with respect to which the application is submitted does not conform to the requirements of subsection (c)(3). A listing of such disapproval submitted to the sponsor with respect to such an application shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application.

''(e) WITHDRAWAL OF APPROVAL.—

''(1) IN GENERAL.—The Secretary may, by administrative order, withdraw the approval of an exemption granted under this section with respect to an in vitro clinical test, including an exemption granted based on the Secretary's failure to act pursuant to subsection (d)(2), if the Secretary determines that the test does not meet the applicable conditions under subsection (c)(3) for such approval.

''(2) OPPORTUNITY TO BE HEARD.—

''(A) IN GENERAL.—Subject to subparagraph (B), an order withdrawing the approval of an exemption granted under this section may be issued only after the Secretary provides the applicant or sponsor of the test with an opportunity for an informal hearing.

''(B) EXCEPTION.—An order referred to in subparagraph (A) with respect to an exemption granted under this subsection may be issued on a preliminary basis before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption will result in an unreasonable risk to the public health. The Secretary will provide an opportunity for an informal hearing promptly following any preliminary action under this subparagraph.

''(f) CHANGES.—

''(1) IN GENERAL.—The regulations promulgated under subsection (b) shall provide, with respect to an in vitro clinical test for which an exemption under this subsection is in effect, procedures and conditions under which the changes to the test are allowed without the additional approval of an ap-

plication for an exemption or the approval of a supplement to such an application. Such regulations shall provide that such a change may be made if—

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

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

"(2) CONDITIONS.—The conditions specified in this paragraph are that—

"(A) in the case of developmental changes to an in vitro clinical test (including manufacturing changes), the changes—

"(i) do not constitute a significant change in design or in basic principles of operation;

"(ii) do not affect the rights, safety, or welfare of the human subjects (if any) involved in the investigation; and

"(iii) are made in response to information gathered during the course of an investigation; and

''(B) in the case of changes to clinical protocols applicable to the test, the changes do not affect—

''(i) the validity of data or information resulting from the completion of an approved clinical protocol;

''(ii) the scientific soundness of a plan submitted under subsection (c)(5); or

''(iii) the rights, safety, or welfare of the human subjects (if any) involved in the investigation.

''(g) CLINICAL HOLD.—

''(1) IN GENERAL.—At any time, the Secretary may impose a clinical hold with respect to an investigation of an in vitro clinical test if the Secretary makes a determination described in paragraph (2). The Secretary shall, in imposing such clinical hold, specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing. The applicant or sponsor may immediately appeal any such determination pursuant to section 587O.

''(2) DETERMINATION.—For purposes of paragraph (1), a determination described in this sub-

paragraph with respect to a clinical hold is a determination that—

"(A) the in vitro clinical test involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the in vitro clinical test, the design of the clinical investigation, the condition for which the in vitro clinical test is to be investigated, and the health status of the subjects involved;

"(B) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish; or

"(C) any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

"SEC. 587S. COLLABORATIVE COMMUNITIES FOR IN VITRO CLINICAL TESTS.

"(a) IN GENERAL.—

''(1) For the purposes of facilitating community solutions and decision making with respect to in vitro clinical tests, the Secretary may participate in collaborative communities comprised of public and private participants that may provide recommendations and other advice to the Secretary on the development and regulation of in vitro clinical tests.

''(2) A collaborative community under this section shall have broad representation of interested private and public-sector stakeholder communities and may include patients, care partners, academics, healthcare professionals, healthcare systems, payers, Federal and State agencies, entities responsible for accrediting clinical laboratories, international regulatory bodies, test developers, or other interested entities or communities.

''(b) GUIDANCE.—The Secretary shall issue a draft guidance not later than 180 days after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, addressing the participation process and framework to build consensus, and how the Secretary may consider, review, and implement recommendations under subsection (c).

''(c) RECOMMENDATIONS.—A collaborative community for in vitro clinical tests may make recommendations to the Secretary on matters including—

''(1) mitigating measures for in vitro clinical tests;

''(2) standards development activities and performance standards for in vitro clinical tests or groups of such tests;

''(3) scientific and clinical evidence to support new claims for in vitro clinical tests;

''(4) new technologies and methodologies related to in vitro clinical tests;

''(5) stakeholder communication and engagement; and

''(6) development of effective policies and processes, including to develop tests, and to regulate such tests in accordance with least burdensome principals under this Act.

''(d) USE BY SECRETARY.—

''(1) IN GENERAL.—The Secretary may adopt recommendations made under subsection (b), or otherwise incorporate the feedback from collaborative communities into regulatory decision making, through rulemaking or guidance, as appropriate.

''(2) CLARIFICATION.—The Secretary is not required to adopt recommendations submitted by collaborative communities.

''(e) TRANSPARENCY.—The Secretary shall—

''(1) publish on the internet website of the Food and Drug Administration matters for which it is seeking comments or recommendations, in a timely manner;

''(2) maintain a list of all collaborative communities in which the Secretary participates and make such list available on the internet website of the Food and Drug Administration; and

''(3) post on the internet website of the Food and Drug Administration at least once every year a report on the recommendations it has adopted and recommendations it has not adopted from collaborative communities.

''(f) PARTICIPATION.—The Secretary may participate in a collaborative community only if such community requires members to disclose conflicts of interest and has established a process to address conflicts of interest.

''(g) EXCEPTION.—The Federal Advisory Committee Act in the appendix to title 5 shall not apply to collaborative communities established and used in accordance with this section.

"SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.

"(a) PURPOSE.—For the purposes of improving the transparency of information on in vitro clinical tests and allowing patients and health care providers better access to information about in vitro clinical tests, the Secretary shall establish a comprehensive test information system.

"(b) ESTABLISHMENT.—Not later than 2 years after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2020, the Secretary shall make available a comprehensive test information system for in vitro clinical tests that is designed to—

"(1) provide a transparent interface on the internet website of the Food and Drug Administration for stakeholders, to the extent permitted by applicable law, to access the—

"(A) regulatory pathway designation information for each in vitro clinical test or tests with the same indications for use;

"(B) registration and listing information provided by developers under section 587I, including the use of a link for labels;

"(C) adverse event reports submitted under section 587L;

"(D) reports of corrections and removals submitted under section 587M; and

''(E) other information pertaining to an in vitro clinical test or tests with the same indications for use, as the Secretary determines appropriate; and

''(2) provide a secure portal for electronic submission, including applications and other in vitro clinical test submissions, registration and listing information, and adverse event reports.

''(c) SUBMISSION FUNCTION.—The comprehensive test information system shall serve as the electronic submission service for test developers submitting information for applications under sections 587B and 587D.

''SEC. 587U. PREEMPTION.

''(a) IN GENERAL.—No State, tribal, or local government (or political subdivision thereof) may establish or continue in effect any requirement related to the development, manufacture, labeling, distribution, sale, or use of an in vitro clinical test that is different from, or in addition to, the requirements of this subchapter.

''(b) EXCEPTIONS.—Subsection (a) shall not be construed to affect the authority of a State, tribal, or local government—

''(1) to license laboratory personnel, health care practitioners, or health care facilities or to regulate

any aspect of a health care practitioner-patient relationship; or

''(2) to enforce laws of general applicability, such as zoning laws, environmental laws, labor laws, and general business laws.

''(c) CLARIFICATION.—This section shall not be construed to shift liability to health care practitioners or other users.

''SEC. 587V. ADULTERATION.

''An in vitro clinical test shall be deemed to be adulterated:

''(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

''(2) If it has been developed, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

''(3) If its container or package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

''(4) If it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a).

''(5) If its analytical or clinical validity, or with respect to a specimen receptacle, its safety, or its strength, purity, or quality, differs from or falls below that which it purports or is represented to possess.

''(6) If it is required to be, declared to be, purports to be, or is represented as being, in conformity with any performance standard established or recognized under section 587Q and is not in all respects in conformity with such standard.

''(7) If it is required to be in conformity with a mitigating measure established under section 587E and is not in all respects in conformity with such mitigating measure.

''(8) If it fails to have an approved premarket application under section 587B unless such in vitro clinical test can be lawfully offered—

''(A) for clinical use pursuant to an exemption under section 587A;

''(B) for emergency use pursuant to an authorization under section 564; or

''(C) for investigational use pursuant to section 587R.

''(9) If it is not in conformity with any condition established under section 587B, 587D, or 564.

''(10) If it purports to be an in vitro clinical test that is offered for clinical use subject to an exemption under section 587A and it fails to meet or maintain any criteria, condition, or requirement of such exemption.

''(11) If it has been granted an exemption under section 587R for investigational use, and the person granted such exemption or any investigator who uses such in vitro clinical test under such exemption fails to comply with a requirement prescribed by or under such section.

''(12) If it fails to meet the quality requirements prescribed in or established under section 587J (as applicable), or the methods used in, or facilities or controls used for, its development, manufacture, packing, storage, or installation are not in conformity with applicable requirements established under such section.

''(13) If it has been developed, manufactured, processed, packed or held in any establishment, factory, or warehouse and the owner, operator or agent of such establishment, factory, or warehouse delays, denies, or limits an inspection, or refuses to permit entry or inspection.

''(14) If it is not in compliance with any restriction required under section 587N.

''SEC. 587W. MISBRANDING.

''An in vitro clinical test shall be deemed to be misbranded:

''(1) If its labeling is false or misleading in any particular.

''(2) If in a package form unless it bears a label containing—

''(A) the name and place of business of the test developer, manufacturer, packer, or distributor; and

''(B) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count with respect to small packages, unless an exemption is granted by the Secretary by the issuance of guidance.

''(3) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling, including a test report, is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and

understood by the ordinary individual under customary conditions of purchase and use.

''(4) Unless its labeling bears adequate directions for use and such adequate warnings as are necessary for the protection of users of the in vitro clinical test and recipients of the results of such in vitro clinical test, including patients, consumers, donors, and related health care professionals. Required labeling for in vitro clinical tests intended for use in health care facilities or by a health care professional may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the test developer, manufacturer, or distributor affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

''(5) If it causes serious or adverse health consequences or death, including through absence, delay, or discontinuation in diagnosis or treatment, when used in the manner prescribed, recommended, or suggested in the labeling thereof.

''(6) If it was developed or manufactured in an establishment not duly registered under section 587I or it was not included in a listing under section

587I, in accordance with timely reporting requirements under this subchapter.

''(7) In the case of any in vitro clinical test subject to restrictions under section 587N, (1) if its advertising is false or misleading in any particular, (2) if it is offered for clinical use, sold, distributed, or used in violation of such restrictions, or (3) unless the test developer, manufacturer, or distributor includes in all advertisements and other descriptive printed matter that such person issues or causes to be issued, a brief statement of the intended uses of the in vitro clinical test and relevant warnings, precautions, side effects, and contraindications. This subsection shall not be applicable to any printed matter that the Secretary determines to be labeling as defined in section 201(m) or section 587K.

''(8) If it was subject to a mitigating measure established under section 587E, unless it bears such labeling as may be prescribed in such mitigating measure.

''(9) If it was subject to a standard established under section 587Q, unless it bears such labeling as may be prescribed in such standard.

''(10) Unless it bears such labeling as may be prescribed by or established under an applicable labeling requirement under this Act.

''(11) If there was a failure or refusal to comply with any requirement prescribed under section 587I or 587X, or to comply with a requirement under section 587Y, or to provide any report, material, or information required under this subchapter.

''SEC. 587X. POSTMARKET SURVEILLANCE.

''(a) IN GENERAL.—

''(1) IN GENERAL.—In addition to other applicable requirements under this Act, the Secretary may issue an order requiring a developer to conduct postmarket surveillance of a single in vitro clinical test as a condition of approval under section 587B.

''(2) EXEMPT TESTS.—The Secretary may order postmarket surveillance for tests exempt pursuant to section 587A for which the failure of the in vitro clinical test to meet the applicable standard for approval is likely to result in serious or adverse health consequences or death from use of the single in vitro clinical test.

''(3) CONSIDERATION.—In determining whether to require a developer to conduct postmarket surveillance of an in vitro clinical test, the Secretary shall

take into consideration the benefits and risks for the patient and the least burdensome principles under section 587B.

''(b) SURVEILLANCE APPROVAL.—

''(1) Each developer required to conduct a surveillance of an in vitro clinical test shall submit, within 30 days of receiving an order from the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has the appropriate qualifications and experience to undertake such surveillance and if the plan will result in useful data that can reveal unforeseen adverse events or other information necessary to protect the health of patients or the public.

''(2) The developer shall commence surveillance under this section not later than 15 months after the day on which the Secretary orders such postmarket surveillance, unless the Secretary determines more time is needed to commence surveillance.

''(3) The Secretary may order a prospective surveillance period of up to 3 years. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agree-

ment can be reached, after the completion of a dispute resolution process.

"SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.

"(a) IN GENERAL.—All presubmissions and submissions to the Food and Drug Administration with respect to an in vitro clinical test shall include an electronic copy of such presubmission or submission, and, with respect to the information required under sections 587B and 587D, shall utilize the system described in section 587T.

"(b) ELECTRONIC FORMAT.—Beginning on such date as the Secretary specifies in final guidance issued under subsection (c), presubmissions and submissions for in vitro clinical tests (and any appeals of action taken by the Secretary with respect to such presubmissions and submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.

"(c) GUIDANCE.—The Secretary shall issue guidance implementing this section. In such guidance, the Secretary may—

"(1) provide standards for the electronic copy required under subsection (a) or the submission in electronic format required under subsection (b);

"(2) set forth criteria for waivers of or exemptions from the requirements of subsection (a) or (b); and

''(3) provide any other information for the efficient implementation and enforcement of this section.

"SEC. 587Z. POSTMARKET REMEDIES.

''(a) SAFETY NOTICE.—

''(1) IN GENERAL.—If the Secretary determines that an in vitro clinical test presents an unreasonable risk of substantial harm to the public health, and notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate the risk, the Secretary may issue such order as may be necessary to ensure that adequate safety notice is provided in an appropriate form, by the persons and means best suited under the circumstances, to all health care professionals who prescribe, order, or use the in vitro clinical test and to any other person (including developers, manufacturers, importers, distributors, retailers, and users) who should properly receive such notice.

''(2) NOTICE TO INDIVIDUALS.—An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to

be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notice. If the Secretary makes such a determination with respect to such individuals, the order shall advise the health care professionals who prescribed, ordered, or used the in vitro clinical test provide notification to the individuals for whom the health professionals prescribed, ordered, or used such test, of the risk presented by such in vitro clinical test and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons required to give notice under the order.

''(b) REPAIR, REPLACEMENT, OR REFUND.—

''(1) DETERMINATION AFTER AN INFORMAL HEARING.—

''(A) IN GENERAL.—If, after affording opportunity for an informal hearing, the Secretary determines that—

''(i) an in vitro clinical test presents an unreasonable risk of substantial harm to the public health;

"(ii) there are reasonable grounds to believe that the in vitro clinical test was not properly developed or manufactured considering the state of the art as it existed at the time of its development or manufacture;

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a developer, manufacturer, importer, distributor, or retailer of the in vitro clinical test to exercise due care in the installation, maintenance, repair, or use of the in vitro clinical test; and

"(iv) the notice authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the developer, manufacturer, importer, or any distributor of such in vitro clinical test, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order

issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a health professional or user of the in vitro clinical test) other than the person the Secretary determines bears such responsibility.

''(B) SECRETARY APPROVAL OF PLAN.—Within 30 calendar days of issuing an order under subparagraph (A), the Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless the Secretary determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order

was issued will be eliminated. If the Secretary disapproves a plan, the Secretary shall order a revised plan to be submitted within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the in vitro clinical test with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

''(2) ACTIONS ON A PLAN.—The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

''(A) To repair the in vitro clinical test so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1)(A) was issued.

"(B) To replace the in vitro clinical test with a like or equivalent test which is in conformity with all applicable requirements of this Act.

"(C) To refund the purchase price of the in vitro clinical test (less a reasonable allowance for use if such in vitro clinical test has been in the possession of the user for one year or more at the time of notice ordered under subsection (a), or at the time the user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1)(A), whichever occurs first).

"(3) NO CHARGE.—No charge shall be made to any person (other than a developer, manufacturer, importer, distributor or retailer) for using a remedy described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a developer, manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

''(c) REIMBURSEMENT.—An order issued under subsection (b)(1)(A) with respect to an in vitro clinical test may require any person who is a developer, manufacturer, importer, distributor, or retailer of the in vitro clinical test to reimburse any other person who is a developer, manufacturer, importer, distributor, or retailer of such in vitro clinical test for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

''(d) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that an in vitro clinical test approved under section 587B would cause serious, adverse health consequences or death, including by the absence, delay, or discontinuation of appropriate medical treatment, the Secretary shall issue an order requiring the appropriate person (including the developers, manufacturers, importers, distributors, or retailers of the in vitro clinical test)—

"(A) to immediately cease distribution of such in vitro clinical test; and

"(B) to immediately notify health professionals and user facilities of the order and to instruct such professionals and facilities to cease use of such in vitro clinical test.

"(2) INFORMAL HEARING.—The order issued under paragraph (1)(A), shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 calendar days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such in vitro clinical test. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(3) AMENDED ORDER.—

"(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that the order should be amended to include a recall of the in vitro clinical test with respect to which the order was issued, the Secretary shall, except

as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the recall will occur and shall require periodic reports describing the progress of the recall.

''(B) REQUIREMENTS.—An amended order under subparagraph (A)—

''(i) shall not include recall of the in vitro clinical test from individuals;

''(ii) shall not include recall of an in vitro clinical test from test user facilities if the Secretary determines that the risk of recalling such in vitro clinical test from the facilities presents a greater health risk than the health risk of not recalling the in vitro clinical test from use; and

''(iii) shall provide for notice to individuals subject to the risks associated with the use of such in vitro clinical test. In providing the notice required by this clause, the Secretary may use the assistance of health professionals who prescribed, ordered, or used such an in vitro clinical test for individuals.

''(4) CLARIFICATION.—The remedy provided by this subsection shall be in addition to remedies provided by subsections (b) and (c).''.

SEC. 4. ENFORCEMENT AND OTHER PROVISIONS.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in paragraphs (a), (b), (c), (g), (k), (q), (r), and (y), by inserting ''in vitro clinical test,'' after ''device,'' each place it appears;

(2) in paragraph (y) by inserting ''or 587P'' after ''section 523'' each place it appears; and

(3) by adding at the end, the following:

''(fff)(1) The introduction or delivery for introduction into interstate commerce of an in vitro clinical test in violation of section 587B(a).

''(2) The false, fraudulent, or deceptive claiming for an in vitro clinical test of an exemption from the premarket review required under section 587B.

''(3) When claiming an exemption under section 587A from the premarket review required under section 587B, the failure to maintain complete and accurate documentation for the exemption as required under section 587A or the failure to provide labeling required under section 587A.

''(4) With respect to an in vitro clinical test, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

''(5) The making of a false, fraudulent, or materially deceptive analytical or clinical claim for an in vitro clinical test—

''(A) in any application, report, or notification submitted to the Secretary under this Act; or

''(B) in the labeling or advertising of an in vitro clinical test.

''(6) The failure to comply with a condition of approval, performance standard, mitigating measure, or restriction established in an order approving an application or supplement under section 587B; the failure to perform a risk analysis required by section 587B; the failure to submit an annual report required under section 587B(k); or the failure to complete postmarket studies required under section 587V.

''(7) The marketing of an in vitro clinical test in violation of—

''(A) an order issued by the Secretary under section 587A; or

''(B) any requirement under section 587A.

''(8) With respect to technology certification under section 587D, the refusal to permit, or unreasonable delay

in permitting, an inspection authorized under section 587D(f)(3)(G); the failure to comply with applicable requirements to submit an application or report under section 587D(e); or the failure to comply with applicable maintenance requirements under section 587D(h).

''(9) The failure to comply with an applicable mitigating measure established under section 587E or to maintain the documentation required under section 587E(b); or the failure to comply with a performance standard established under section 587Q.

''(10) The failure to register in accordance with section 587I, the failure to provide information required under section 587I(b), or the failure to maintain or submit information required under section 587I(c).

''(11) The failure to submit a report required under section 587L or 587M; the failure to comply with a restriction imposed under section 587N; or the failure to comply with labeling and advertising requirements under section 587N(b).

''(12) The failure to comply with the requirements of section 587P (relating to accredited persons).

''(13) The failure to comply with any requirement prescribed or established under section 587R; the failure to furnish any notification, information, material, or re-

port required under section 587R; or the failure to comply with an order issued under section 587R.''.

(b) PENALTIES.—Section 303(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)) is amended—

(1) in subparagraph (A), by inserting ''or in vitro clinical tests'' after ''devices''; and

(2) in subparagraph (B)(i)—

(A) by inserting '', or 587J or 587L,'' after ''520(f)''; and

(B) by inserting '', or who violates section 587M(b) with respect to a correction report'' after ''risk to public health''.

(c) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(E) Any''; and

(B) by inserting '', and (F) Any adulterated or misbranded in vitro clinical test'' after ''tobacco product'';

(2) in subsection (d)(1), by inserting ''in vitro clinical test,'' after ''device,''; and

(3) in subsection (g)—

(A) in paragraph (1), by inserting ", in vitro clinical test," after "device" each place it appears; and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ", in vitro clinical test," after "device"; and

(ii) in subparagraph (B), by inserting "or in vitro clinical test" after "device" each place it appears.

(d) DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION.—Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended by adding at the end the following:

"(n) IN VITRO CLINICAL TESTS; MANDATORY DEBARMENT REGARDING THIRD-PARTY INSPECTIONS AND REVIEWS.—

"(1) IN GENERAL.—If the Secretary finds that a person has been convicted of a felony under section 301(gg), 301(fff)(2), 301(fff)(5), or 301(fff)(8), the Secretary shall debar such person from being accredited under section 587P and from carrying out activities under an agreement described in section 803(b).

''(2) DEBARMENT PERIOD.—The Secretary shall debar a person under paragraph (1) for the following periods:

''(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

''(B) The debarment of an individual shall be permanent.

''(3) TERMINATION OF DEBARMENT; JUDICIAL REVIEW; OTHER MATTERS.—Subsections (c)(3), (d), (e), (i), (j), and (l)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.''.

(e) JUDICIAL REVIEW.—Section 517(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)) is amended—

(1) in paragraph (8), by striking ''or'' at the end;

(2) in paragraph (9), by inserting ''or'' after the comma at the end; and

(3) before the matter that follows paragraph (9), by inserting the following:

''(10) an order issued pursuant to section 587B, 587D, 587R, or 587S,''.

(f) EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.—Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended—

(1) in subsections (a) through (d)—

(A) by striking ''or investigational devices'' each place it appears and inserting '', investigational devices, or investigational in vitro clinical tests''; and

(B) by striking ''or investigational device'' each place it appears (other than the second such place in paragraph (3)(A)) and inserting '', investigational device, or investigational in vitro clinical test'';

(2) in subsection (b)(4) by striking ''or 520(g)'' and inserting '', 520(g), or 587R'' each place it appears;

(3) in subsection (c)—

(A) by amending the subsection heading to read: ''TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS, TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS, AND TREATMENT INVESTIGATIONAL IN VITRO CLINICAL TEST EXEMPTIONS'';

(B) in paragraph (3)(A), by striking ''or investigational device exemption in effect under section 520(g)'' and inserting '', investigational device exemption in effect under section 520(g), or investigational in vitro clinical test exemption under section 587R'';

(C) by striking ''or treatment investigational device exemption'' each place it appears and inserting '', treatment investigational device exemption, or treatment investigational in vitro clinical test exemption''; and

(D) in the matter following paragraph (7) by striking ''or 520(g)'' each place it appears and inserting '', 520(g) or 587R''; and

(4) by amending subsection (e) to read as follows:

''(e) DEFINITIONS.—In this section, the terms 'investigational drug', 'investigational device', 'investigational in

vitro clinical test', 'treatment investigational new drug application', 'treatment investigational device exemption', and 'treatment investigational in vitro clinical test exemption' shall have the meanings given the terms in regulations prescribed by the Secretary.''.

(g) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8a(b)) is amended by inserting ''an in vitro clinical test, as defined in subsection (ss) of such section,'' before ''or a biological product''.

(h) PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION.—The heading of subsection (a) of section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended by striking ''DRUGS AND DEVICES'' and inserting ''DRUGS, DEVICES, AND IN VITRO CLINICAL TESTS''.

(i) REGULATIONS AND HEARINGS.—Section 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting ''and in vitro clinical tests'' after ''devices''.

(j) FACTORY INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other than subsection (g)) is amended—

(1) by striking ''drugs or devices'' each place it appears and inserting ''drugs, devices, or in vitro clinical tests'';

(2) in subsection (a)(1), in the third sentence, by striking ''or chapter IX'' and inserting ''section 587R or chapter IX'';

(3) in subsection (a)(2)(B)—

(A) by inserting ''or in vitro clinical tests'' after ''prescribe or use devices''; and

(B) by inserting ''or in vitro clinical tests'' after ''process devices'';

(4) by inserting ''in vitro clinical test,'' after ''device,'' each place it appears;

(5) after making the amendments in paragraphs (1) and (2), by inserting ''in vitro clinical tests,'' after ''devices,'' each place it appears;

(6) in subsection (e), by inserting '', or section 587L, 587M, or 587R,'' after ''section 519 or 520(g)''; and

(7) in subsection (f)(3)—

(A) in subparagraph (A), by striking ''or'' at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ''; or''; and

(C) after subparagraph (B), by inserting the following:

''(C) is accredited under section 587P.''.

(k) PUBLICITY.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended by inserting ''in vitro clinical tests,'' after ''devices,''.

(l) PRESUMPTION.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by inserting ''in vitro clinical test,'' after ''device,''.

(m) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''in vitro clinical tests,'' after ''devices,'' each place it appears; and

(B) by inserting ''in the case of an in vitro clinical test, the test does not conform to the applicable requirements of section 587J, or'' after ''requirements of section 520(f), or'';

(2) in subsection (d)(3)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by inserting ''and no component of an in vitro clinical test or other article of in vitro

clinical test that requires further processing,'' after ''health-related purposes'';

(ii) in clause (i), by striking ''drug or device'' and inserting ''drug, device, or in vitro clinical test''; and

(iii) in clause (i)(I), by inserting ''in vitro clinical test,'' after ''device,''; and

(B) in subparagraph (B), by inserting ''in vitro clinical test,'' after ''device,''; and

(3) in subsection (e)(1), by inserting ''in vitro clinical test,'' after ''device,''.

(n) OFFICE OF INTERNATIONAL RELATIONS.—Section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383) is amended—

(1) in subsection (b)—

(A) in the matter preceding paragraph (1), by inserting ''and in vitro clinical tests'' after ''devices''; and

(B) in paragraph (1), by inserting ''quality requirements established under section 587J; and'' at the end; and

(2) in subsection (c)—

(A) in paragraph (2), by inserting ''in vitro clinical tests,'' after ''devices,''; and

(B) in paragraph (4), by inserting ''or in vitro clinical tests'' after ''devices''.

(o) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by inserting '', or section 587I'' after ''510(h)''.

(p) FOOD AND DRUG ADMINISTRATION.—Section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)) is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the semicolon at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(F) in vitro clinical tests are analytically and clinically valid;''.

(q) OFFICE OF WOMEN'S HEALTH.—Section 1011(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399b(b)) is amended—

(1) in paragraph (1), by inserting ''in vitro clinical tests,'' after ''devices,''; and

(2) in paragraph (4), by striking ''and device manufacturers'' and inserting ''device manufacturers, and in vitro clinical test developers,''.

(r) COUNTERMEASURE PROVISIONS OF THE PHSA.—Title III of the PHSA is amended—

(1) in section 319F–2(c)(1)(B) (42 U.S.C. 247d–6b(c)(1)(B)) is amended—

(A) by striking ''or device'' and inserting ''device''; and

(B) by inserting ''or an in vitro clinical test (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss)))'' after ''Act (21 U.S.C. 321(h)))'';

(2) in section 319F–1(a)(2) (42 U.S.C. 247d–6a(a)(2)), by inserting ''an in vitro clinical tests (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss))),'' before ''or device''; and

(3) in section 319F–3(i)(7) (42 U.S.C. 247d–6d(i)(7)), by inserting ''an in vitro clinical tests (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss))),'' before ''or device''.

SEC. 5. TRANSITION.

(a) IMPLEMENTATION.—

(1) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this

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

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

(A) within 2 years of the date of enactment of this Act hold the public meetings described in subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 3;

(B) within 2 years of the date of enactment of this Act promulgate regulations required under sections 587L, 587M, 587V, and 587W;

(C) issue final guidance on premarket review requirements under section 587B, technology certification review requirements under section 587D, and applicability under section 587A; and

(D) promulgate additional regulations required by such amendments made by this Act.

(3) APPLICABILITY OF REGULATIONS.—Notwithstanding the date on which guidance or regulations are issued under paragraph (2), no guidance or regulations issued pursuant to the amendments made by this Act shall take effect until the effective date of this Act, as described in paragraph (1), except as otherwise provided for transitional tests.

(b) APPLICATION OF AUTHORITIES TO IN VITRO CLINICAL TESTS UNTIL AND AFTER EFFECTIVE DATE OF THIS ACT.—Except as provided in subsection (d), for any product or test that is an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, the following authorities shall apply:

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

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

(2) TESTS OFFERED ON OR AFTER ENACTMENT BUT BEFORE IMPLEMENTATION.—Before any product or test that is an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, is first offered, sold, or distributed after the date of enactment of this Act, but prior to 90 days before the effective date of this Act, such product or test shall be considered a transitional test as described under subsection (d) and comply with the applicable device provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.).

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

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

(c) APPLICATION OF AUTHORITIES TO TRANSITIONAL AND GRANDFATHERED IN VITRO CLINICAL TESTS.—

(1) DEFINITION.—For purposes of this paragraph, the term ''transitional in vitro clinical test'' means an in vitro clinical test, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, that—

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

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

(B) does not have an approval under section 515, a clearance under section 510(k), an authorization under section 513(f)(2), an approval under section 520(m), or an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e, 360(k), 360c(f)(2), 360j(m), 360bbb–3) or approval under the Public Health Service Act (42 U.S.C. 201 et seq.); and

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

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

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

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

(d) CONVERSION.—

(1) DEEMED PREMARKET APPROVAL.—Any in vitro clinical test (as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act) with a premarket approval under section 515, a clearance under section 510(k), an authorization under section 513(f), or a licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) is deemed to have an approved application under section 587B of the Federal Food, Drug, and Cosmetic Act, as added by this Act, beginning on the later of—

(A) the effective date of this Act; or

(B) such other date, not later than 3 years after such effective date, as the person responsible for the device selects.

(2) DEEMED INVESTIGATIONAL USE APPROVAL.—Any in vitro clinical test (as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act) that has an approved investigational device exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is deemed to have an approved investigational use under section 587Q of such Act, as added by this Act, beginning on the effective date of this Act.

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

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

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

SEC. 6. EMERGENCY USE AUTHORIZATION.

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

(1) in paragraphs (1) and (4)(C) of subsection (a), by inserting ''in vitro clinical test,'' before ''or biological product'' each place such term appears; and

(2) in subsection (e)(3)—

(A) in subparagraph (B), by striking ''and'' at the end;

(B) in subparagraph (C), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(D) quality system requirements (with respect to in vitro clinical tests) under section 587J.''.

SEC. 7. ANTIMICROBIAL SUSCEPTIBILITY TESTS.

Section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a–2) is amended—

(1) in subsection (a)(1)(C)—

(A) by striking ''or approve under section 515'' and inserting ''approve under section 515, or approve, exempt, or issue a technology certification order under subchapter J''; and

(B) by striking ''testing devices'' and inserting ''tests'';

(2) in subsection (c)(5), by striking ''drug or device'' each place it appears and inserting ''drug, device, or in vitro clinical test'';

(3) in subsection (e)—

(A) in the heading, by striking ''TESTING DEVICES'' and inserting ''IN VITRO CLINICAL TESTS'';

(B) in paragraph (1)—

(i) by striking ''and 515,'' and inserting ''515, 587B, and 587D'';

(ii) by striking ''antimicrobial susceptibility testing device'' and inserting ''anti-

microbial susceptibility in vitro clinical test''; and

(iii) by striking ''such device'' and inserting ''such test'';

(C) in paragraph (2)—

(i) in the heading, by striking ''TESTING DEVICES'' and inserting ''IN VITRO CLINICAL TESTS''; and

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

''(C) The antimicrobial susceptibility in vitro clinical test meets all other requirements to be approved under section 587B or exempted from premarket review under section 587D.''; and

(D) after making the amendments in subparagraphs (B)(ii), (B)(iii), and (C)(ii), by striking ''device'' each place it appears and inserting ''in vitro clinical test'';

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

''(1) The term 'antimicrobial susceptibility in vitro clinical test' means an in vitro clinical test that utilizes susceptibility test interpretive criteria to de-

termine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).''; and

(5) in subsection (g)(2)—

(A) by amending the matter preceding subparagraph (A) to read as follows:

''(2) with respect to clearing under section 510(k), classifying under section 513(f)(2), approving under section 515 or section 587B, or exempting from approval requirements under section 587D—''; and

(B) in subparagraph (A)—

(i) by striking ''device'' and inserting ''in vitro clinical test''; and

(ii) by striking ''antimicrobial susceptibility testing device'' and inserting ''antimicrobial susceptibility in vitro clinical test''.

SEC. 8. COMBINATION PRODUCTS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) by inserting ''(except for a combination product constituted of a device

and an in vitro clinical test)'' after ''agency center,''; and

(ii) by inserting ''in vitro clinical test,'' before ''or biological product''; and

(B) in subparagraph (D)—

(i) in the matter preceding clause (i), by striking ''. If the Secretary determines'' and inserting '', except for a combination product constituted of a device and an in vitro clinical test. For other combination products, if the Secretary determines''; and

(ii) in clause (ii)—

(I) by inserting ''or in vitro clinical test'' after ''device''; and

(II) by inserting ''and in vitro clinical tests'' before ''shall'';

(2) in paragraph (3), by striking ''safety and effectiveness or substantial equivalence'' and inserting ''safety and effectiveness, substantial equivalence, or analytical validity and clinical validity'' before ''for the approved constituent part'';

(3) in paragraph (4)—

(A) in subparagraph (A), by striking ''or 513(f)(2) (submitted in accordance with paragraph (5))'' and inserting ''513(f)(2) (sub-

mitted in accordance with paragraph (5)), 587B, or an exempt test under section 587A, as applicable''; and

(B) in subparagraph (B), by inserting ''or 587B'' after ''section 515'';

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

(5) in paragraph (7), by striking ''or substantial equivalence'' and inserting '', substantial equivalence, or analytical validity and clinical validity'';

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

''(I) This paragraph shall not apply to a combination product constituted of a device and an in vitro clinical test.''; and

(7) in paragraph (9)—

(A) in subparagraph (C)(i), by striking ''or 520(g)'' and inserting ''520(g), or 587B''; and

(B) in subparagraph (D), by striking ''or 520'' and inserting ''520, or 587B''.

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

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

SEC. 9. RESOURCES.

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

(b) ESTABLISHMENT OF USER FEE PROGRAM.—

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

(A) IN GENERAL.—Beginning not later than October 1, 2020, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process of the review of in vitro clinical test applications submitted under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, for the first 5 fiscal years after fiscal year 2021. In developing

such recommendations, the Secretary shall consult with—

(i) the Committee on Energy and Commerce of the House of Representatives;

(ii) the Committee on Health, Education, Labor, and Pensions of the Senate;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the authorization of such subchapter J, the Secretary shall—

(i) publish a notice in the Federal Register requesting public input on the authorization of user fees;

(ii) hold a public meeting at which the public may present its views on the authorization, including specific suggestions for the recommendations submitted under subparagraph (E);

(iii) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to such subchapter J; and

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

(C) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of the authorization under such subchapter J and to solicit suggestions to be included in the recommendations transmitted to Congress under subparagraph (E).

(D) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Com-

mittee on Energy and Commerce of the House of Representatives;

(ii) publish such recommendations in the Federal Register;

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

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(E) TRANSMITTAL OF RECOMMENDATIONS.—

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

(ii) RECOMMENDATION REQUIREMENTS.—The recommendations transmitted under this subparagraph shall—

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

(II) provide that the amount of operating reserve balance in the user fee program established under this section is not more than the equivalent of 10 weeks of operating reserve;

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

(IV) include an operating reserve adjustment such that, if the Secretary has an operating reserve balance in excess of 10 weeks of such operating reserves, the Secretary shall decrease

such fee revenue and fees to provide for not more than 10 weeks of such operating reserves;

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

(VI) provide that the fees assessed and collected for the full-time equivalent employees at the Center for Devices and Radiological Health, with respect to which the majority of time reporting data indicates are dedicated to the review of in vitro clinical tests, are not supported by the funds authorized to be collected and assessed under section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j).

(F) PUBLICATION OF RECOMMENDATIONS.—The Secretary shall publish on the internet website of the Food and Drug Administration the revised recommendations under

subparagraph (A), a summary of the views and comments received under subparagraphs (B) through (D), and any changes made to the recommendations originally proposed by the Secretary in response to such views and comments.

(G) MINUTES OF NEGOTIATION MEETINGS.—

(i) PUBLIC AVAILABILITY.—Before transmitting the recommendations developed under subparagraphs (A) through (F) to Congress, the Secretary shall make publicly available, on the internet website of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(ii) CONTENT.—The minutes described under clause (i) shall summarize any substantive proposal made by any party to the negotiations, any significant controversies or differences of opinion during the negotiations, and the resolution of any such controversy or difference of opinion.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—Effective on October 1, 2021, provided that the Secretary transmits the recommendations under paragraph (1)(E), the Secretary is authorized to collect user fees relating to the submission of in vitro clinical test applications submitted under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act. Fees under such program shall be assessed and collected only if the requirements under paragraph (4) are met.

(3) AUDIT.—

(A) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to submission of an in vitro clinical test application submitted under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and on a biennial basis thereafter until October 1, 2027, the Secretary shall perform an audit of the costs of reviewing such applications under such subchapter J. Such an audit shall compare the costs of reviewing such applications under such subchapter J to the amount of the user fee applicable to such applications.

(B) ALTERATION OF USER FEE.—If the audit performed under subparagraph (A) indicates that the user fees applicable to applications submitted under such subchapter J exceed 30 percent of the costs of reviewing such applications, the Secretary shall alter the user fees applicable to applications submitted under such subchapter J such that the user fees do not exceed such percentage.

(C) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under subparagraph (A) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United States Code, to ensure the validity of any potential variability.

(4) CONDITIONS.—The user fee program described in this subsection shall take effect only if the Food and Drug Administration issues draft guidance related to the review requirements for in vitro diagnostic tests that would be subject to premarket review under section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 3, the review requirements for test categories eligible for tech-

nology certification under section 587D of such Act, as added by section 3, and the parameters for the test categories that would be exempt from any review under subchapter J of chapter V of such Act.

(5) USER FEE PROGRAM DEFINITIONS AND RESOURCE REQUIREMENTS.—

(A) IN GENERAL.—The term ''process for the review of in vitro clinical test applications'' means the following activities of the Secretary with respect to the review of premarket applications under section 587B of the Federal Food, Drug, and Cosmetic Act (as added by section 3), technology certification applications under section 587D of such Act (as added by section 3), and supplements for such applications:

(i) The activities necessary for the review of premarket applications, premarket reports, and supplements to such applications.

(ii) The issuance of action letters that allow the marketing of in vitro clinical tests or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and,

where appropriate, the actions necessary to place them in condition for approval.

(iii) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, technology certifications, and supplements.

(iv) Monitoring of research conducted in connection with the review of such applications, supplements, and submissions.

(v) Review of in vitro clinical test applications subject to section 351 of the Public Health Service Act (42 U.S.C. 262), investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)), or investigational test exemptions under section 587A(m) of the Federal Food, Drug, and Cosmetic Act (as added by section 3), and activities conducted in anticipation of the submission of such applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act or investigational use under section 587R of the

Federal Food, Drug, and Cosmetic Act (as added by section 3).

(vi) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, technology certification applications, and supplements.

(vii) The development of voluntary test methods, consensus standards, or mandatory performance standards in connection with the review of such applications, supplements, or submissions and related activities.

(viii) The provision of technical assistance to in vitro clinical test developers in connection with the submission of such applications, reports, supplements, or submissions.

(ix) Any activity undertaken in connection with the initial classification or reclassification of an in vitro clinical test in connection with any requirement for approval of an in vitro clinical test.

(x) Evaluation of postmarket studies required as a condition of an approval of

a premarket application of an in vitro clinical test.

(xi) Compiling, developing, and reviewing information on relevant in vitro clinical tests to identify issues with the applicable standard for premarket applications, technology certification applications, and supplements.

(B) RESOURCE REQUIREMENTS.—Fees collected and assessed under this section shall be used for the process for the review of in vitro clinical test applications, as described in subparagraph (A), and shall—

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

(ii) include travel expenses for officers and employees of the Food and Drug Administration only if the Secretary determines that such travel is directly related to

an activity described in subparagraph (A); and

(iii) not be allocated to purposes described under section 722(a) of the Consolidated Appropriations Act, 2018 (Public Law 115–141).

(c) REPORTS.—

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—

(i) GENERAL REQUIREMENTS.—Beginning with fiscal year 2021, for each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(ii) ADDITIONAL INFORMATION.—Beginning with fiscal year 2021, the annual report under this subparagraph shall include the progress of the Food and Drug Administration in achieving the goals, and future plans for meeting the goals, including—

(I) the number of premarket applications filed under section 587B of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year;

(II) the number of technology certification applications submitted under section 587D of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year for each review division; and

(III) the number of breakthrough designations under section 587C of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year.

(iii) REAL-TIME REPORTING.—

(I) IN GENERAL.—Not later than 30 calendar days after the end of the second quarter of fiscal year 2021, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the internet website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

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

(aa) The number and titles of draft and final guidance on topics related to the process for the review of in vitro clinical tests, and whether such guidances were issued as required by statute or pursuant to the recommendations transmitted to

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

(bb) The number and titles of public meetings held on topics related to the process for the review of in vitro clinical tests, and if such meetings were required by statute or pursuant to the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(iv) RATIONALE FOR IVCT USER FEE PROGRAM CHANGES.—Beginning with fiscal year 2022, the Secretary shall include in the annual performance report under paragraph (1)—

(I) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) and the number of full-time equivalents funded by budget authority at the Food and Drug Administration by each division

within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of in vitro clinical tests, including identifying drivers of such changes; and

(III) for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

(v) ANALYSIS.—For each fiscal year, the Secretary shall include in the report under clause (i) an analysis of the following:

(I) The difference between the aggregate number of premarket applications filed under section 587B or section 587D of the Federal Food, Drug, and Cosmetic Act and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

(aa) the number of applications filed under each of sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications under each of sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act for each fiscal year that did not meet the goals as identified by the recommendations transmitted to Congress by

the Secretary pursuant to subsection (b)(1)(E).

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(III) The most common causes and trends for external or other circumstances affecting the ability of the Food and Drug Administration to meet review time and performance enhancement goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E).

(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E), the Secretary shall make such information publicly available

on the internet website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies.

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all in vitro clinical test premarket applications and technology certification orders and supplements, premarket, and technology certification notifications in the cohort.

(2) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2022, for each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit a corrective action report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives. The report shall include the following information, as applicable:

(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis

under paragraph (1)(A)(v), that each of the goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the in vitro clinical test premarket application and technology certification review process.

(B) GOALS MISSED.—For each of the goals identified by the letters described in recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(E) for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(i) a justification for such determination;

(ii) a description of the types of circumstances, in the aggregate, under which applications or reports submitted under sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act missed the review goal times but were approved during the first cycle review, as applicable;

(iii) a summary and any trends with regard to the circumstances for which a review goal was missed; and

(iv) the performance enhancement goals that were not achieved during the previous fiscal year and a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

(3) FISCAL REPORT.—For fiscal years 2021 and annually thereafter, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(A) CONTENTS.—Such report shall include expenditures delineated by budget authority and

user fee dollars related to administrative expenses and information technology infrastructure contracts and expenditures.

(B) OPERATING RESERVE.—Such report shall provide the amount of operating reserve balance available each year, and any planned allocations or obligations of such balance that is above 10 weeks of operating reserve for the program.

(4) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) through (3) available to the public on the internet website of the Food and Drug Administration.

(5) ENHANCED COMMUNICATION.—

(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of in vitro clinical tests shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives from the Food and Drug Administration shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this section.

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